OCULUS BINOPTOMETER® 4P

Vision Testing Device

INSTRUCTIONS FOR USE

OCULUS®

Preface

The Binoptometer® 4P has been manufactured and tested in accordance with the strictest quality criteria. You have chosen a modern, technically mature product.

With the Binoptometer® 4P you can determine visual acuity, test binocular vision, colour vision, contrast vision and peripheral visual field perception, accommodation width and optionally attenuation vision and glare sensitivity.

Using the device correctly is essential for safe operation. Therefore, familiarise yourself with the contents of these instructions for use before use. Pay particular attention to the safety instructions.

- These Instructions for Use describe the management of patient data, the presets in the Binoptometer® 4P program, and the measurement process.
- Information that goes beyond the operating concept can be found in the user manual for the Binoptometer® 4P vision testing device.

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

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

OCULUS Optikgeräte GmbH

Item number: GA/59860/XXXX/EN
Revision 01
Released: 10/07/2025

Table of Contents

1 Scope of Delivery

Standard scope of delivery
Binoptometer® 4P with/without height adjustment
Accessory set, consisting of: ■ Dust protection cover ■ Instructions for Use ■ User Manual ■ Software installation ■ Patient instructions ■ Forehead rest (as a replacement) ■ Disinfection and cleaning set, consisting of: Mikrozid sensitive wipes premium Lens and glasses cleaning cloth, 10 pieces (double pack) ■ Device connection lead, 2.5 m black
Software module Binoptometer® 4P ■ USB stick with software ■ USB connection cable 3 m ■ USB connection cable 1.8 m

Optional components
Netbook “State of the art” ■ Mini mouse, black, with cable ■ Protective cover for netbook
“Mesopic vision/glare sensitivity” module
Software for eyesight tests suitable for children incl. instructions
External light shield for the examination of mesopic vision
Carrying case for Binoptometer® 4P
Trolley case with telescopic pull handle
USB FS MED isolator
To order: Fuses (with extra high breaking capacity), 1.25A H

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

- If you discover transport damage upon delivery, report this to the transport company immediately.
- Confirm the damage on the delivery note in order to ensure that claims can be settled properly.
- Keep the original packaging for return shipment in the event of service or repair.

2 Safety

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

- ➔ Read the instructions for use carefully.
- ➔ Keep the instructions for use in a safe place near the device.
- ➔ Pay attention to the statutory accident prevention regulations.
- ➔ If the scope of delivery includes a netbook, read the operating instructions for the netbook.

2.1 Symbols

2.1.1 On the Device and Type Plate

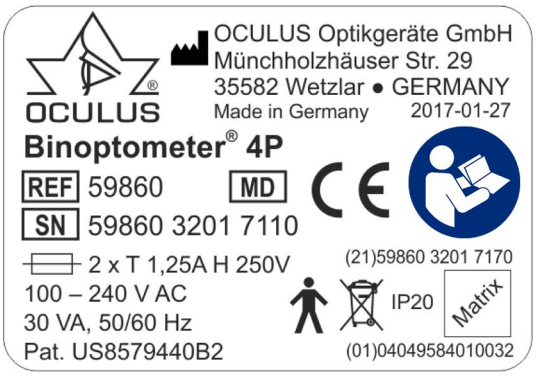


Fig. 1: Type plate (example)

Symbol	Description	Symbol	Description
	Name and address of the manufacturer		Protection class
yyyy-mm-dd	Date of manufacture	IP XX	Degree of protection
CE	CE mark	REF	Item number
	Follow the instructions for use	SN	Serial number
	Disposal via household waste is prohibited	#	Model number
	Application part Type B	MD	Medical device (Medical device)
ABCDEFG123456789 Matrix (01) 04049584000040	UDI number (example) consisting of: UDI-PI (device identifier) UDI-DI (product identifier) Machine-readable matrix code		

2.1.2 On the Packaging

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

2.1.3 In this Manual

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

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

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

> This sign indicates menu paths and screen shots. For example, calling up a new patient:
Binoptometer® 4P > Examination > New patient / End
Specifically:
➔ Open the Binoptometer® 4P program.
➔ In the menu bar, select the “Examination” menu item.
➔ Click “New patient / End”.

2.2 Safety Instructions for Use

Caution!
Incorrect operation can injure people or damage the device.
➔ Observe and follow the safety instructions in these instructions for use.

Caution!
Unauthorised modifications to the device may result in personal injury or damage to the device.
➔ Do not modify this device or the corresponding lift table without the manufacturer's permission.
➔ Only OCULUS Service or an authorised dealer is entitled:
- to rebuild or otherwise modify the device or the associated lift table.
- to install software or software updates.

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

2.2.1 Information regarding operating an ME System

The Binoptometer® 4P and a connected computer form a medical electrical system (ME system) per IEC 60601-1. If you connect additional devices, such as a printer, those devices become part of the ME system.
➔ Ensure that all devices in the ME system meet the requirements of IEC 60601-1 or IEC 60950-1.

2.2.2 Information regarding Electrical Safety

The mains cable supplied must be used for the power supply. Other connection cables are not permitted.

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

Connecting the Binoptometer® 4P with non-medical electrical equipment (e.g. data processing equipment) to a medical electrical system must not result in a patient safety level below that prescribed by DIN EN 60601-1. If this connection leads to the leakage current threshold being exceeded, protective measures including a circuit breaker must be in place.

- ➔ Ensure that connections to non-medical devices are established correctly.
- ➔ If the device is connected to a computer that does not comply with the IEC 60601-1 standard, supply the computer with power via an isolating transformer or establish a USB connection via the OCULUS USB FS MED Isolator (No. 01 56920 00 010).
- ➔ If the computer is supplied with power via an isolating transformer or is located in the patient's environment:
- ➔ Establish electrical isolation between the computer and the peripheral devices if you connect peripheral devices to the computer (e.g. via LAN or USB) that do not comply with the IEC 60601-1 standard (with the exception of devices that are supplied with power directly from the computer, such as a mouse, keyboard or USB stick).
- ➔ Use only a computer that meets the specifications in these Instructions for Use → Chap. 12 (page 53).
- ➔ Please note that a device connected via USB may supply a maximum output voltage of 5.5 V DC.

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

If you are using a multi-socket to connect the Binoptometer® 4P, you must adhere to the following instructions:

- ➔ Use a multi-socket that complies with the requirements of IEC 60601-1.
- ➔ Do not place the multi-socket on the floor.
- ➔ Do not use more that one multi-socket.
- ➔ Only plug the Binoptometer® 4P and the computer that is being used, if applicable, into the multi-socket.
- ➔ The multi-socket must be supplied via an isolating transformer.
- ➔ If you are using your own computer or a new computer for the Binoptometer® 4P, you must have the electrical safety checked. Contact OCULUS customer service.

Caution!
Personal injury or damage to property due to electromagnetic interference
Portable and mobile RF communications equipment can affect medical electrical equipment thereby compromising electromagnetic compatibility (EMC/cables) → Annex (page 55).

- ➔ Ensure that portable and mobile RF communications equipment does not cause interference.
- ➔ If necessary, keep a distance from RF communication devices to ensure that the Binoptometer® 4P functions correctly.

2.3 Information regarding Cyber Security

Note
Observe the regulations, instructions and recommendations of the competent authority for data security (in Germany: Federal Office for Information Security (BSI) for the Protection of Critical Infrastructures).

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

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

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

2.3.1 Precautions against Unauthorised Access

To increase the cyber security of the device

- ➔ Secure the device against unauthorised access by unauthorised persons.

Please note the following for all precautionary measures

- ➔ Secure the computer with a password (for example when Windows starts up).
- ➔ Choose a complex password. A good password consists of eight characters and is not in the dictionary. In addition to letters, it should also include numbers and special characters.
- ➔ Do not choose a name or device name for a password (for example, “Binoptometer”).
- ➔ Change the password regularly.
- ➔ Do not note the password in an accessible location.

- ➔ Use different passwords for different users.
- ➔ Enable the screensaver and use the option to make it obligatory to re-enter the password when exiting the screensaver.
- ➔ Choose an adequate time setting for starting the screensaver if the software session is inactive (e.g. 10 minutes).
  An adequate time setting should consider the examination duration, number of patients, time between examinations, use of other devices in the examination room, several users, etc.
- ➔ Lock the computer if you are leaving the workstation (shortcut: Windows logo key + 'L').
- ➔ If necessary, contact your administrator.

2.3.2 User Responsibility

Do not share usernames or passwords with colleagues or anyone else, even if they are permitted by law and your employer's policies to view the same type of information (e.g. two users who test the same patient samples).

Users have access to sensitive patient data (ePHI). No snapshots, screenshots or images (e.g. with another device) of information displayed via the device may be taken.

Operators should not enter identifying data into the device. All data on the device should be anonymised and relate to the sample ID and not to the patient.

2.3.3 Reporting Device Security or Data Protection Breaches

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

2.3.4 Recovering from Compromised Accounts or Devices

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

2.3.5 Unavailable Service

Users should report unavailable services or prohibited access to information to their local healthcare organisation's IT department.

2.3.6 Precautions if the Computer is Connected to a LAN or Internet Network

- ➔ Do not connect to the internet while using the device. This is considered misuse!
- ➔ If you connect the computer to the internet for other purposes, you are responsible for ensuring data security.

If you connect the computer to LAN or the internet, you are responsible for ensuring data security!

Please note here:

- Use wired connections when connecting the computer to the network. Do not use any wireless technologies (e.g. Bluetooth)!
- If you are using Wi-Fi connections despite this, ensure that adequate security protocols methods are used (for example, WPA2/AES – Wi-Fi Protected Access / Advanced Encryption Standard – with a strong network key).
- Using a firewall (software or hardware) is recommended.
- Observe the instructions for integration into an IT network → “Annex F Instructions for Integration into an IT Network” (page 61).

3 Device Description

3.1 Parts of the Device

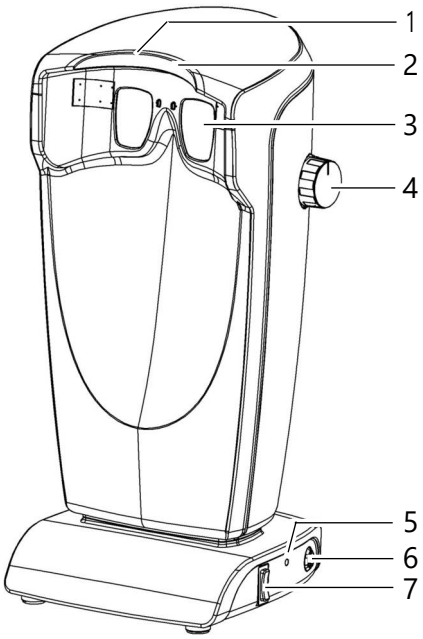


Fig. 2: Front view

No.	Description
1	Holder for external light shield The device's external light shield enables twilight vision and glare sensitivity to be tested when the room is not darkened,
2	Forehead rest: The forehead rest supports the positioning of the patient.
3	Viewing window: The light-protected yet open viewing area protects against disruptive reflections and contributes to a pleasant examination atmosphere.
4	Rotary knob for adjusting the viewing angle: The angle of the test field can be infinitely adjusted by the patient themselves in order to carry out the vision test under physiological conditions even with multifocal or varifocal spectacles. Use the rotary knob on the side to move the test field downwards (viewing angle).
5	Indicator light: The indicator light shows whether the Binoptometer® 4P is supplied with power.
6	Netbook/laptop/PC connection
7	Rocker switch for height adjustment (optional); The height of the device can be adjusted to an ergonomic sitting position for the patient using the rocker switch.

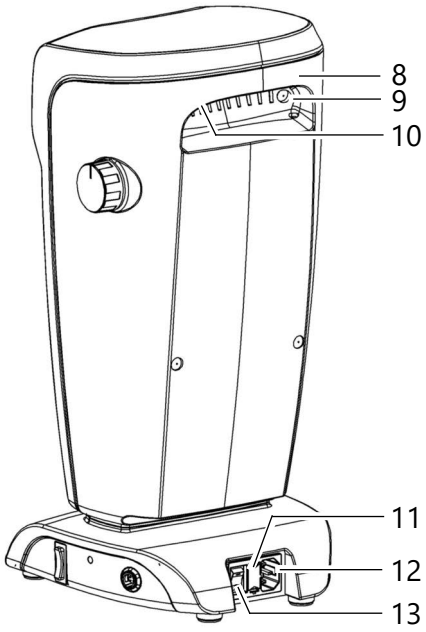


Fig. 3: Rear view

No.	Description
8	Grip
9	Opening for service button
10	Ventilation openings
11	Fuse holder
12	Mains connection socket
13	On/off switch

3.2 Application Parts

Application parts are the parts of the device that come into contact with the patient.

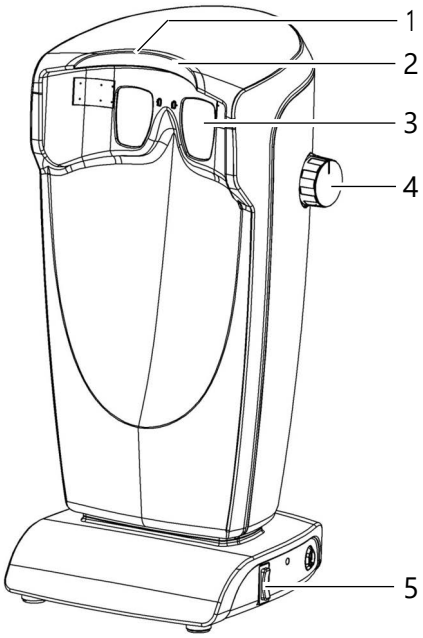


Fig. 4: Application parts

No.	Description
1	Holder for external light shield
2	Forehead rest
3	Viewing window
4	Rotary knob for adjusting the viewing angle
5	Rocker switch for height adjustment (optional)

3.3 Functionality of the Device

The Binoptometer® 4P is a vision testing device with a comprehensive test presentation. The tests are shown on a high-resolution micro colour display. This technology enables almost unlimited visualisation of vision tests.

A precisely calculated three-lens achromatic objective lens ensures exact imaging for the tests. This lens ensures that visual performance can be tested regardless of the pupil distance of the patient.

3.4 Proper Use

3.4.1 Intended Purpose

The Binoptometer® 4P is designed exclusively for the use described in these instructions for use.

The Binoptometer® 4P has the following test options:

- Visual acuity test with Landolt rings, numbers, letters, etc.
- Binocular tests (phoria and stereo tests)
- Colour differentiation test (Ishihara colour charts, Velhagen-Broschmann colour charts[1] and Matsubara colour charts)
- Contrast testing under photopic conditions
- Mesopic vision test with and without glare in accordance with DIN 58220 Part 7, suitable for driving license
- Testing for latent hyperopia, presbyopia and myopia, especially night myopia
- Range of accommodation
- Testing of peripheral visual field perception

➔ Pay attention to the aforementioned safety instructions.

3.4.2 Intended Medical Indication

The OCULUS Binoptometer® 4P is intended for testing visual acuity, binocular vision, colour vision, contrast sensitivity and peripheral visual field perception.
The Binoptometer® 4P also has mesopic vision and glare sensitivity test options.

The device serves as a comparison aid between the visual functions and normative data. The device serves as an aid for assessing the quality of vision, e.g. but not limited to the following applications:

- Driving licence test
- Preschool test
- Occupational medicine
- Assessment of pre- and postoperative status in refractive surgery
- Colour differentiation test
- Visual acuity

3.4.3 Contraindications

None known

3.4.4 Possible Side Effects

None known

1. Panels for testing colour differentiation. Edited by Dieter Broschmann and Jörn Kuchenbecker. 34th Edition. Stuttgart 2011

3.4.5 Intended Users

Make sure that the Binoptometer® 4P is only used by persons,

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

3.4.6 Patient Group

For children aged 3 and over and adults.
No restrictions regarding weight and state of health.

4 Setup and Connection

Caution!

Incorrect setup may result in incorrect measurements or even damage to the device.

- ➔ Have the device installed and connected by our service department or by a specialist authorised by OCULUS.
- ➔ Place the device on a flat surface so that it cannot fall over.
- ➔ Position the device so that it is protected from dripping, gushing or splashing water.

Damage to the device due to incorrect handling of the device

- ➔ Do not expose the device to vibrations, impacts, contamination, moisture, or high temperatures.
- ➔ Handle the device with care.

Device damage due to condensation after transport or storage

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

4.1 Setup

- ➔ Set the device up so that the mains plug is easily accessible. You can therefore disconnect the device from the mains easier for maintenance work.
- ➔ Select the installation location in such a way as to ensure a reflection-free examination and that no direct light can influence the measurement. Ideally, you should be able to darken the examination room or alternatively use the external light shield.
- ➔ Do not place the device in the immediate vicinity of other devices. If you use the Binoptometer® 4P in the vicinity of other devices, you must ensure that the Binoptometer® 4P functions faultlessly.
- ➔ Do not stack the device.
- ➔ Operate the Binoptometer® 4P in rooms used for medical purposes if the installation regulations of VDE 0100-710 are complied with.
- ➔ Do not operate the supplied devices in potentially explosive areas where flammable anaesthetics or volatile substances such as alcohol or petrol are nearby.

4.1.1 Ambient and Operating Conditions

Temperature	+10 – +40°C
Air humidity	30 – 75%
Air pressure	700 – 1060 hPa

4.1.2 Notes on the Patient Environment

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

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

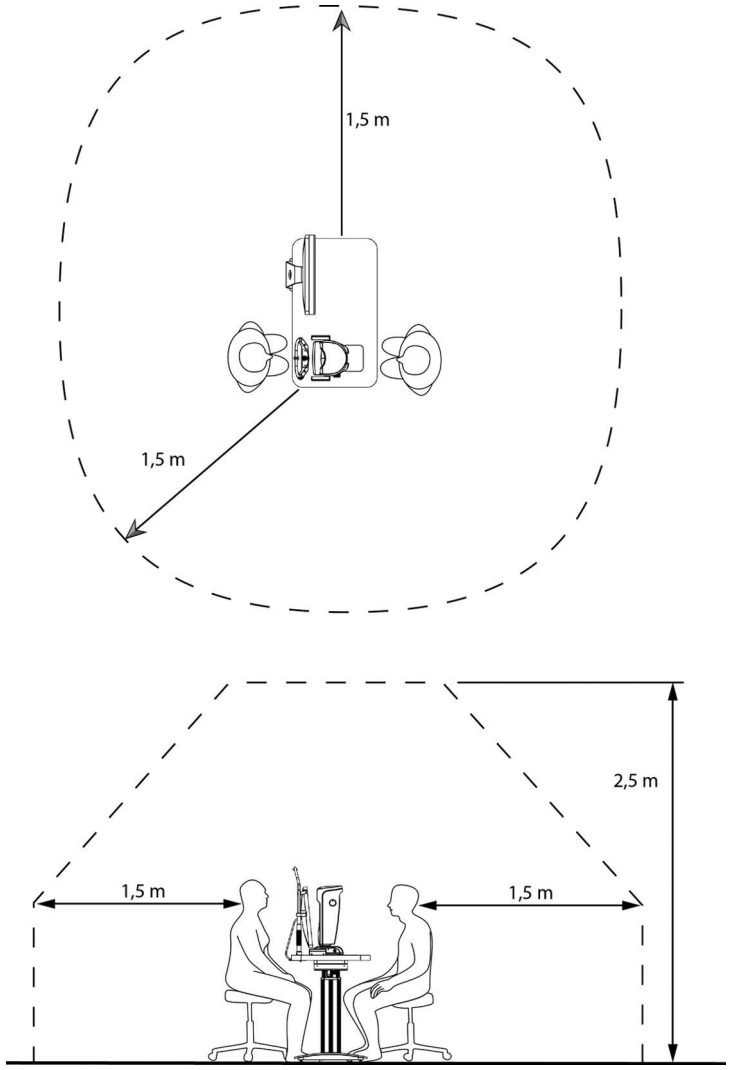


Fig. 5: Patient environment

4.2 Connection

You must connect the Binoptometer® 4P to the mains power and to the netbook or laptop/PC, depending on the version.

Caution!

Risk to electrical safety

- ➔ Only use the power supply unit included in the scope of delivery.
- ➔ Only use a mains cable that meets the requirements of IEC 60227-1, type 53, min. 0.75 mm^2 and IEC 60320-1, type C7.
- ➔ If you are using a multi-socket to connect the Binoptometer® 4P: Use a multi-socket that complies with the requirements of IEC 60601-1.
- ➔ Do not place the multi-socket on the floor.
- ➔ Do not use more that one multi-socket.
- ➔ Only plug the Binoptometer® 4P and the computer that is being used, if applicable, into the multi-socket.
- ➔ Use a socket outlet that has a flawless protective conductor connection.

Note

Device damage due to improper connection!

If you do not connect the Binoptometer® 4P properly and voltage is present, the device can get damaged quickly.

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

Connecting a netbook/laptop/PC

- ➔ If you are using a computer that was not supplied by OCULUS together with the Binoptometer® 4P, first install the software on the computer before connecting the device to the computer → Software installation.
- ➔ On the computer that controls the Binoptometer® 4P, no other software may run in the foreground in parallel with the examination program (screensaver, user programs, etc.).
  Power-saving modes (BIOS or Windows) must be deactivated.

1. Connect the Binoptometer® 4P and netbook/laptop/PC with the corresponding connection cable.

Fig. 6: Example: Binoptometer® 4P connected to a netbook

➔ Ensure that the plug is inserted in the correct position.

➔ Follow the operating instructions for the netbook/laptop/PC.

4.3 Software Installation

Before using the device for the first time, you may need to install the Binoptometer® 4P software on your laptop or PC. Proceed as described in Software installation.

This is already installed on the netbook supplied.

Caution!

Incorrect measurements / device damage caused by unauthorised personnel

➔ Ensure that only a specialist authorised by OCULUS carries out software updates.

5 Measurement Process

The general procedure for an examination is shown here using a netbook as an example.

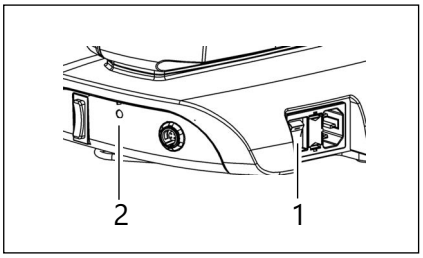
You will find basic information on how to operate the examination programs as well as detailed information on the examination programs, individual tests and how to proceed in the User Manual.

The following steps are part of the examination procedure:

- Call up or create patients in patient data management
- Prepare patients for the examination
- Carry out an examination
- Displaying and print results

5.1 Switching on

1. Switch the Binoptometer® 4P on/off switch to on.
   The indicator light illuminates green.
   If the device is mounted on an OCULUS lifting table and connected to it, the device is switched on using the power switch at the bottom of the table base.



No.	Description
1	On/off switch
2	Indicator light

Fig. 7: Switch on the device

2. Now start the software if you have connected the Binoptometer® 4P to a netbook, laptop or PC.
   Wait until the software has loaded completely and patient data management is shown on the screen.

5.2 Creating or Calling up Patient Data

3. Press the Binoptometer® 4P icon:  .
   The patient data management user interface is then displayed.
4. Create a new patient in the patient data management or select the patient from the list of existing patients.

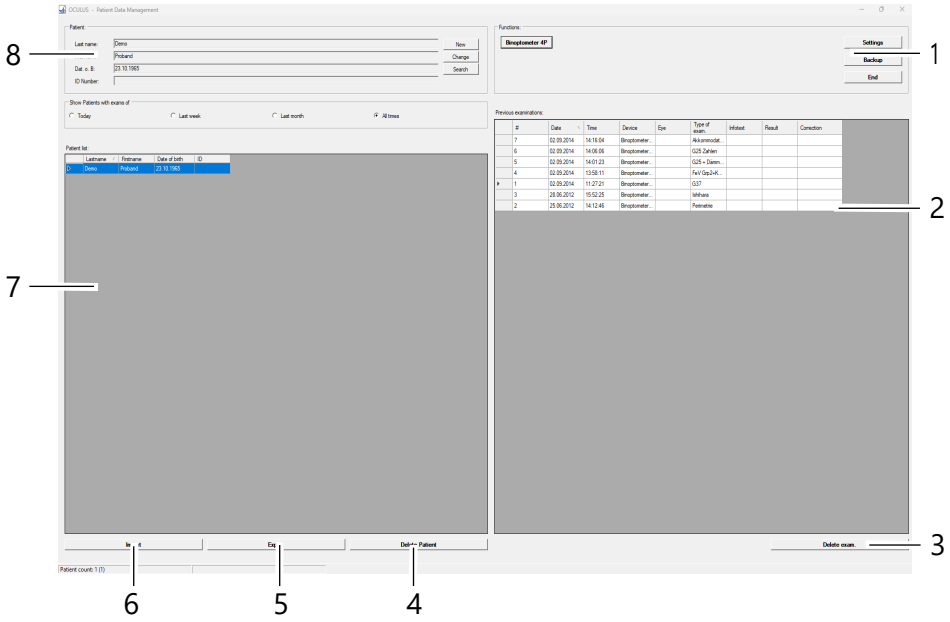


Fig. 8: Patient data management user interface

No.	Description	No.	Description
1	“Functions” group box	5	[Export] button
2	Existing examinations for the selected patient	6	[Import] button
3	[Delete exam.] button	7	List of created patients
4	[Delete Patient] button	8	“Patient” group frame

In order to be able to access the Binoptometer® 4P program later, you must first enter a new patient or select an existing patient from the patient list.

5.2.1 Entering a new Patient

Press the [New] button to enter a new patient into patient data management.

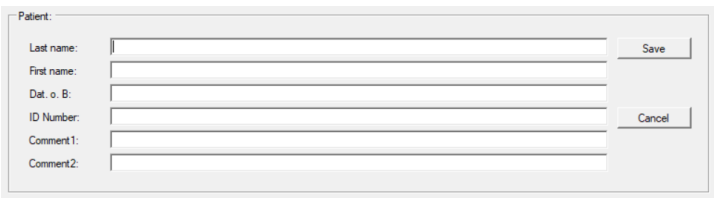


Fig. 9: Enter patient

➔ Enter the surname, first name and date of birth in full in the patient window. You can also enter an optional ID number for the patient.
➔ Press [Save] to save your entries. The new patient is displayed in the patient list.
➔ Now start the device software.
Select the newly created patient in the list of patients and double-click on the selected patient to start the Binoptometer® 4P program.

5.2.2 Selecting an existing Patient

The patient data list on the left-hand side of the screen lists all previously examined patients alphabetically.

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

Extended patient search: [Extended] checkbox

➔ Select the [Extended] checkbox.

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

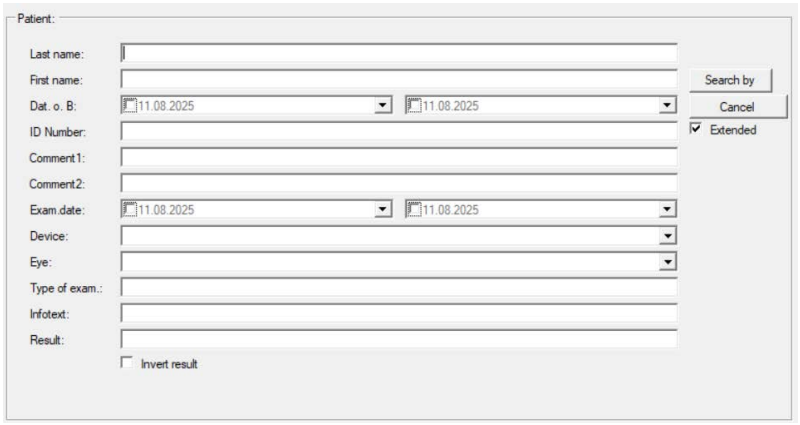


Fig. 10: Extended search

5.3 Preparing the Patient Area

5. Prepare the area for the examination:
   - ➔ Make sure that no stray light falls into the device viewing area.
   - ➔ Darken the room slightly for optimum results.
   - ➔ Ensure that the examination takes place in a quiet atmosphere and that the patient is not distracted.
   - ➔ Clean and disinfect the forehead rest if necessary, if you have not already done so → Chap. 8.3 (page 46).
   - ➔ Check the device viewing area for soiling.
     Clean the viewing area windows if necessary → Chap. 8.2 (page 46).

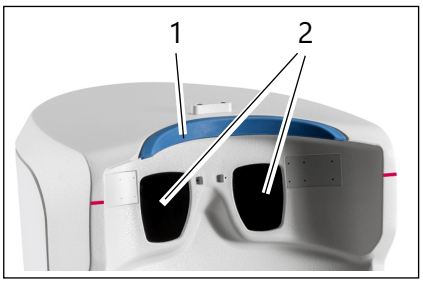


Fig. 11: Check device viewing area

No.	Description
1	Forehead rest
2	Viewing lenses

5.3.1 Using the External Light Shield

You can test mesopic vision and glare sensitivity even if you cannot darken the room. To do this, you need the external light shield (optional).

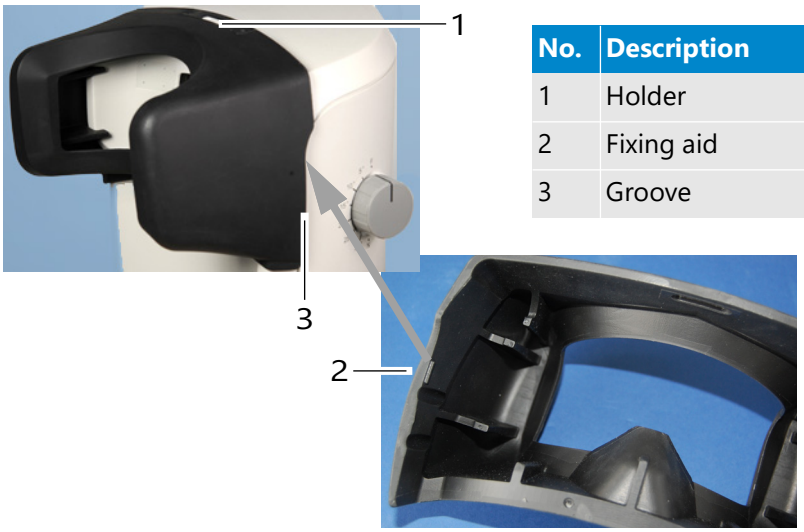


Fig. 12: Use an external light shield

No.	Description
1	Holder
2	Fixing aid
3	Groove

- ➔ Hook the external light shield onto the holder.
- ➔ Fix the external light shield with the fixing aids on both sides. The fixing aid must fit into the groove.

5.4 Instructing Patients

6. Check whether a possible adaptation disorder has subsided.

7. Check the patient's spectacles for damage or soiling.
8. Explain the examination procedure and the visual signs to the patient.
   You can show the patient the following illustration and explain it as follows:

"A ring with an opening serves as the test object. The opening can appear in eight different positions.
Specify the direction of the opening as follows:"

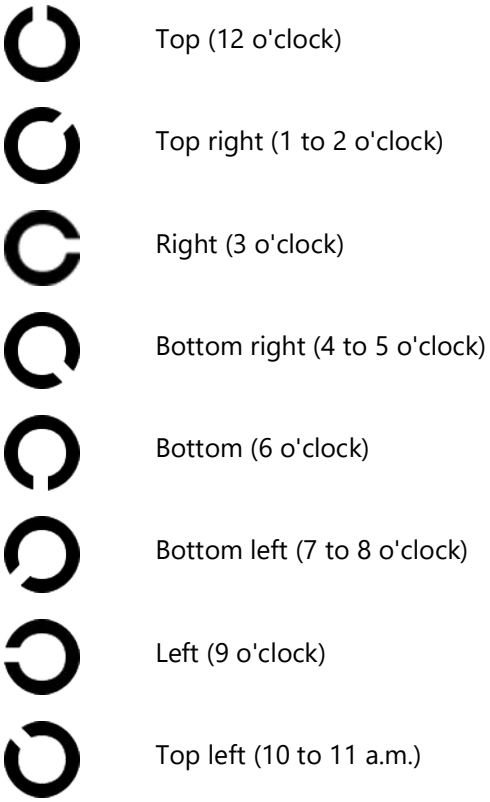


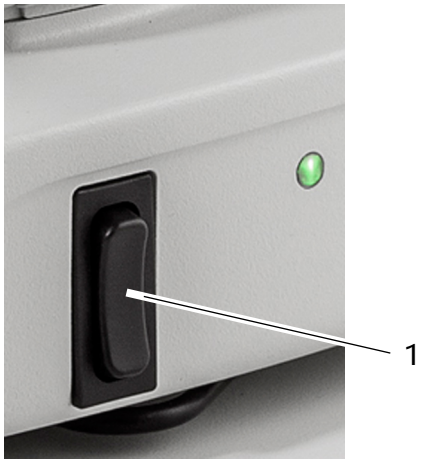
Fig. 13: Example: Name the direction of the Landolt rings

5.5 Adjusting the Device to the Patient

9. Set the height of the device.

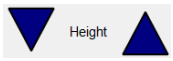
- If you have a Binoptometer® 4P with height adjustment, you can adjust the height as follows:

➔ Via rocker switch:



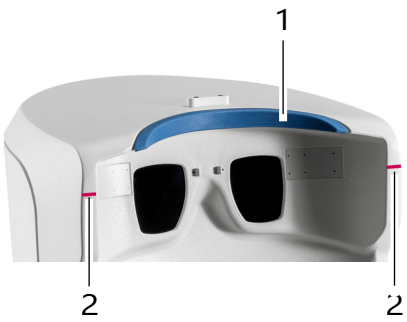
No.	Description
1	Rocker switch

Fig. 14: Adjust height with rocker switch

➔ Via software:
To do this, press the requisite arrow button 

→ Fig. 19 (page 30), item 9.

- The patient is sitting in a good position when their head is held straight and is relaxed.
- The patient's forehead should lie firmly against the forehead rest during the entire examination.
- Do not touch the patient and the device at the same time.
- The patient's eyes should be level with the marking lines. Otherwise, the test image may be cut off and the subject will not see all the visual signs.



No.	Description
1	Forehead rest
2	Marking lines

Fig. 15: Position patient

10. Set the viewing angle.

➔ To carry out a distance vision test, set the viewing angle to 0 degrees.

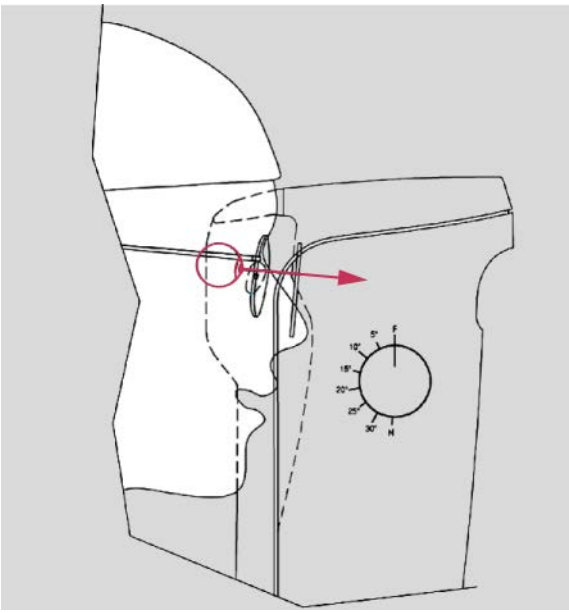


Fig. 16: Adjusting the viewing angle

For patients with multifocal or progressiv lenses

➔ Change the viewing angle if the inspection distance is shortened. The selected viewing angle is displayed in the examination menu → Fig. 19 (page 30), item 5. We recommend letting the patient carry out the adjustment, as they can best judge for themselves when they can see the test image well.

5.6 Selecting and Starting an Examination Program

11. If necessary, press the [Binoptometer® 4P] button in the patient data management to start the Binoptometer® 4P program.

12. Press the Screening ETDRS button in the Binoptometer® 4P software menu.

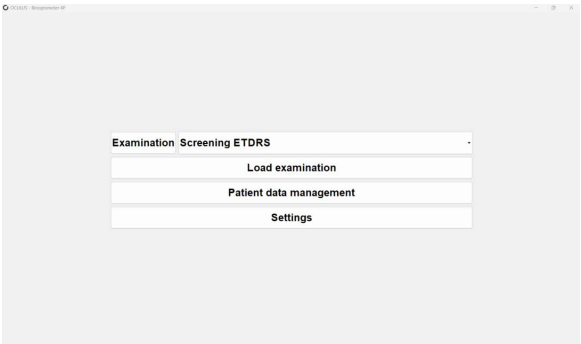


Fig. 17: Menu of the Binoptometer® 4P software

A drop-down list with all preset programs is displayed.

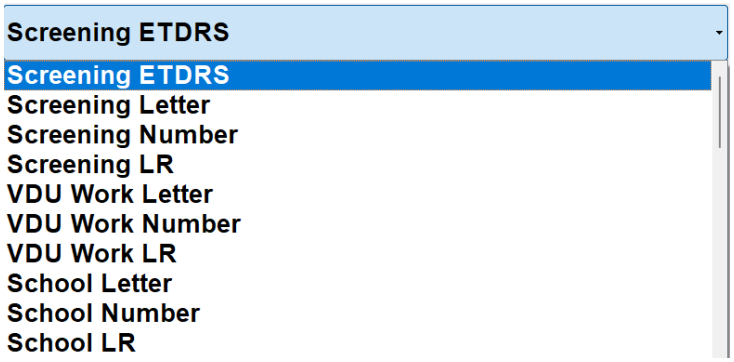


Fig. 18: Drop-down list with the preset programs

13. For example, select the examination program “Driver’s License LR”.
Press the [Examination] button.
The menu for the selected examination is displayed:

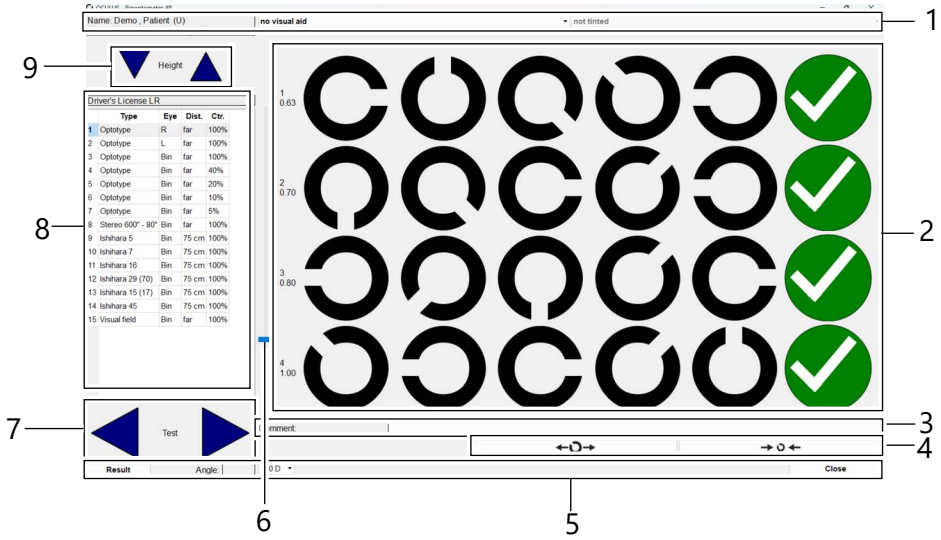


Fig. 19: Examination menu example

No.	Description	No.	Description
1	Header with information on the patient and selection “Visual aid”	6	Slider for setting the test distance
2	Test pattern display	7	“Test step forwards and backwards” arrow keys
3	“Comment” input field		
4	Buttons for changing the size of the visual symbols	8	Display of the examination program with test steps
5	Base line with [Close] and [Result] buttons, viewing angle display, selectable prescription lenses	9	“Height adjustment” arrow buttons (version 59860 only)

14. Carry out the test steps of the examination → User Manual.

You will find basic information on how to operate the examination programs as well as detailed information on the examination programs, individual tests and how to proceed in the User Manual.

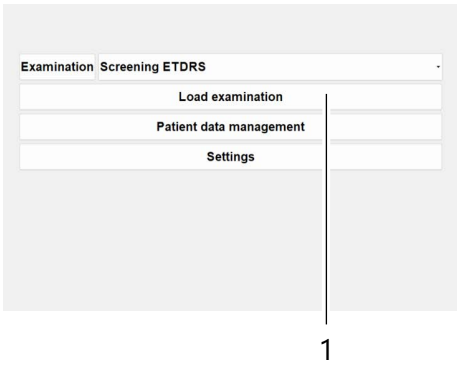
5.6.1 Loading an Existing Examination

You can load an existing examination in order to print it, for example.
If you are working with OCULUS patient data management, you can load an existing examination from there.

➔ Double-click the desired list entry in the examination list → Fig. 8 (page 24), item 8.
The examination is displayed in the examination menu.

If you are not working with OCULUS patient data management, you can load an existing examination from the Binoptometer® 4P software. You must have activated the corresponding button in the settings → Chap. 7.7 (page 40).

➔ Press the **Load examination** button.



No.	Description
1	[Load examination] button

Fig. 20: Menu (Binoptometer® 4P)

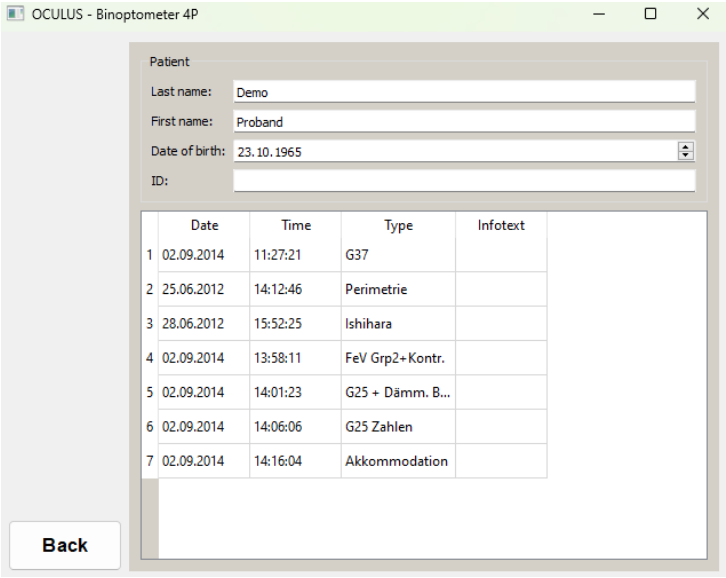


Fig. 21: Load examination without patient data management

➔ Move the cursor to the desired examination.
➔ Double-click on the examination.
The examination is displayed in the examination menu.
If you do not want to load any of the analyses, press the [Back] button. You will return to the Binoptometer® 4P menu.

5.6.2 Displaying and Printing Results

You can display the results of the examination:
➔ To do this, press this button: **Result**

You can display and print details of the visual acuity test, the colour tests and the Amsler test. The corresponding settings must be activated for this → Chap. 7.15 (page 43).
In addition to the standard printout, various result forms are available for some tests (e.g. driving license vision test) → User Manual.

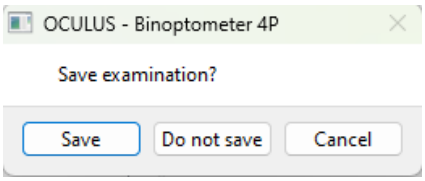
You can then print out the test result:

➔ To do this, press the button opposite.

For more information → User Manual.
If you do not have a printer connected, you can save the data on a USB stick and print it later from another netbook/laptop or PC. The software for Binoptometer® 4P must be installed on the other device. Further information can be found at → Chap. 6 “Forwarding Results via Patient Data Management” (page 35).

5.6.3 Finishing the Examination

15. Press the [Close] button.
The following selection dialogue is displayed:



16. Press the desired button:
    - [Save]: the examination is saved;
    - [Do not save]: the examination is not saved;
    - [Cancel]: to return to the examination.

    The Binoptometer® 4P overview menu is displayed.
    You can start a new test → Chap. 5.6 (page 29) or switch to a new patient. To do this, press the [Select patient] button or load an existing examination [Load examination].
17. Clean and disinfect the forehead rest after each examination → Chap. 8.2 (page 46).
18. Set the viewing angle to 0 degrees to be able to perform the next examination.

5.7 Switching off

1. End the current examination.
2. Close the Binoptometer® 4P device software and the patient data management.
3. Shut down the operating system or the computer.
4. Switch the Binoptometer® 4P on/off switch to off.
5. Cover the Binoptometer® 4P with the dust cover supplied.

If you want to transport or store the Binoptometer® 4P after an examination, you must do so properly.

➔ Proceed as described in → Chap. 10 (page 50).

Caution!

Risk of electric shock if the Binoptometer® 4P is not disconnected from the power supply at all poles for transport, cleaning, maintenance, disinfection and repair.

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

5.8 Switching off the ME System

➔ Switch off the ME system at the main switch on the table base.

6 Forwarding Results via Patient Data Management

Note

Loss of data due to computer viruses!

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

6.1 Exporting Patient Data

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

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

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

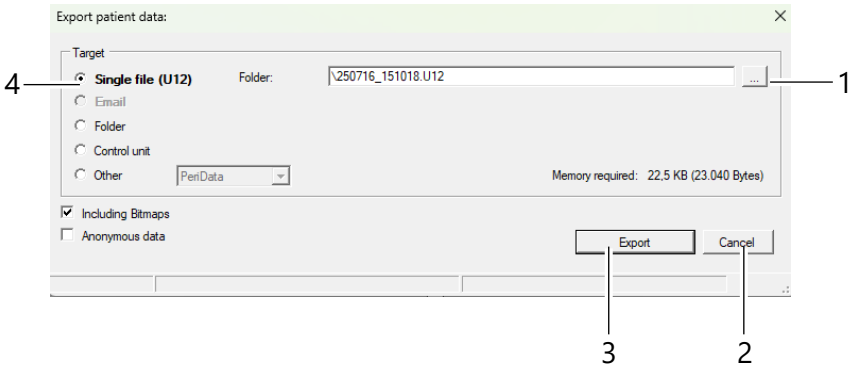


Fig. 22: "Export patient data" dialogue box

No.	Description	No.	Description
1	Button [...]	3	[Export] button
2	[Cancel] button	4	Selecting the save target

The import and export options are pre-set in the "Settings" area → User Manual.
You may not need to perform all of the following steps (e.g. selecting the destination) depending on the settings.
Recommendation: Use the "Single file (U12)" option to export the patient data.

For more information regarding patient data management → User Manual.

➔ In "Target" (4), select how you wish to export the data.

➔ Press the [...] button.

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

➔ Press [OK] or [Open] to confirm.

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

6.2 Importing Patient Data

If you receive patient data on a USB stick for example, you can import this data. To do this, the version of the Binoptometer® 4P program into which you want to import the data must match the version with which the data was previously exported.

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

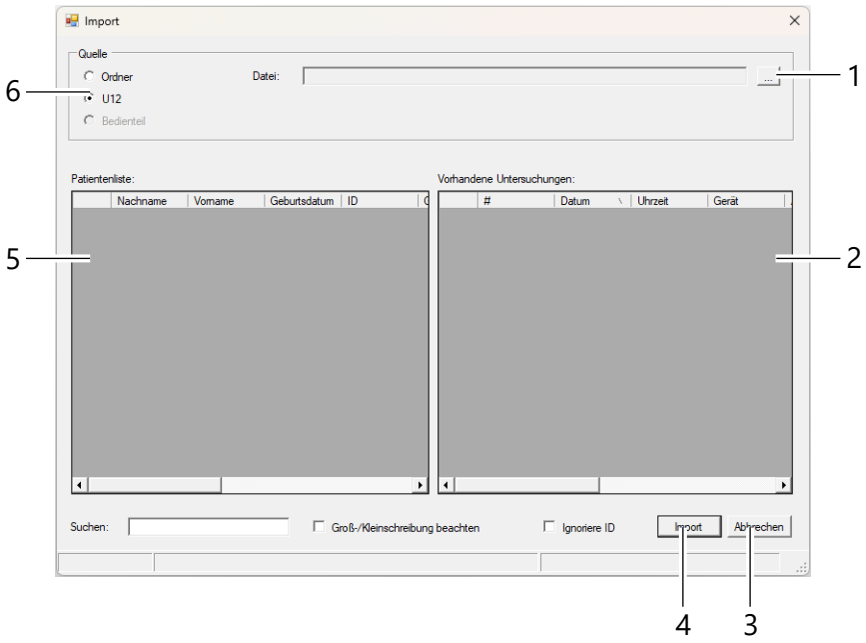


Fig. 23: "Import" dialogue box

No.	Description	No.	Description
1	Button [...]	4	[Import] button
2	List of analyses	5	List of patients
3	[Cancel] button	6	Selection of data source

The import and export options are pre-set in the "Settings" area → User Manual. You may not need to perform all of the following steps (e.g. selecting a directory) depending on the settings.

➔ Select the option in which the source data is available ("Folder" or "Single file (U12)").
➔ Press the [...] button.
➔ In the dialogue box, select the directory or file in which the patient data is available.
➔ Press [OK] or [Open] to confirm.
The patients that were found and the corresponding examinations are displayed in the bottom part of the dialogue box.
➔ Press the [Import] button to import the data.
The data is then available in patient data maintenance.

7 Changing the Operating Software Settings

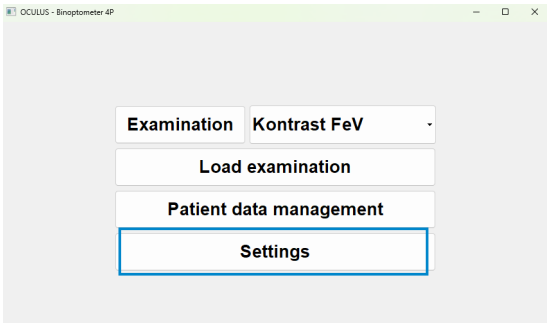


Fig. 24: Settings in the "Binoptometer® 4P" software menu

If required, you can change some basic settings in the Binoptometer® 4P program. If you do not want to change any settings, proceed as described at → Chap. 5.3 (page 26).

➔ Select a patient from the list of patients and click twice on the selected patient to start the Binoptometer® 4P program. The "Binoptometer® 4P" menu is displayed.

You can change the following settings:

- Selecting language and changing units of measurement → page 38
- Set date format → page 38
- Changing the font size of the examination window → page 39
- Changing visual acuity data → page 39
- Selecting verification criteria → page 39
- Activate correction lenses → page 39
- Activate the option to include the gender of a patient in the patient data management → page 40
- Activate the facility to load existing examinations from the Binoptometer® 4P software → page 40
- Enable the program to be displayed as a full screen at start-up → page 40
- Activating demo mode → page 40
- Activating optional software modules → page 41
- Editing examination program → page 42
- Exporting to external patient data management systems → page 43
- Change the presentation times of the colour tests → page 43
- Generating detailed printouts → page 43

Proceed as follows:

➔ Press the [Settings] button.
The following screen is displayed.

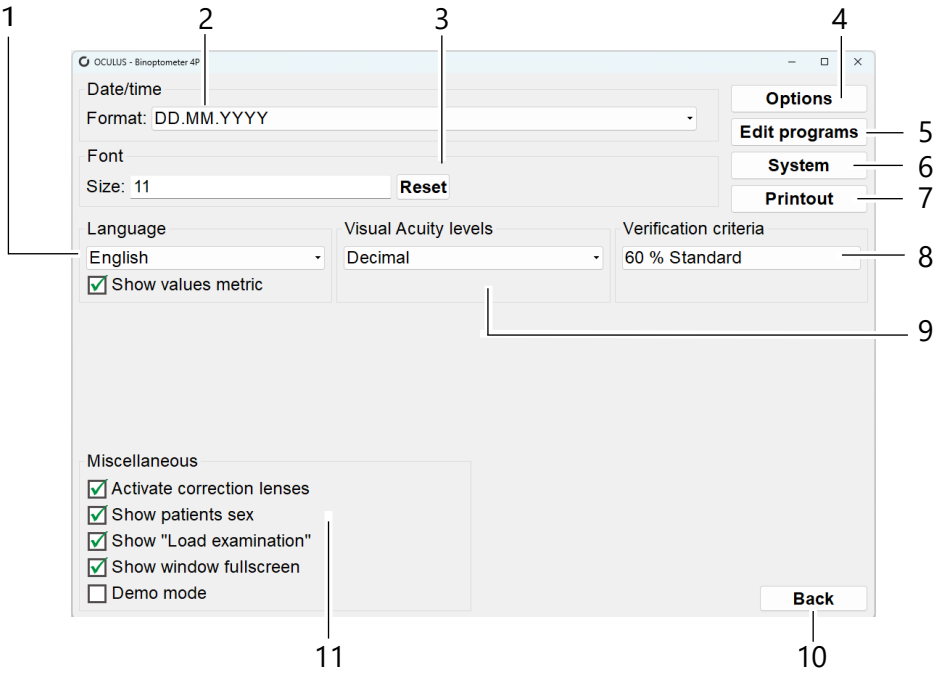


Fig. 25: "Settings" screen

No.	Description	No.	Description
1	"Language" group box	6	[System] button
2	"Date/time" group box	7	[Printout] button
3	"Font" group box	8	"Verification criteria" group box
4	[Options] button	9	"Visual acuity levels" group box
5	[Edit programs] button	10	[Back] button
		11	"Miscellaneous" group box

7.1 Selecting Language and Changing Units of Measurement

"Language" group box → Fig. 25 (page 38), item 1:

➔ Select the desired language from the drop-down list.
The selected language is activated after the next start of the Binoptometer® 4P program.

➔ Activate the [Show values metric] checkbox to display in metric units.
If the checkbox is deactivated, the units are output in the imperial measurement system.

7.2 Changing the Date Format

"Date/time" group box → Fig. 25 (page 38), item 2:

➔ Select the desired date format from the drop-down list.

7.3 Changing the Font Size of the Examination Window

"Font" group box → Fig. 25 (page 38), item 3:

➔ Enter the font size for the examination windows.
Use the [Reset] button to reset to the factory default font size.

7.4 Changing Visual Acuity Data

"Visual acuity levels" group box → Fig. 25 (page 38), item 9:

➔ Select the desired setting for the visual acuity information from the drop-down list.

7.5 Selecting Verification Criteria

"Verification criteria" group box → Fig. 25 (page 38), item 8:
Select the desired setting for the verification criteria from the drop-down list.

Note
Visual acuity testing as part of authorisation procedures and for expert opinion purposes is subject to DIN EN ISO 8596. This requires a cancellation criterion of 60%, i.e. a visual acuity level is deemed to have been passed if at least 60% of the visual signs presented are named correctly.
The verification criteria in Binoptometer® 4P is therefore set to 60% by default.

7.6 Activating Correction Lenses

"Miscellaneous" group box → Fig. 25 (page 38), item 11:
If you activate this function, a selection of corrective lenses is displayed in the examination program, which can be placed in front of the patient during the examination if required.
Indications are:

- Suspicion of latent hyperopia
- Subject is less able to recognise visual signs at close range than at a distance (presbyopia)
- Suspected myopia (visual signs in the distance are not clearly recognised)
- Testing for night myopia during the mesopic vision test

➔ Activate the [Activate correction lenses] checkbox
Prescription lenses in the range from +4.5 dpt to -3.5 dpt can be fitted.

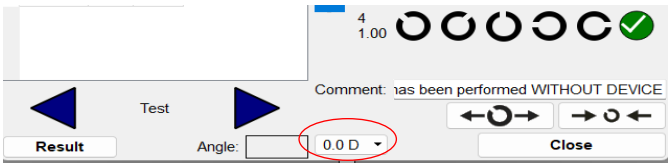
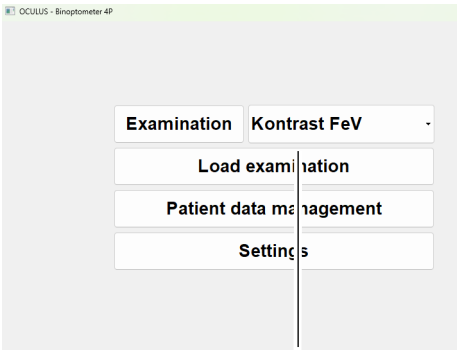


Fig. 26: Drop-down list with correction lenses is activated

7.7 Showing “Load Examination”

If you are not working with OCULUS patient data management, you can use this function to load an existing examination.



No.	Description
1	[Load examination] button

Fig. 27: “Load examination” button

“Miscellaneous” group box → Fig. 25 (page 38), item 11:

➔ Activate the checkbox [Show “Load examination”].
The corresponding button is added to the Start menu.

7.8 Showing Gender

“Miscellaneous” group box → Fig. 25 (page 38), item 11:

➔ Activate the checkbox [Show patients sex].
You can now include the gender of the patient in the list of test persons.

7.9 Showing Full Screen

“Miscellaneous” group box → Fig. 25 (page 38), item 11:

➔ Activate the [Show window fullscreen] checkbox.

7.10 Activating Demo Mode

“Miscellaneous” group box → Fig. 25 (page 38), item 11:

This function is only for demonstration purposes if no Binoptometer® 4P is connected to your laptop/netbook/PC.

➔ Activate the [Demo mode] checkbox.

7.11 Activating Optional Software Modules

Screen options:

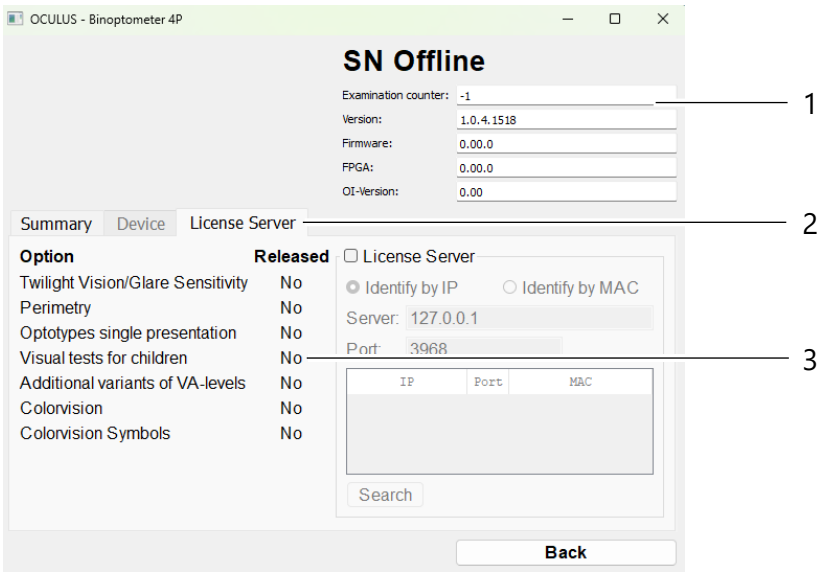


Fig. 28: "Options" screen

No.	Description	No.	Description
1	Device information	3	Status of the software modules
2	Register		

You may need this screen to order optional software modules → User Manual.

➔ Press the [Options] button → Fig. 25 (page 38), item 4.
The current software status is displayed.
Have the serial number (SN....) → Type Plate of the Binoptometer® 4P to hand.

➔ Switch to the "Device" tab.

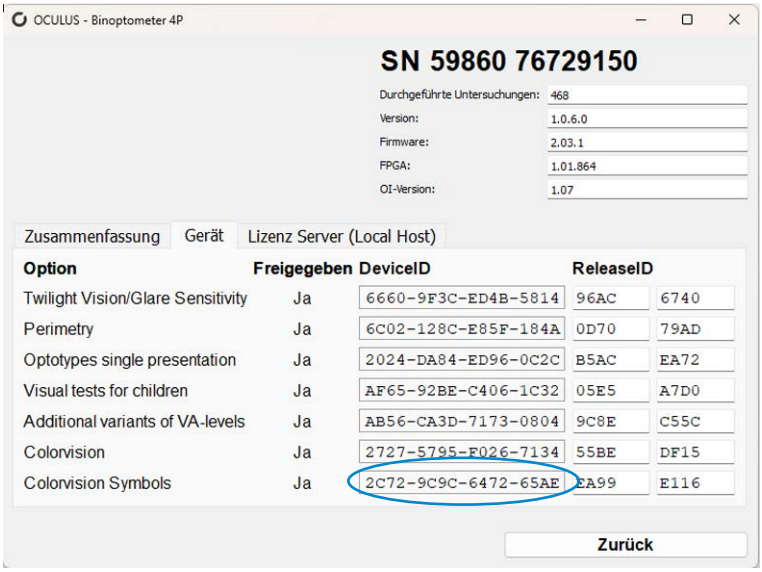


Fig. 29: "Device" tab, example device ID "Colorvision Symbols"

➔ Have the device ID of the desired option to hand, e.g. the device ID “Colorvision Symbols”.
➔ Call OCULUS Service → page 64 and ask for your release code.
➔ Enter the release code received in the “Colorvision Symbols” line in the “ReleaseID” field.
The selected option is now enabled.

Register: Licence Server

The “Licence server” tab provides information about the available options in the network.

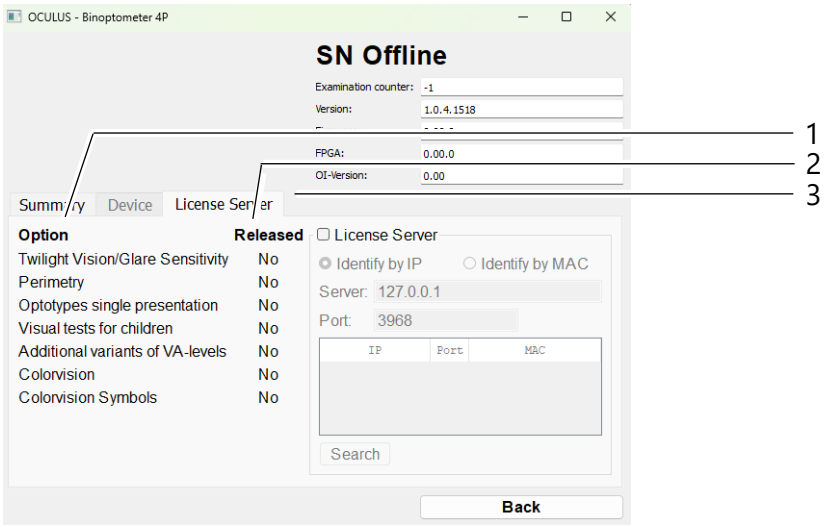


Fig. 30: “Licence Server” screen

No.	Description	No.	Description
1	List of options	3	“Licence server” tab
2	Information on option activation		

The “Options” list provides information about the possible options.
Information on option activation:
Yes: Licence for the option is available
No: Licence for the option is not available
You need the “Licence server” field to establish the connection from the Binoptometer® 4P to the network.

7.12 Editing an Examination Program

➔ Press the [Edit programs] button → Fig. 25 (page 38), item 5.
You can:
- Change the displayed sequence of the examination programmes
- Copy and modify an existing examination program
- Create and edit a new examination program.

For more information → User Manual.

7.13 Exporting to External Patient Data Management Systems

You can use this function to export patient data.

➔ Press the [System] button → Fig. 25 (page 38), item 6.

Fig. 31: GDT and CSV export

➔ Activate the [GDT] or [CSV] checkbox.

➔ Select the directory to which the patient data is to be exported.
GDT: Data is transferred to external practice management software or to generate examination results in PDF format.
CSV: Export of the examination data to an Excel file

7.14 Changing the Presentation Time of the Colour Tests

You can use this screen function to set how long the colour charts are displayed during a colour differentiation test.

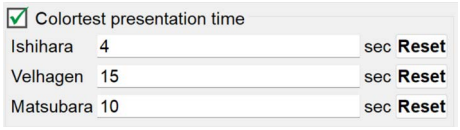


Fig. 32: Presentation time

➔ Press the [System] button → Fig. 25 (page 38), item 6.

➔ Activate the checkbox [Colour test presentation time].

➔ Enter the desired presentation time.

➔ Press the [Reset] button to reset the setting: Ishihara 4 sec, Velhagen 15 sec and Matsubara 10 sec.
The Ishihara test is preset to 4 seconds, as recommended by Prof Dr H. Krastel. According to the instructions for the Ishihrara test, 3 seconds are sufficient.

7.15 Generating Detailed Printouts

You can use this screen function to specify that the results of the visual acuity and colour differentiation test or the Amsler test are output in detail. You can enter further information here, such as the address of your practice and your logo, which will later appear on the results printout. You can set whether the comment line should be displayed on the results printout or not.

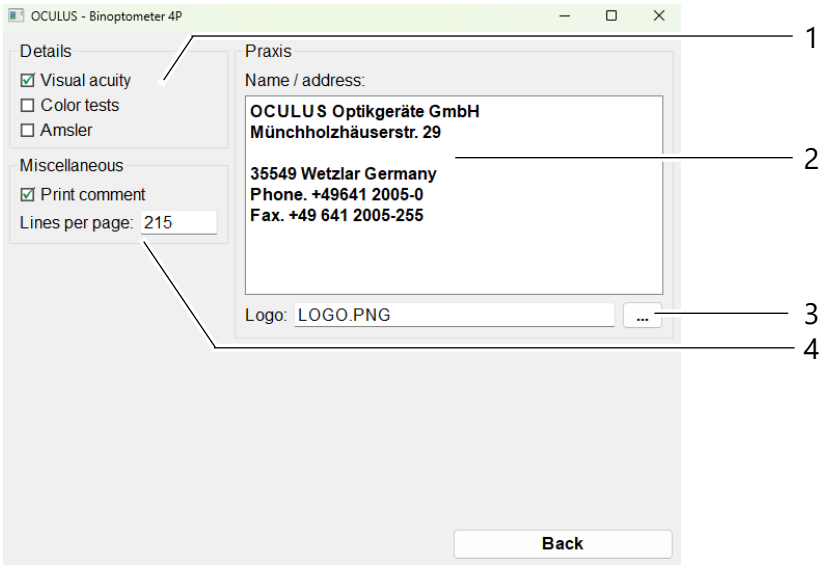


Fig. 33: "Print settings" screen

No.	Description	No.	Description
1	Activating the detailed printouts of results	3	Button for uploading an image
2	"Name/Address" input field	4	Activate printing of the comment line

➔ Press the [Printout] button → Fig. 25 (page 38), item 7.
➔ Activate the [Visual acuity], [Colour tests] or [Amsler] checkbox if you want detailed results for the individual examinations.
➔ In the "Name/Address" input field, enter the text that is to be displayed later on the printout, e.g. your practice address.
➔ Use the [...] button to search for the file with the desired image, e.g. your practice logo, and confirm your selection.
➔ Activate the [Print comment] checkbox in the "Miscellaneous" group box if you want the comment line to be displayed on the results printout.
➔ Generate page break: The pagination of the results printout depends on your printer. If you want the page break to be at a different position, you can change it here. To do this, enter the number of lines after which the page break should be inserted in the "Lines per page" input field in the "Miscellaneous" group box.

7.16 Ending the Adjustments

➔ Press the [Back] button → Fig. 25 (page 38), item 10.

With the exception of the language setting, the settings are applied immediately.

8 Cleaning, Disinfection and Maintenance

This chapter describes how to clean and disinfect the Binoptometer® 4P and how to replace forehead rest and the fuses.

In order to guarantee faultless and safe functions, we recommend: Let our customer service department or an authorised dealer inspect the Binoptometer® 4P every two years. If a fault occurs, which you cannot rectify, mark the Binoptometer® 4P as out of order and inform our customer service department.

Caution!

There is a risk of electric shock if the Binoptometer® 4P is not securely disconnected from the mains power supply at all poles for these tasks.

➔ Switch the Binoptometer® 4P off → Chap. 5.7 (page 34).

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

8.1 Intervals for Cleaning, Disinfection and Maintenance

Cleaning	
Activity	**Time period**
Clean the forehead rest	After each examination
Cleaning the housing	As required

Disinfection	
Activity	**Time period**
Disinfecting the forehead rest	After each examination
Disinfect the housing	As required

Maintenance	
Activity	**Time period**
Replace forehead rest	In the event of wear and heavy soiling
Replace fuse	As required

8.2 Cleaning

➔ Observe the product descriptions and instructions for use of the agents and devices that you use for device or accessory care, cleaning and disinfection.
➔ Do not use aggressive, chlorinated, abrasive or caustic cleaning agents to clean the Binoptometer® 4P.

Note
Damage to appliance due to moisture penetration!
➔ Ensure that no liquid can penetrate the appliance.

8.2.1 Required Materials

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

8.2.2 Cleaning the Outside of the Binoptometer® 4P

➔ Switch the Binoptometer® 4P off → Chap. 5.7 (page 34).
➔ Remove the mains plug.
➔ When cleaning with a damp cloth, ensure that no liquid can penetrate the Binoptometer® 4P.
➔ Clean the plastic surfaces and painted surfaces with the appropriate cleaning agents.
➔ Clean the viewing lenses with a soft cloth or optical brush, if necessary with alcohol or an optical cleaner.

8.3 Disinfection

Special wipes that are suitable for disinfecting medical devices are suitable for disinfecting all surfaces (except for Plexiglass).

We recommend	Mikrozid sensitive wipes premium Schülke & Mayr GmbH Various pack sizes: e.g. 2x 50 pieces in a soft pack, Item no. 59882

➔ Disinfect the forehead rest after every examination. Disinfect the housing and the accessories as required.

Note
Damage to appliances due to disinfectant solution!
The disinfectant solution can damage the device surface if it sprayed directly onto it.
➔ Only spray disinfectant solution onto a cleaning cloth and not directly onto the device.

8.4 Maintenance

In order to guarantee faultless and safe functions, we recommend:

➔ Let our customer service department or an authorised dealer inspect the Binoptometer® 4P every two years.

Caution!

There is a risk of electric shock if the Binoptometer® 4P is not disconnected from the mains power supply at all poles for these tasks.

➔ Switch off the Binoptometer® 4P → Chap. 5.7 (page 34).

➔ Remove the mains plug prior to maintenance work.

➔ Hold the plug to do this. Do not pull the cable.

8.4.1 Replacing the Forehead Rest

If the forehead rest is worn or heavily soiled, you can replace it (order number 07 59860 01 007).

1. Pull off the forehead rest.
2. Attach the new forehead rest.

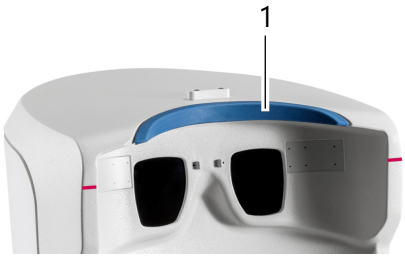


Fig. 34: Replacing the forehead rest

No.	Description
1	Forehead rest

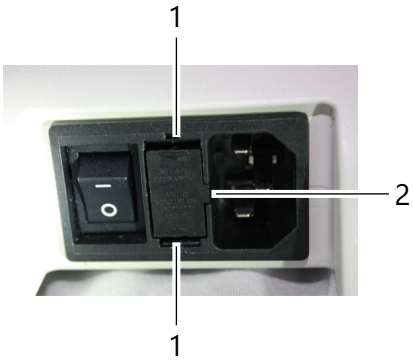
8.4.2 Replacing the Fuse

Note

Functional damage due to incorrect fuse!

➔ Only use the fuse specified in the scope of delivery (order number 05100171).

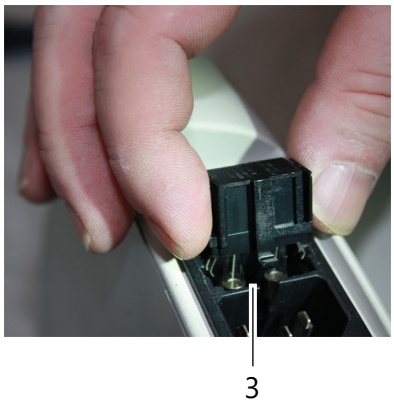
1. Switch the Binoptometer® 4P off → Chap. 5.7 (page 34).
2. Remove the mains plug.
3. Unplug the mains cable from the Binoptometer® 4P.
4. Press the catches → Fig. 35 (page 48) together.



No.	Description
1	Catches
2	Coding pin

Fig. 35: Fuse holder

5. Pull out the fuse holder (→ Fig. 36 (page 48).
6. Replace the defective fuse.
7. Insert the fuse holder. Make sure that it fits correctly. The pin → Fig. 35 (page 48) must sit in the recess.
8. Connect the Binoptometer® 4P to the power supply.
   You can now switch on Binoptometer® 4P and start the examinations.



No.	Description
3	Fuse holder

Fig. 36: Replacing the fuse

9 Troubleshooting

Caution!

A damaged or faulty device can cause personal injury and/or incorrect measurements.

If a fault occurs, which you cannot rectify:

➔ Mark a damaged device as out of order.

➔ Contact OCULUS Service or your authorised specialist dealer.

➔ Do not use a faulty device!

Fault	Possible cause	Remedy
No function after pressing the on/off switch. The Binoptometer® 4P program does not start.	No connection between the device and the power supply.	Check whether: ■ The mains cable is plugged in correctly ■ The mains cable is not defective ■ Netbook/laptop/PC is connected correctly ■ The fuse is defective If yes, replace the fuse → Chap. 8.4.2 (page 47).
Error message: “Binoptometer® 4P could not be found. Error code=-1” is displayed.	The Binoptometer® 4P is not correctly connected to the netbook/laptop/PC.	Check the plug connections between the device and the netbook/laptop/PC.

10 Transport, Packaging and Disposal

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

Note

Device damage due to improper transport or storage!

- ➔ Avoid impacts, shaking and contamination.
- ➔ Avoid high temperatures and moisture.

- ➔ Transport the device properly.
- ➔ Store the device in accordance with the storage conditions.
- ➔ Avoid being close to radiators and moisture.
- ➔ Check the device for damage each time after transporting.

10.1 Dismantling and Packing

- ➔ End the current examination.
- ➔ Drive the device's height adjustment to the lowest position.
- ➔ Switch the Binoptometer® 4P on/off switch to off.
- ➔ Remove the mains plug.
- ➔ Disconnect the connection cable from the netbook/laptop/PC.
  Hold the plug to do this. Do not pull the cable. To do this, grip the plug itself. Pull the thicker end slightly backwards to release the lock. Make sure that the cable and plug connection are not damaged.

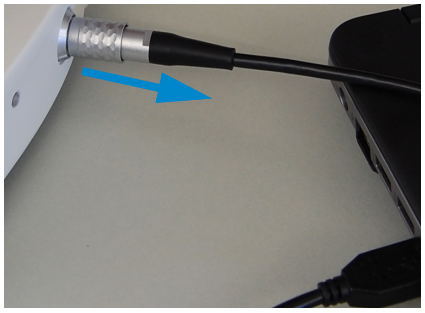


Fig. 37: Disconnect the plug of the connection cable

- ➔ If necessary, remove the external light shield.
- ➔ Hold the Binoptometer® 4P by the handle and place it in the transport box/bag so that the rotary knob for adjusting the viewing angle is pointing upwards.
- ➔ Place the accessories in the corresponding compartments.

Fig. 38: Packing the Binoptometer® 4P in the original packaging (Example with trolley)

Note

Damage to the external light shield due to incorrect insertion!

If you bend or kink the external light shield, the reinforcement may break.

➔ Do not bend or kink the external light shield.

➔ Carefully insert the external light shield.

10.2 Transport and Storage Conditions

	Transport	Storage
Ambient temperature	-30°C – +70°C	-30°C – +70°C
Relative humidity (incl. condensation)	10% – 90%	10% – 90%
Air pressure	500 hPa – 1060 hPa	500 hPa – 1060 hPa

10.3 Disposal

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

➔ Dispose of the Binoptometer® 4P properly.

11 Warranty Conditions

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

12 Technical Data

Measuring equipment

Weight incl. mains cable with height adjustment incl. mains cable	4.8 kg 5.6 kg
Dimensions (WxDxH) with height adjustment	224 x 220 x 455 mm 224 x 220 x 455 - 560 mm
Test distances	300 mm to infinity
Field of view setting	Infinitely adjustable up to approx. 35°
Viewing height	Optionally electrically height-adjustable, optionally operated by rocker switch Button on the device or via PC / laptop / netbook
Operation	With software via PC / laptop / netbook.
Electric height adjustment (optional)	Rocker switch on the device. The height of the measuring head can be motorised via the software.
Eye cover	LCD shutter
Test field brightness	Approx. 130 - 300 cd/m^2 - corresponding to standard illuminant D65 (colour tests D55)
Vision test generation	Micro colour display, 800 x 600 pixels
Lighting	LED
Expected service life	Up to 10 years

Operating conditions

Temperature	+10 – +40 °C
Air humidity	30 – 75%
Air pressure	700 – 1060 hPa

Power supply / mains adapter

Power consumption	max. 30 VA
Voltage	100-240 V
Frequency	50/60 Hz
Fuses (with maximum switching capacity)	2x 1.25 A H 250 V

Classification per IEC 60601-1

Type of protection against electric shock	Protection class 1
Degree of protection against electric shock	Type B
Housing protection type	IP 20

Recommended computer specification

The computer must meet the requirements of IEC 62368-1.

Minimum specification	Intel® Pentium N6000/ 3,3 GHz, 8GB RAM, Windows® 11 Professional
Recommended screen size	24"
Recommended screen resolution	1920 x 1080 pixels (Full HD)
Interfaces	USB

CE marking

In accordance with EU ordinance 2017/745 on medical devices

CE

The device is a product in product class I.

Conformity evaluation procedure in accordance with EU ordinance 2017/745, MDR, Annex II and III.

Annex

A Electromagnetic Compatibility (EMC)

Medical electrical equipment is subject to special precautions 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 environments in professional healthcare facilities, e.g. medical practices or clinics, except in the vicinity of RF surgical equipment and outside the RF-shielded room of an ME system for magnetic resonance imaging.

No special measures need be observed for OCULUS devices and systems.

Portable and mobile RF communications equipment can affect medical electrical equipment and impair its performance.

➔ Observe the recommended safety distances in the table on → page 59.

Definition of minimum operating quality or significant performance characteristics:

- A short interruption to the USB connection during the examination is permissible, as it does not affect the diagnosis, treatment or monitoring.

Caution

Using accessories, transformers and cables that are not specified by OCULUS can cause increased emission or reduced immunity for the Binoptometer® 4P. Likewise, the use of the accessories, transformers and cables specified by OCULUS in conjunction with devices other than the OCULUS device may result in increased emissions or reduced immunity for the other devices.

➔ Only use the accessories, transformers and cables specified by OCULUS.

➔ Do not use OCULUS-specified accessories, transducers, and cables with devices other than the OCULUS device.

In order to ensure compliance with the requirements in IEC 60601-1-2 6.1 and 6.2, you must use the following devices, accessories, transformers and cables:

Order number	Description	
59860 59862	Binoptometer® 4P with height adjustment Binoptometer® 4P without height adjustment	
05200320	Cable with plug, EU standard	2.5 m
05200210 (110 Volt)	Cable with plug, US standard	2.5 m
02 59860 00 004 02 59860 00 005	USB connection cable USB connection cable	3 m 1.8 m
01 56920 00 010	USB FS MED isolator (optional)	

B Electromagnetic Interference

Emitted interference Measurements	Compliance	Electromagnetic environment – guidelines
The OCULUS Binoptometer® 4P is intended for operation in the electromagnetic environment specified below. The user of the Binoptometer® 4P should ensure that it is being used in such an environment.		
HF emissions in accordance with CISPR 11	Group 1	The device uses high frequency energy only for its internal functions. Therefore, its HF emissions are very low and are not likely to cause any interference in nearby electronic devices.
HF emissions in accordance with CISPR 11	Class B	
Harmonics emissions in accordance with IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions in accordance with IEC 61000-3-3	complies	

C Electromagnetic Immunity

Immunity tests	Test level	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharge (ESD) in accordance with IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV ±15 kV	Floors should be made of wood or concrete, or covered with ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Power frequency (50/60 Hz) magnetic field in accordance with IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
Electrical fast transients/bursts in accordance with IEC 61000-4-4	±2 kV for mains cables 100 kHz repetition frequency ±1 kV for signal input and output parts	±2 kV ---------- ±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surges Per IEC 6100-4-5	±1 kV symmetrical voltage ±2 kV synchronous voltage	±1 kV ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines in accordance with IEC 61000-4-11	0% U_τ; 1/2 period at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0% U_τ; 1 period and 70% U_τ; 25/30 periods Single-phase: at 0 degrees 0% U_τ; 250/300 periods	0% U_τ; 1/2 period at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0% U_τ; 1 period and 70% U_τ; 25/30 periods Single-phase: at 0 degrees 0% U_τ; 250/300 periods	Mains power quality should be that of a typical commercial or hospital environment If the user of the Binoptometer® 4P requires continued operation during power cuts, we recommend powering the Binoptometer® 4P from an uninterruptible power supply or battery.
Note: U_τ is the A.C. mains voltage prior to applying the test level			

Immunity tests	Test level	Compliance level	Electromagnetic environment – guidelines
Conducted HF transients in accordance with IEC 61000-4-6	3 V_{eff} 150 KHz to 80 Mhz 6 V in ISM bands and amateur radio bands between 150 kHz and 80 MHz 80% AM at 1 kHz		Portable and mobile HF communications equipment should be used no closer to any part of the Binoptometer® 4P, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \left[\frac{3,5}{(V_1)}\right]\sqrt{P}$ $d = \left[\frac{3,5}{(E_1)}\right]\sqrt{P}$ for 80 MHz to 800 MHz $d = \left[\frac{7}{(E_1)}\right]\sqrt{P}$ for 800 MHz to 2.5 GHz
Radiated HF transients in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	V_{eff} = 3 V	where P is the rated output of the transmitter in watts [W] according to the transmitter manufacturer and d is the recommended separation distance in metres [m]. The field strength for fixed radio transmitters should be less than the compliance level[b] in each frequency range as determined by an electromagnetic site survey[a]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: Note 2:	The higher frequency range applies at 80 Hz and 800 MHz. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

a) Field strengths from fixed transmitters, such as base stations for radio telephones and land mobile radios, amateur radios, AM and FM radio broadcasts, and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed transmitters, a site survey should be considered. If the measured field strength in the location in which the Binoptometer® 4P is used exceeds the aforementioned compliance level, the Binoptometer® 4P should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Binoptometer® 4P.

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

D Recommended Separation Distances

Recommended separation distances between portable and mobile HF telecommunication equipment and the Binoptometer® 4P

The Binoptometer® 4P is intended for use in an electromagnetic environment in which HF transients are controlled. The Binoptometer® 4P user can make a significant contribution to avoiding electromagnetic interference by keeping a minimum distance of between the portable and mobile HF telecommunication devices (transmitters) and the device, depending on the communication device's output power as specified below.

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

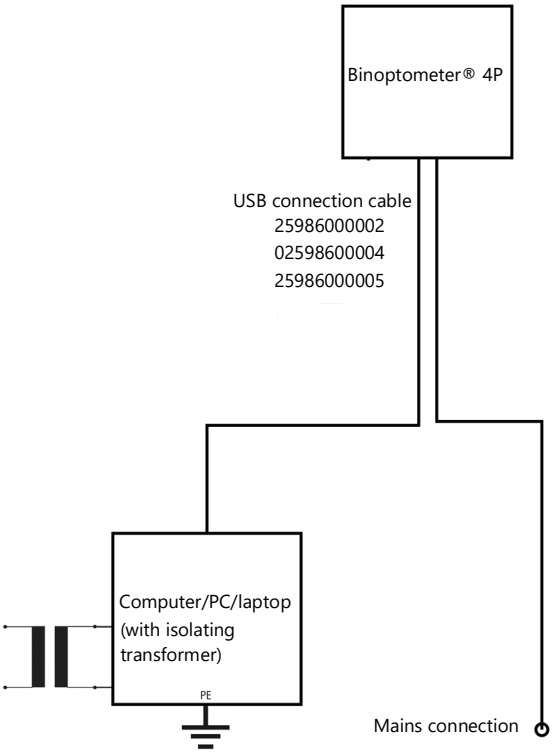
For transmitters with a maximum rated output not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the relevant column, where P is the maximum transmitter rated output in watts (W) according to the transmitter manufacturer's specifications.

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

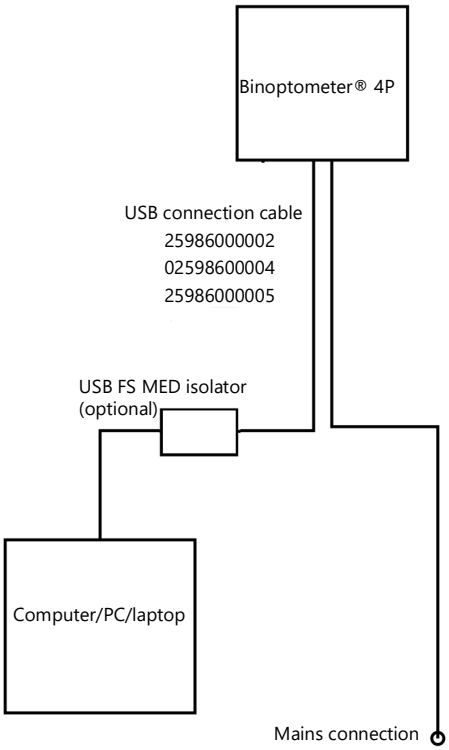
Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

E Connection Diagram

Computer with isolating transformer:



Computer without isolating transformer:



F Instructions for Integration into an IT Network

The device, in conjunction with the connected computer and the device software running on it, forms a programmable electrical medical system (PEMS) according to IEC 60601-1.

Please refer to → Chap. 2.3 "Information regarding Cyber Security" (page 12) at → Chap. 2 "Safety" (page 8) in these operating instructions for the appliance.

Observe the following instructions for integrating the PEMS into an IT network.

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

- Licensing by local license server;
- Storage and retrieval of the examination data on a local network drive;
- Printing;
- Data export;
- DICOM workflow.

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

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

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

- Licensing: Required open ports: 3968 TCP; 51371 - 51372 UDP;
- Storage, printing, data export: File and Printer Sharing for Microsoft Networks (SMB 3.0 or higher - required opened port: 445);
- DICOM Storage Service Class = PACS;
- DICOM Worklist Management Service class (Modality Worklist Server).

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

- Read the → Chap. 2.3 "Information regarding Cyber Security" (page 12) at → Chap. 2 "Safety" (page 8) in these operating instructions for the device;

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

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

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

- Data loss;
- Unsuitable data exchange;
- Data corruption;
- Unsuitable temporal data allocation;
- Unexpected data reception;
- Unauthorised access to data.

Connection of the PEMS to an IT network that includes other equipment could result in previously unidentified risks to patients, operators or third parties.

The responsible organisation should identify, analyse, evaluate and control these risks.

Subsequent changes to the IT network could introduce new risks and make additional analyses necessary.

Changes to the IT network include:

- Changes to the IT network configuration;
- Connecting additional items to the IT network;
- Disconnecting items from the IT network;
- Updating equipment connected to the IT network.

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