OCULUS Binoptometer® 4P

INSTRUCTION MANUAL
Vision Test Device

OCULUS®

Notes on this Instruction Manual

To ensure safe operation, it is essential that you use the device correctly. For this reason you should familiarize yourself thoroughly with the contents of this instruction manual before operating the device. In particular, pay attention to the safety instructions.

Also read the User Guide Binoptometer 4P. There you will find all information about the screening programs and testing.

With the Binoptometer 4P you can determine visual acuity, test binocular vision, color vision, contrast sensitivity and peripheral visual field perception.

You also have the option to test mesopic vision and glare sensitivity.

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

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

OCULUS Optikgeräte GmbH

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

Table of Contents

1 Delivery and Packing List

Component	Order number
Binoptometer® 4P with height adjustment	59860
Alternative: Binoptometer® 4P without height adjustment	59862
Accessory kit, consisting of:	59871
Dust protection cover	02 59860 00 003
Instruction Manual	G/59860/EN/08/19_Rev.00
User Guide	BH/59860/../en
Software Installation	SI/50000/.../en
Patient Instructions	PA/59860/.../in
Forehead rest (as a replacement)	07 59860 01 007
Disinfectants and cleaning kit, comprising:	59869
Mikrozid sensitive wipes premium	05490175
Optical lens and spectacle glass wipes, 10x (double pack)	05490165
Device connection lead, 2.5 mm, black	05200320
Software module Binoptometer® 4P	59866
USB memory stick with software	59880
USB-cable 80 cm	02 59860 00 002
Alternative: USB-cable 3 m	02 59860 00 004
Alternative: USB-cable 1,8 m	02 59860 00 005
Optional: Tablet-PC	59870
Tablet-PC	05460851
Optional: Netbook „state of the art"	59867
Netbook	05460038
Mini Maus black, with cable	05460582
Protetection cover for the netbook	05460583
Optional: Software for testing the mesopic vision and glare sensitivity	59863
Cover, black	027070000006
Wash instruction for cover	027070000007
Software for eyesight tests suitable for children	59885
incl. Patient Instructions	PA/59887/.../en
Optional: External light shield	59873
Optional: Carrying case for Binoptometer® 4P	59864
Optional: Trolley case with telescopic pull handle	59868
Optional: USB FS MED Isolator	015692000010
To order: Fuses (with extra high breaking capacity), 1,25A H	05100171

- If transport damage is discovered from the shipment, please file a

complaint with the shipping company immediately.

- Have the damage confirmed on the bill of lading so that an orderly handling of the complaint for damages is possible.

Note:

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

2 Symbols

Symbols on device				Symbols packaging	
	Manufacturer		Protection class		Keep dry
	Date of manufacture	IP XX	Type of protection		This way up
CE	Conformité européenne	REF	Article number		Fragile
	Follow instruction for use	SN	Serial number	Transport	Limit of temperature for transport
	Disposal in household trash is prohibited		Caution	Storage	Limit of temperature for storage
	Applied part Type B				Limit of humidity
(21) ABCDEFG123456789 Matrix (01) 04049584000040		Example: UDI number, consisting UDI-DI (Device-Identification) UDI-PI (Product Identifier) machine-readable matrix code			Limit of air pressure

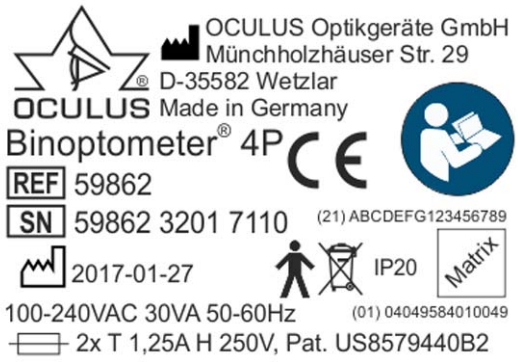


Fig. 2-1: Name plate (example)

3 About this Manual

3.1 Structure of the Documentation

A folder containing a set of documentation is supplied with your Binoptometer® 4P:

- **Instruction Manual:** The design of the unit is described in detail in this document. In the Instruction Manual, you will also find all safety-related instructions for use of the Binoptometer® 4P and the examination procedure.
- **User Guide:** The User Guide describes the basic operation of the Binoptometer® 4P program; all tests are described, how to create an examination program is explained and more detailed information about the Patient Data Management system is given.
- **Software Installation:** The introduction to the Software Installation describes how to install the Binoptometer® 4P software and the associated drivers.
- **Patient Instructions:** This user guide assists you in your communication with the patient.

3.2 Software Version

This User Guide describes the following Binoptometer® 4P software versions and the Patient Data Management:

- Binoptometer® 4P software: from version 1.0.4.x
- Patient Data Management: from version 6.08

Note

- The Patient Data Management software version is displayed on the "Settings" screen **in the Patient Data Management** *(User Guide)*.
- The software version of the Binoptometer® 4P program is shown on the "Setting" screen **within the Binoptometer® 4P program** *(User Guide)*.

4 Safety Instructions

This chapter contains a summary of the most important safety-related information.

4.1 About this Manual

- ➔ Read the User Instructions and the User Manual carefully.
- ➔ Keep the User Instructions handy and in the immediate vicinity of the equipment.
- ➔ When the device is delivered with a netbook: Read the User Instructions for the netbook.
- ➔ Observe the legal requirements for accident prevention.

4.1.1 Used Graphic Symbols

Caution

Denotes a potentially hazardous situation which can easily result in minor physical injury or property damage.

Note:

Identifies situations which can result in property damage, or denotes application information and useful or other important information.

Provides more thorough information on the product or its handling which require more careful attention.

4.2 Safety Instructions for Use of the Binoptometer® 4P

Caution

Personal injury or property damage due to improper operation

➔ Observe the following safety instructions.

Personal injury or property damage due to equipment modifications which impair safety

➔ No modifications may be made to this device without the permission of the manufacturer. Only the OCULUS service and authorized dealers are allowed to modify the device

Instructions for Operating Personnel

➔ Make certain that the Binoptometer® 4P is used exclusively by personnel that have the training and practical experience to safely and properly operate the equipment.

Transport and Storage Instructions

Refer to the notes in *sec. 12, page 47*.

Instructions for Setup and Connection

➔ Do not use or store the Binoptometer® 4P in rooms that are humid.

➔ Keep the Binoptometer® 4P away from water that may drip, surge or splash on it, and make sure that no liquids can enter the device. Do not place any containers with liquid either close to or on the Binoptometer® 4P.

➔ Germany: Only operate the Binoptometer® 4P in rooms used for medical purposes after they have been set up according to the VDE Regulations 0100-710.

➔ Do not operate the equipment included in the packing list in explosive environments, in the presence of combustible narcotic agents or volatile solvents such as alcohol, benzene, etc.

➔ Set up the Binoptometer® 4P so that the power plug is easy to access. That way, you can easily disconnect it from the power supply for any repairs or maintenance work.

➔ Do not use excessive force when connecting the electrical plug.

If a connection is not possible, check whether the plug fits the jack.

Make sure that the mains plug is plugged completly into the socket.

If you find damage to the plug connector, have the damage corrected by our service department.

➔ If the device is connected to a computer which does not comply with the standard IEC 60601-1, you should supply the computer with power by means of an isolation 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 isolation transformer or is located in proximity to the patient:

Ensure that a galvanic isolation is provided between the computer and the peripherals, if you connect peripherals to the computer (e.g. via LAN or USB) which do not comply with the standard IEC 60601-1 (with the exception of devices which are supplied with power directly by the computer, such as mouse, keyboard or USB flash drive).

➔ Note that devices connected via USB may only supply a maximum output voltage of 5.5 V DC. Under no circumstances should you use the Binoptometer® 4P with wireless technologies such as wireless USB.

➔ **Responsibility for data:** The device itself is only designed for connection to a PC and not for connection to the Internet. It does not require Internet access for regular use.

Do not connect the device to the Internet during use. This is considered misuse.

If you decide to connect the PC to the Internet for other purposes, you are responsible for ensuring data security.

Patient environment information

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

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

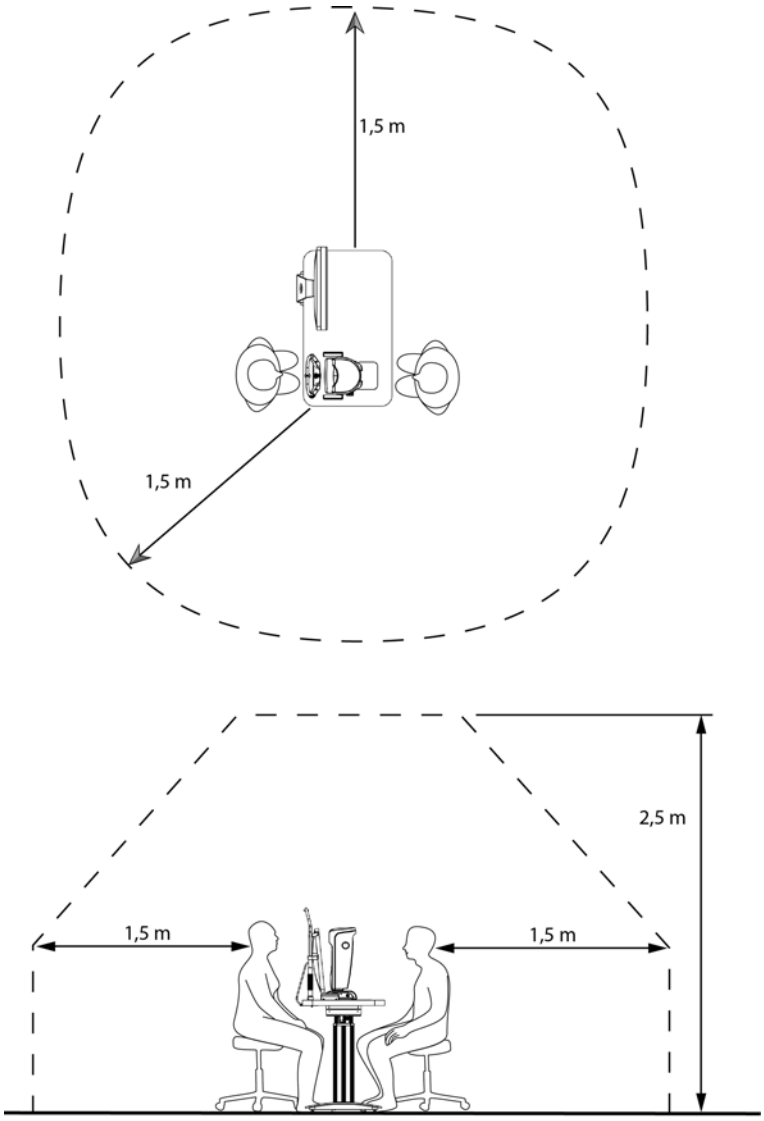


Fig. 4-1: Patient environment

Information about the operation of an ME system

The Binoptometer® 4P and a connected computer form a medical electrical system (ME system) according to DIN EN 60601-1. If you connect additional devices, such as, for example a printer, those devices become part of the ME system.

- ➔ Make sure that all devices of the ME system meet the requirements of IEC 60601-1 or IEC 60950-1.
- ➔ Note that an output voltage of maximum 5.5 V DC is supplied by a device connected via USB.
- ➔ If the device is connected to a computer which does not comply with the standard IEC 60601-1, you should supply the computer with power by means of an isolation 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 isolation transformer or is located in proximity to the patient:

  Ensure that a galvanic isolation is provided between the computer and the peripherals, if you connect peripherals to the computer (e.g. via LAN or USB) which do not comply with the standard IEC 60601-1 (with the exception of devices which are supplied with power directly by the computer, such as mouse, keyboard or USB flash drive).

Instructions for Operation

- ➔ Never put a damaged Binoptometer® 4P into operation.
- ➔ Only operate the Binoptometer® 4P using original accessory parts supplied by us, and when the device is in technically perfect working order.
- ➔ Before initial operation: Let OCULUS or an authorized dealer train you in the operation of the Binoptometer® 4P.
- ➔ Only operate the equipment after your have read and understood the User Instructions.
- ➔ 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 place heavy objects or the device itself onto the connection cable.
- ➔ Make sure that the power chord has no contact with hot surfaces (for example heater).
- ➔ Do not cover the ventilation openings.

Instructions for Maintenance

To ensure satisfactory and reliable operation, we recommend that you have the Binoptometer® 4P checked every two years by our service

department or an authorized dealer. If an error occurs which you are unable to correct, label the Binoptometer® 4P as "out of order" and contact our service department or an authorized dealer, *sec. 15, page 50*.

Only use the fuses mentioned in this operating manual.

Instructions for Disassembly and Disposal

- ➔ When you disconnect the electrical connections, pull on the respective connectors, not on the cord.
- ➔ Dispose of the equipment in compliance with the applicable legal requirements.

Instructions on Electrical Safety

Caution

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

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

- ➔ Ensure that connections with non-medical devices are made correctly.
- ➔ If the device is connected to a computer which does not comply with the standard IEC 60601-1, you should supply the computer with power by means of an isolation 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 isolation transformer or is located in proximity to the patient:

  Ensure that a galvanic isolation is provided between the computer and the peripherals, if you connect peripherals to the computer (e.g. via LAN or USB) which do not comply with the standard IEC 60601-1 (with the exception of devices which are supplied with power directly by the computer, such as mouse, keyboard or USB flash drive).
- ➔ Use only a computer that meets the specifications given in this instruction manual, *sec. 16, page 52*.
- ➔ Note that an output voltage of maximum 5.5 V DC is supplied by a device connected via USB.

Caution

Use of a multiple socket extension cord

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

If you use a multiple socket extension cord to connect the Binoptometer® 4P to the power supply, you must heed the following information:

- ➔ Use an extension cord that complies with the requirements of DIN EN ISO 60601-1: 20005, section 16.
- ➔ Do not place the multiple socket extension cord on the floor.
- ➔ Do not use more than one multiple socket extension cord.
- ➔ Plug only the Binoptometer® 4P and the computer that is being used with the unit (if applicable) into the multiple socket extension cord.

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

If you are using a new computer for the Binoptometer® 4P, you must have the electrical safety checked. Call OCULUS Service for this purpose.

Electromagnetic Compatibility (EMC) / Cables

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

Portable and mobile RF communications equipment can affect medical electrical equipment *sec. 17, page 55*.

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

Cybersecurity

Precaution

Do not use the Binoptometer® 4P with wireless technology, for example with wireless USB

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

Precautions for access control of the computer

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

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

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

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

Note

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

5 Intended Use

The Binoptometer® 4P is intended for the use described in this operating manual.

The Binoptometer® 4P has the following testing options:

- Visual acuity test with Landolt rings, numbers, letters, and similar
- Binocular tests (phoria and stereo vision tests)
- Color perception test (Ishihara color charts, Velhagen-Broschmann color charts and Matsubara color charts)
- Contrast sensitivity testing under photopic conditions
- Mesopic (twilight) vision test with and without glare, in acc. with DIN 58220 Part 7, DVLA and G25 (optional)
- Test for latent hyperopia
- Range of accommodation measurement
- Peripheral visual field test

➔ Only operate the device using original accessory parts supplied by us, and when the device is in technically prefect working order.

➔ Heed the safety instructions listed above.

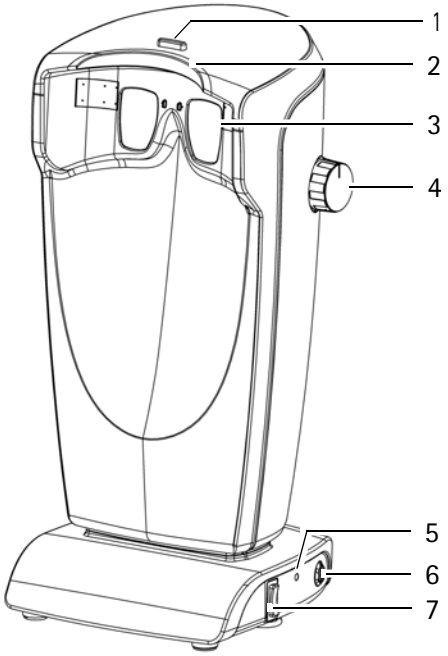
➔ Make sure that the following power supply types are used: 100-230V, 50-60 Hz.

Contraindication

none

6 Device Description

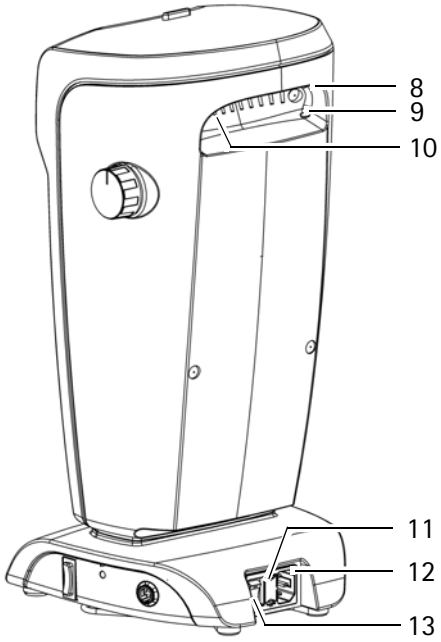
6.1 Front View



1) Holder for external light shield
2) Forehead rest
3) Viewing window
4) Knob to adjust the viewing angle
5) Indicator light
6) Netbook/laptop/PC connection
7) Rocker switch for height adjustment (optional)

Fig. 6-1: Front View

6.2 Rear View



8) Handhold
9) Opening for service buttons
10) Ventilation openings
11) Fuse holder
12) Power connection jack
13) On / Off switch

Fig. 6-2: Rear View

6.3 Mode of Operation of the Binoptometer® 4P

The Binoptometer® 4P is a vision screening instrument that provides a comprehensive set of tests. The tests are presented on a high-resolution micro-color display. This technology allows a virtually unlimited presentation of vision tests.

A precisely calculated, three-element achromatic lens provides an exact image of the tests. This lens allows vision to be tested irrespective of the patient's interpupillary distance.

Function of Some Components

Knob for infinitely adjustable viewing angle *(fig. 6-1, page 14, item 4)*: The patient can adjust the angle of the test field himself, so that the vision test can also be conducted with multifocals or varifocals under physiological conditions. With the adjustment knob, the test field is moved downward (down-gaze angle).

Viewing window *(fig. 6-1, page 14, item 3)*: The light-protected, yet open viewer prevents interfering reflections and contributes to a pleasant test atmosphere.

Rocker switch for height adjustment (optional) *(fig. 6-1, page 14, item 7)*: The rocker switch for height adjustment allows the patient to adjust the height him/herself.

Indicator light *(fig. 6-1, page 14, item 5)*: The indicator light shows whether the Binoptometer® 4P is receiving power.

7 First-time Operation

Before the Binoptometer® 4P is operated for the first time, you must complete the following actions:

- Set up
- Connection
- If necessary, install the software

➔ After transport or after a long storage period, do not operate the Binoptometer® 4P for 3-4 hours. In the event of extreme temperature changes from cold areas to warm rooms, the optical components can become fogged.

Caution

Risk of incorrect measurements/equipment damage due to improper setup

➔ Before using the Binoptometer® 4P for the first time, have our service department or an OCULUS-authorized specialist give you training.

7.1 Set Up for Initial Use

The ambient conditions for operation are given in *"Ambient Conditions" page 52*.

- ➔ Remove the Binoptometer® 4P from the packaging. Lift it with the handhold *(fig. 6-2, page 14, item 8)*.
- ➔ Place the Binoptometer® 4P on a level surface.
- ➔ Position the Binoptometer® 4P so that the patient is not affected by sunlight or artificial light sources.
- ➔ Avoid reflections from windows, mirrors etc. on the lenses of the patient and the viewers.
- ➔ Dispose of the packaging in an environmentally-friendly manner.

Caution

Interruption of the examination due to overheating

If the unit overheats, it shuts itself off and the test results are lost.

- ➔ Do not cover the ventilation openings.

7.2 Connecting

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

Caution

Electrical safety hazard

- ➔ Do not use the Binoptometer® 4P adjacent to or stacked with other equipment.
- ➔ If you have to use the Binoptometer® 4P adjacent to or stacked with other equipment, verify the correct operation of the Binoptometer® 4P.
- ➔ If you use a power strip to connect the Binoptometer® 4P: Use a power strip that complies with the requirements of DIN EN 60601-1.
- ➔ Do not place the multiple socket extension cord on the floor.
- ➔ Do not use more than one multiple socket extension cord.
- ➔ Plug only the Binoptometer® 4P and the computer that is being used with the unit (if applicable) into the multiple socket extension cord.
- ➔ Use a socket with a protective earth connection which is fully operating.

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

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

➔ Set up the Binoptometer® 4P so that the power plug is easy to access. That way, you can easily disconnect it from the power supply for any repairs or maintenance work.

Note

Risk of equipment damage due to incorrect connection

If you do not connect the Binoptometer® 4P properly, and the connection is live, the unit can be damaged within a short period of time.

➔ Do not use excessive force when connecting the electrical plug.

➔ Please pay attention to the specifications on the nameplate.

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

Netbook/ Laptop / PC Connection

If the device is connected to a computer which does not comply with the standard IEC 60601-1, you should supply the computer with power by means of an isolation 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 isolation transformer or is located in proximity to the patient:

Ensure that a galvanic isolation is provided between the computer and the peripherals, if you connect peripherals to the computer (e.g. via LAN or USB) which do not comply with the standard IEC 60601-1 (with the exception of devices which are supplied with power directly by the computer, such as mouse, keyboard or USB flash drive).

- Connect the Binoptometer® 4P and netbook / laptop / PC with the appropriate cable.

Fig. 7-1: Example: Connect to a netbook

➔ Make sure that the plug is inserted in the correct position.

➔ Heed the manual of the netbook / laptop / PC.

7.3 Software Installation

Before first use, you must install the Binoptometer® 4P software on your laptop or PC. Proceed as described in the *Software Installation*.

It is already installed on the supplied netbook. Prerequisite for the installation on the PC / laptop, see *sec. 16, page 52*.

Caution

Faulty measurements/damage to the device due to unauthorised personnel

➔ Ensure that software updates are only carried out by a specialist technician authorised by OCULUS.

8 Daily Startup

To start the Binoptometer® 4P for daily operation, you must:

- Install and connect the device
- Check the device viewer
- Turn on the device

Note:

Risk of equipment damage due to incorrect transport

➔ Check the Binoptometer® 4P after each transport and before any examinations for damage.

➔ Label the damaged Binoptometer® 4P as "out of order".

➔ Report the damage to the service department.

➔ Use only undamaged Binoptometer® 4P devices.

8.1 Setup and Connection for Daily Operation

Fig. 8-1: Take out the unit

The ambient conditions are given in *"Ambient Conditions" page 52*.

➔ Take the Binoptometer® 4P from the trolley / bag. Lift it with the handhold (1).

➔ Place the Binoptometer® 4P on a level surface.

➔ Position the Binoptometer® 4P so that the patient is not affected by sunlight or artificial light sources.

➔ Avoid reflections in the lenses of the patient and viewers, e.g. through windows or mirrors.

Caution

Interruption of the examination due to overheating

If the unit overheats, it shuts itself off and the test results are lost.

➔ Do not cover the ventilation openings.

➔ Connect the Binoptometer® 4P, *sec. 7.2, page 16*.

8.2 Clean the Device Viewer

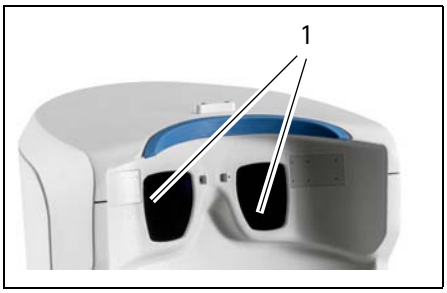


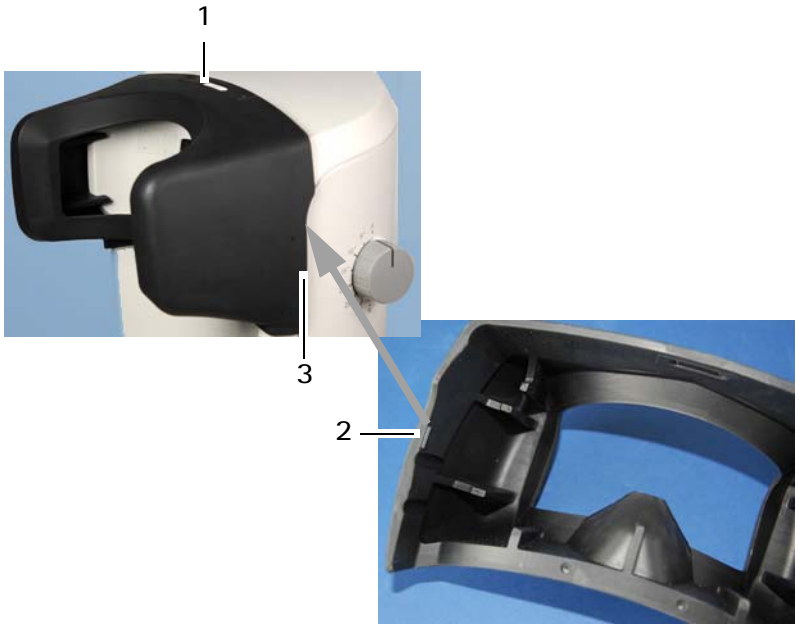
Fig. 8-2: Check the device viewer

➔ Check the device viewer for impurities.

➔ If impurities are found: Clean the viewer glass (1), also see *sec. 11.1, page 43*.

8.3 Use of the External Light Shield

You can then still conduct the mesopic (twilight) vision test and glare sensitivity test, even if you cannot darken the room. You need the external light shield (optional extra) for this purpose.



1 Holder
2 Securing tab
3 Groove

Fig. 8-3: Use of the external light shield

➔ Hook the external light shield into place at the holder (1).

➔ Secure the external light shield with the securing tabs (2) at both sides. The securing tab (2) must fit into the groove (3).

8.4 Turning On

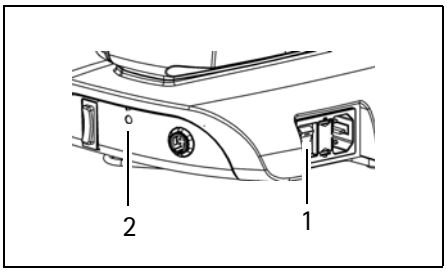


Fig. 8-4: Gerät einschalten

➔ Switch on the Binoptometer® 4P at the On / Off switch.
If the Binoptometer® 4P is connected with a netbook, laptop or PC, you must start the software.

9 Conducting an Examination

How to proceed with an examination is shown here with an example using a netbook.

If you do not want to document the test results with the software, you can record them in a test block.

➔ Proceed as described in *sec. 9.3, page 33*.

General instructions on how to use the examination programs, detailed information about the screening programs of individual tests and how to proceed can be found in the User Guide.

The following steps are part of the examination:

- Find the patient in the patient data management or create a new record
- Prepare the patient for the examination
- Carry out the examination
- Display and print results

9.1 Find the Patient in the Patient Data Management or Create a New Record

If the Binoptometer® 4P is connected with a netbook, laptop or PC, you can enter data for the patients using the patient data management screen.

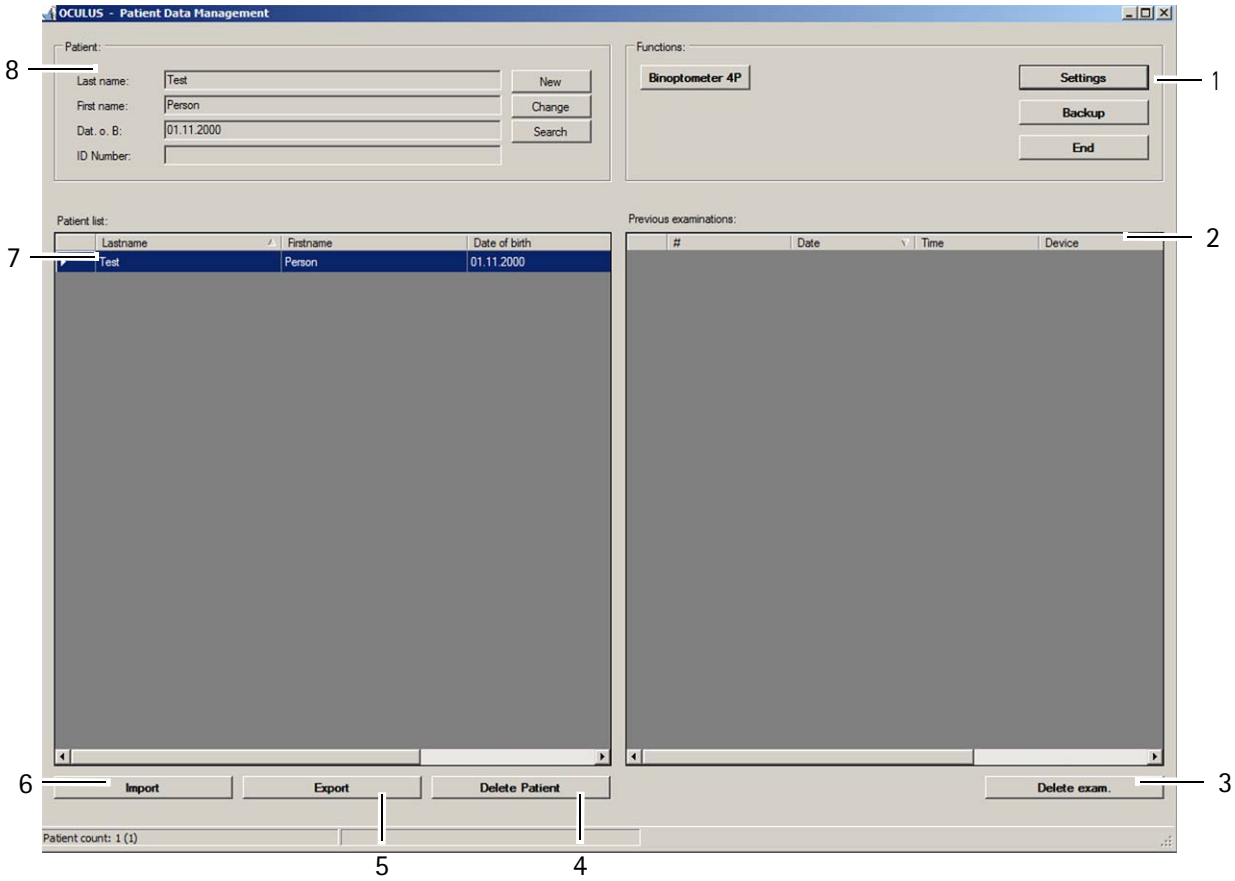
For more information on patient data management, refer to the *User Guide*.

9.1.1 Starting the Patient Data Management

After turning it on, the operating system boots up.

➔ Click on the Binoptometer® 4P icon: .

It then displays the user interface for "patient data management".



1 "Functions" box
2 Previous examinations
3 [Delete exam] button
4 [Del. Patient] button
5 [Export] button
6 [Import] button
7 Patient list
8 "Patient" box

Fig. 9-1: User interface for patient data management

To get to the Binoptometer® 4P program, you must first enter a new patient (8) or select an existing patient from the patient list (7).

9.1.2 Entering a New Patient

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

➔ Enter the patient's complete last name, first name and date of birth in the patient window (8).

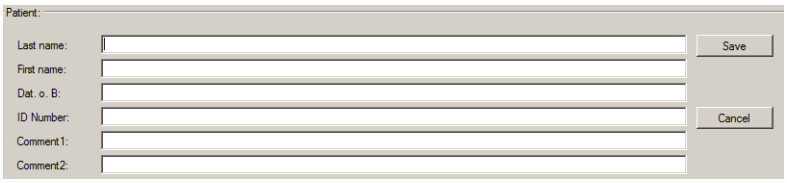


Fig. 9-2: Entering patients

Optionally you can enter an ID number for the patient.

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

➔ Select the newly entered patient from the patient list and double-click on the selected patient name to start the Binoptometer® 4P program.

9.1.3 Selecting an Existing Patient

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

➔ Press the [Search] button to quickly find the patient you want in the list.

➔ Enter the patient's name or the first letter of the name in the "Last name" field.

Optionally, you can search through the patient's ID number, first name or date of birth, if it was entered when you first created the patient data.

➔ To transfer the patient's name to the patient window, click the entry that you need in the list. This also brings up a list of any previous examinations for that patient in the examination window (bottom right side).

Extended Patient Search: [Extended] Checkbox

➔ Click on the [Extended] checkbox.

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

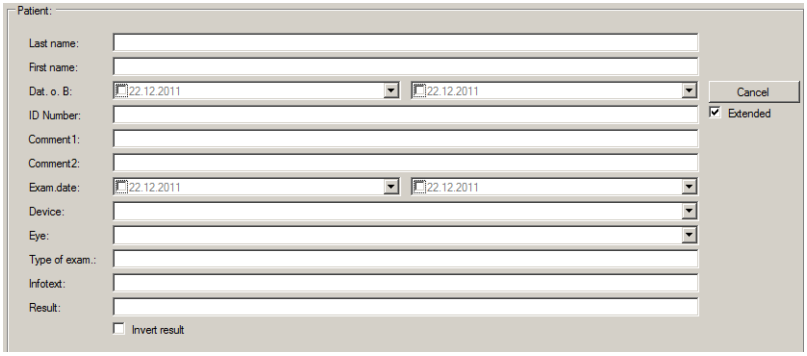


Fig. 9-3: Advanced search

9.2 Change Settings

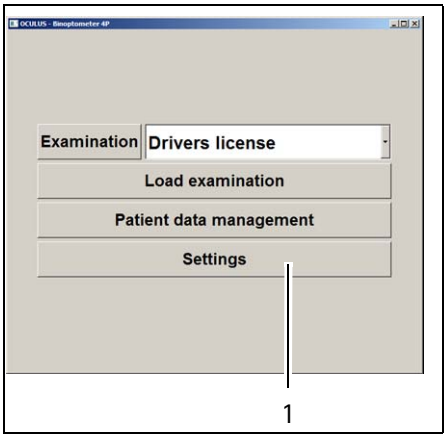


Fig. 9-4: Menu "Binoptometer® 4P"

If necessary you can make some basic adjustments in the Binoptometer® 4P program (1). If you want to change a setting, follow the instructions described in *sec. 9.3, page 33*.

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

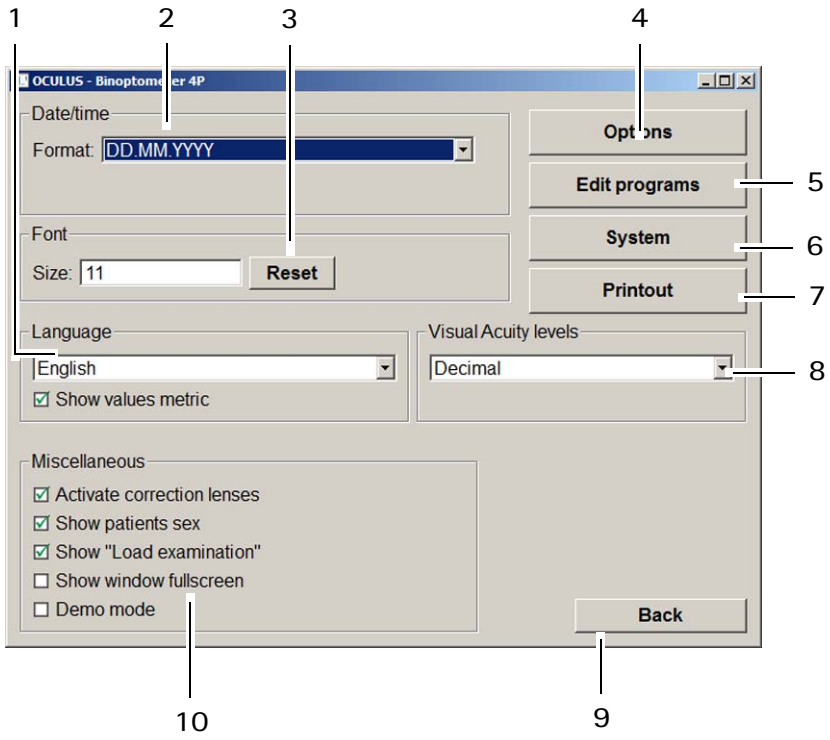
The following settings can be changed:

- Select language and change units of measure, *page 26*
- Set the date format, *page 26*
- Change font size of examination display, *page 27*
- Change the visual acuity data, *page 27*
- Activate correction lenses, *page 27*
- Enable the option to allow the patient's gender to be entered in the patient data management, *page 28*
- Enable to load an existing examination without using the OCULUS patient data management, *page 28*
- Enable full screen mode when the program is started, *page 28*
- Enable Demo mode, *page 28*
- Release optional software modules, *page 29*
- Edit examination program, *page 30*
- Export to external patient data management, *page 31*
- Change the colour test presentation times, *page 32*
- Generate detailed print outs, *page 32*

Proceed as follows:

➔ Press the button [Settings].

The following dialog is displayed:



1	*"Language" box*	6	*Button [System]*
2	*"Date / Time" box*	7	*Button [Print settings]*
3	*"Font" box*	8	*Box "Visual acuity data"*
4	*[Options] button*	9	*[Back] button*
5	*Button [Edit programs]*	10	*"Miscellaneous" box*

Fig. 9-5: "Settings" screen

Select Language and Change Units of Measure

"Language" box *(fig. 9-5, page 26, item 1)*:

➔ Select the desired language from the drop-down list.

The selected language will be active after the next start of the Binoptometer® 4P.

➔ Activate the checkbox [Show metric values] to switch over to metric units of measure.

If the checkbox is deactivated, the units of measure are output in a non-metric system of measure.

Change Date Format

"Date / Time" box *(fig. 9-5, page 26, item 2)*:

➔ From the drop-down list, select the desired date format.

Change font size of examination display

"Font" box *(fig. 9-5, page 26, item 3)*:

➔ Enter the font size for the examination display.
Enable the [Reset] tab to use the default font size.

Change Visual Acuity Data

"Visual acuity data" box *(fig. 9-5, page 26, item 8)*:

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

Activate correction lenses

"Miscellaneous" box *(fig. 9-5, page 26, item 10)*:

If you activate this function, the examination program displays a selection of corrective lenses, which can be placed in front of the patient's eyes during the examination, if necessary.
Indications:

- Suspected latent hyperopia
- The patient can see close optotypes more poorly than distant ones (presbyopia)
- Suspected myopia (optotypes are not clearly recognized at a distance)
- Test for night-time myopia during the twilight vision test

➔ Activate the checkbox [Activate corrective lenses].

Corrective lenses in the range of +4.5 D to -3.5 D can be used.

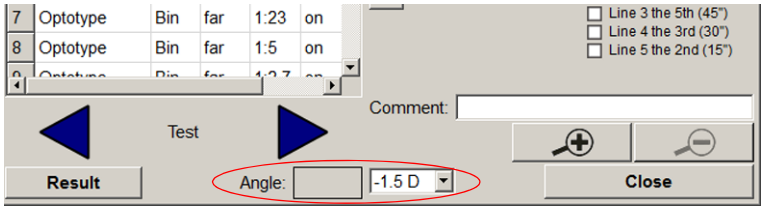


Fig. 9-6: Buttons are activated for plus lenses

Show "Load examination"

If you do not work with the OCULUS patient data management, you can use this function to load an existing examination.

"Miscellaneous" box *(fig. 9-5, page 26, item 9)*:

➔ Enable the [Show "Load examination"] checkbox.
The according button (1) will be added in the "Binoptometer® 4P" menu.

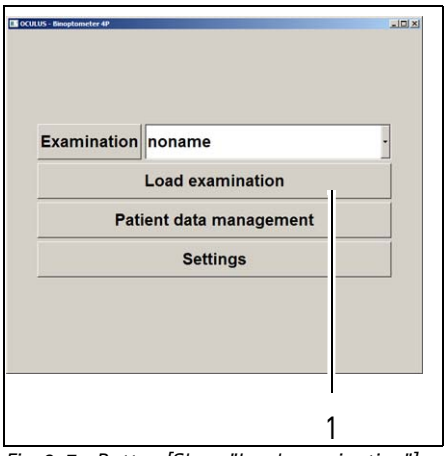


Fig. 9-7: Button [Show "Load examination"]

Display Gender

"Miscellaneous" box *(fig. 9-5, page 26, item 10)*:

➔ Activate the [display gender of patient] checkbox.
Now you can record the gender of the patients in the list of patients.

Full Screen Display

"Miscellaneous" box *(fig. 9-5, page 26, item 10)*:

➔ Enable the [full screen at startup] checkbox.

Enable Demo Mode

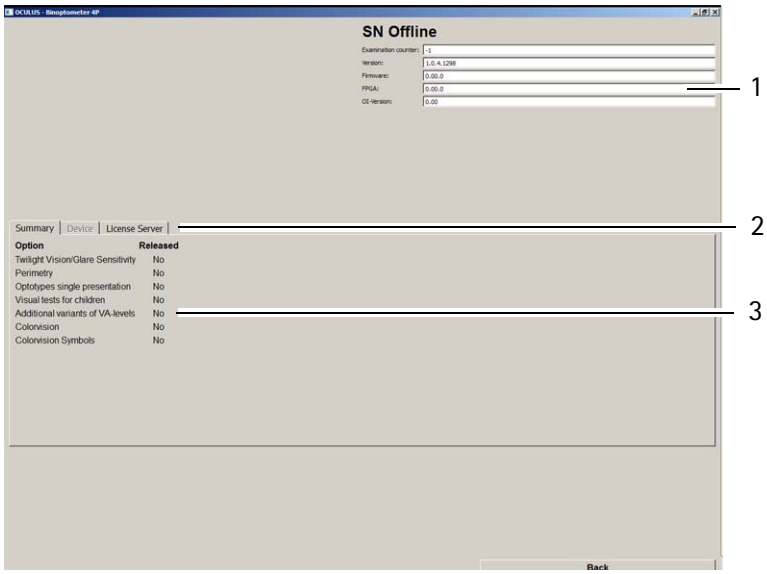
This function is for demonstration purposes only, if a Binoptometer® 4P is not connected to your laptop/netbook/PC.

"Miscellaneous" box *(fig. 9-5, page 26, item 10)*:

➔ Enable the [Demo Mode] checkbox.

Release Optional Software Modules

Screen options:



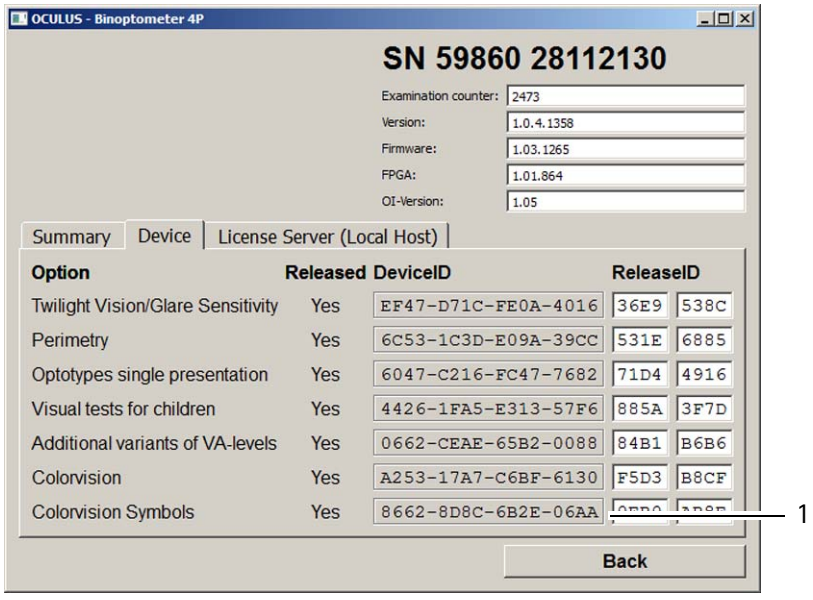
1 Device information
2 Tabs
3 Status of the software modules

Fig. 9-8: "Options" screen

You need this screen if you want to order optional software modules, see *User Guide*.

➔ Press the [Options] button *(fig. 9-5, page 26, item 4).*
The current software status is displayed (3).
Have the serial number (SN....) (see rating plate) of the Binoptometer® 4P available.

➔ Switch over to the "Device" tab.



1 Device ID example "Colorvision Symbols"

Fig. 9-9: "Device" tab

➔ Have the Device ID of the desired option available, e.g. the Device ID "Colorvision Symbols" (1).

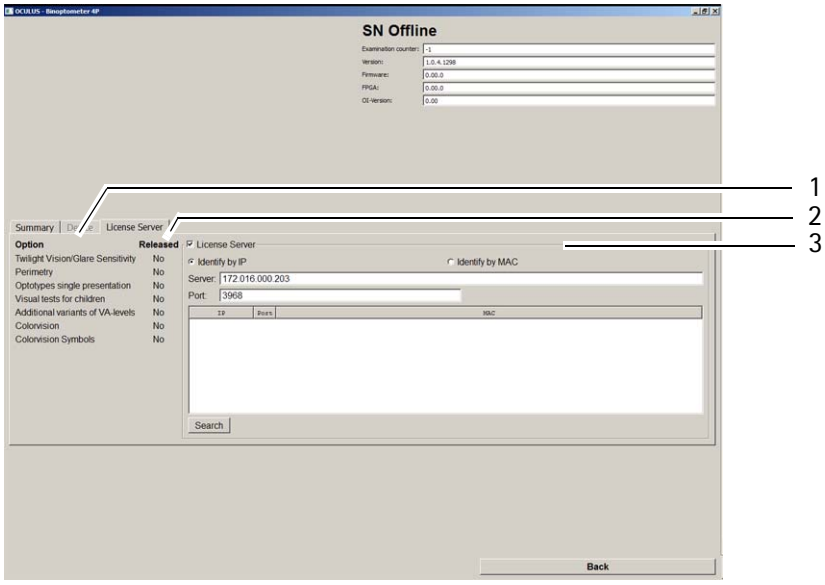
➔ Call OCULUS service and ask them for your release code, *sec. 15.3, page 51*.

➔ Enter the received release code in the line "Colorvision Symbols" in the "ReleaseID" field.

The selected option is now released.

Tab: License Server

The "License Server" tab (1) gives information about the options that are available in the network.



1 List of options
2 Information about the release status
3 "License Server" box

Fig. 9-10: "License Server" screen

The "Options" list (1) lists the available options.

Release status of the option (2)

Yes: License for the option is present

No: License for the option is not present.

You need the field "License Server" (3) to connect the Binoptometer® 4P to the network.

Edit Examination Program

➔ Press the button [Edit programs] *(fig. 9-5, page 26, item 5)*.

You can

- change the order in which the examination programs are displayed
- copy and edit an existing examination program
- create and edit a new examination program.

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

Export to external patient data management

You can export the patient data with this function.

➔ Press the button [System] *(fig. 9-5, page 26, Pos. 6)*.

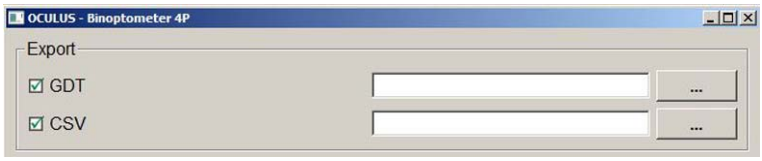


Fig. 9-11: GDT- und CSV-Export

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

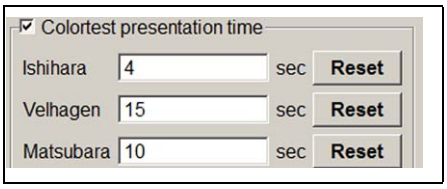
➔ Select the directory into which the patient data are to be exported.

GDT: The data are exported to an external practice management software, or are exported in PDF format for generating examination results.

CSV: Export of the examination data to an Excel file

Change the Presentation Time of the Colour Test

With this screen function, you can set the length of time that the color charts are presented for the color vision test.



➔ Press the button [System] *(fig. 9-5, page 26, item 6)*.

➔ Activate the checkbox [Color test presentation time].

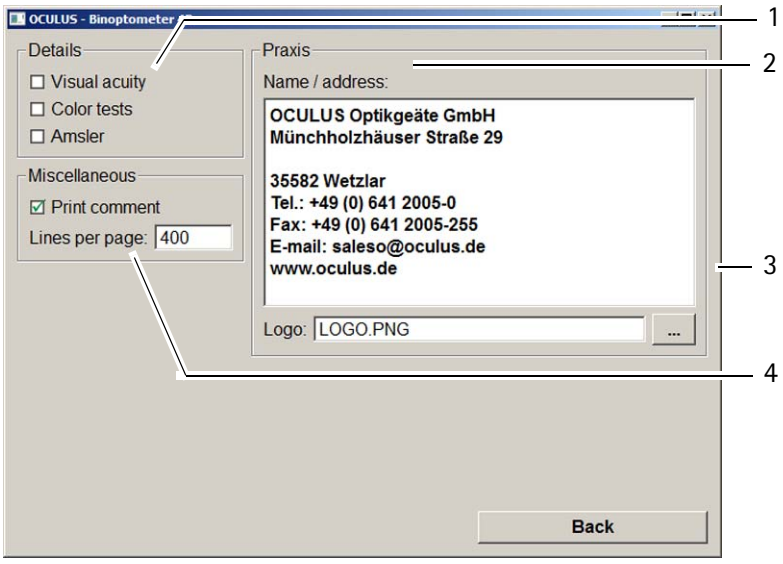
➔ Enter the desired presentation time.

➔ Press the [Reset] button to reset the settings to: Ishihara 4 sec, Velhagen 15 sec and Matsubara 10 sec.

The Ishihara test is preset to 4 seconds in accordance with Prof. Dr. H. Krastel's recommendation. According to the instructions for the Ishihara test, 3 seconds are enough.

Generate Detailed Printouts

With this screen function, you can choose to output detailed results of the visual acuity and color sensitivity tests, or of the Amsler test. You can also enter additional information here, such as e.g. your office address and your logo, which will then subsequently appear on the results printout.



1 Enable the detailed result printouts
2 Input field "Name/Address"
3 Button for uploading an image
4 Enable the printing of comment

Fig. 9-12: "Print Settings" screen

➔ Press the [Print settings] button *(fig. 9-5, page 26, item 7)*.

➔ Enable the respective checkbox [Visual acuity], [Color tests] or [Amsler] (1) if you want detailed results for the individual examinations.

➔ In the input field "Name/Address" (2), enter the text that you want to have printed out on the printout, such as e.g. your office address.

➔ Press the [...] button (3) to find the file that contains the wanted image, e.g. your office logo, and confirm your selection.

➔ In the in the input field "Miscellaneous" (4), enable the [Print comment] checkbox to generate the comment on the printout.

➔ To generate a page break: The page break of the printout depends on the printer. If the page break should be carried out on another position, you can change it here. In the input field "Lines per page" (4), enter the amount of lines per page. There will be a page break after this amount of lines.

Switch to the Binoptometer® 4P Program

➔ Press the [Back] button *(fig. 9-5, page 26, item 9)*.

The settings will take effect immediately, except for the language change.

9.3 Prepare Patient for the Examination

After you have entered the patients in the patient list and possibly changed the settings, you must now prepare the patients for the examination.

- ➔ Check to be sure that any adaptation disorder has been resolved.
- ➔ Check the patient's glasses for damage or dirt.
- ➔ Explain the procedure and the optotypes to the patient. You can show the patient the figure:

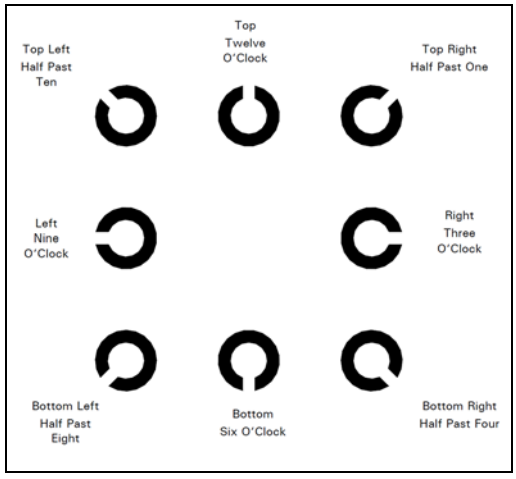


Fig. 9-13: Example: Landolt rings explained

If you have a Binoptometer® 4P with height adjustment feature, you can adjust the height either with the rocker switch, or via the Binoptometer® 4P program.

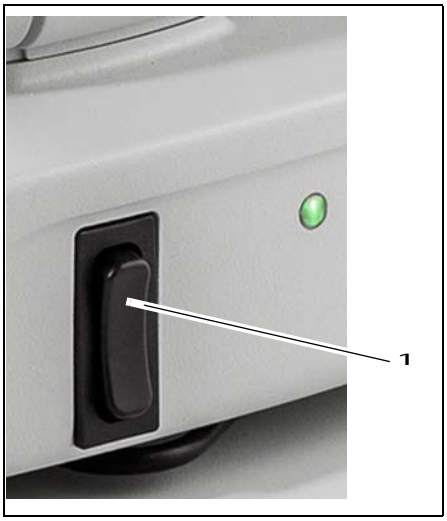


Fig. 9-14: Adjust height with rocker switch

➔ With the rocker switch (1): Adjust the height of the device with the rocker switch (1). The patient is sitting properly if he keeps his head straight and is relaxed.

➔ Via the Binoptometer® 4P program: Press the appropriate arrow button, see *(fig. 9-19, page 37, item 9)*.

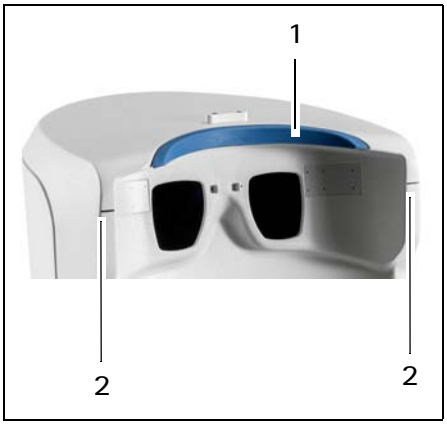


Fig. 9-15: Position patient

➔ Make sure that the forehead of the patient rests firmly on the forehead rest during the entire exam (1).

➔ Always make sure that the patient's eyes are approximately level with the marker lines (2). Otherwise, the test image may be cut off and the patient may not see the optotypes.

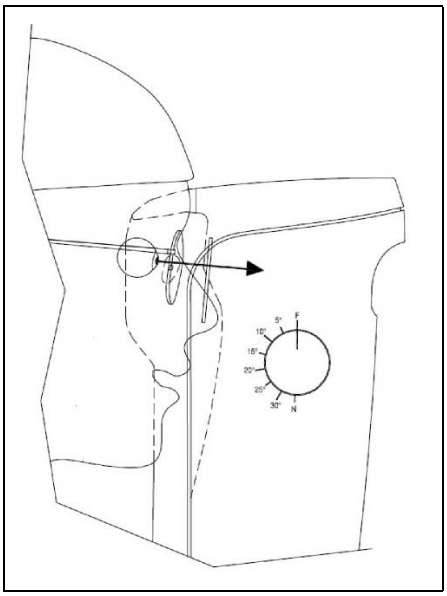


Fig. 9-16: Adjust viewing angle

➔ Adjust the viewing angle to 0 degrees to complete a distance test.

Patients with multi-focal or progressive lenses: Change the viewing angle if the test distance is shortened. The selected viewing angle is displayed in the test menu, see *fig. 9-19, page 37, item 5*.

We recommend that you let the patient adjust the settings, as he/she can judge best when he/she can see the test pattern well.

9.4 Select and Start Exam

➔ If you're using a netbook, laptop or PC: If necessary, press the [Binoptometer® 4P] button in the patient data management to start the Binoptometer® 4P program.

The following dialog is displayed:

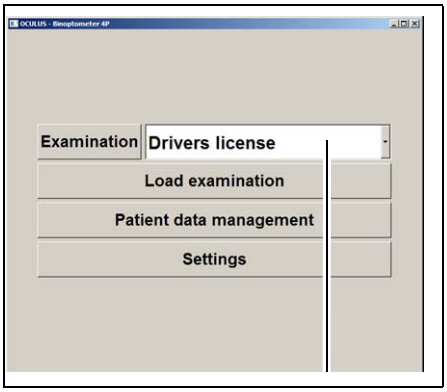


Fig. 9-17: Menu (Binoptometer® 4P)

➔ Press the button (1).

A drop-down list of all predefined applications is displayed.

➔ Select, for example, the examination program "Drivers license".

➔ Press the button [Examination].

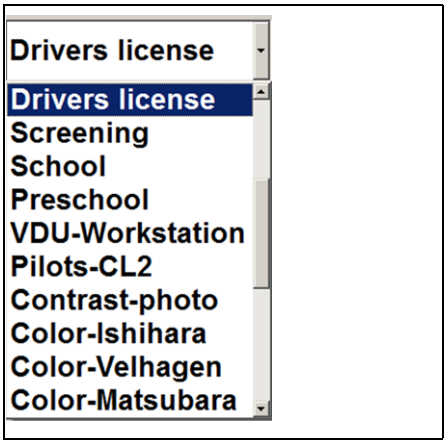
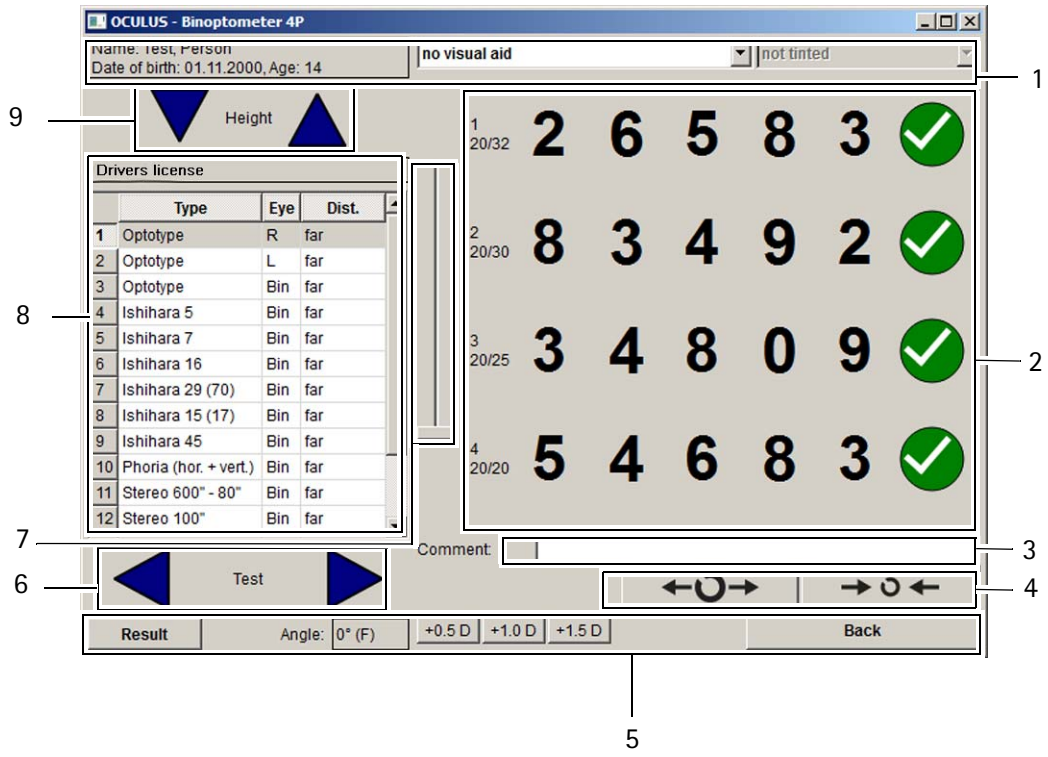


Fig. 9-18: Choose exam menu

The selected exam menu is displayed.



1	*Header with information about patients*	6	*Arrow keys for steps: "back" and "next"*
2	*Test pattern display*	7	*Slider to adjust the test distance*
3	*Input field "Comment"*	8	*Display the exam program with test steps*
4	*Buttons to change the size of the optotypes*	9	*Arrow keys for "height adjustment" (only model 59860)*
5	*Baseline with buttons [back] and [outcome], display "Angle", optional: plus lenses*		

Fig. 9-19: Example Drivers license exam menu

➔ Run through the steps of the examination exam, *User Guide*.

General instructions on how to use the examination programs, detailed information about the screening programs of individual tests and how to proceed can be found in the *User Guide*.

9.5 Display and Print Results

You can view the test results.

➔ To do so, press this button

You can display and print out details of the visual acuity test, the colour tests and the Amsler test. The respective settings must be activated for this purpose, see *sec. 9.2, page 25*.

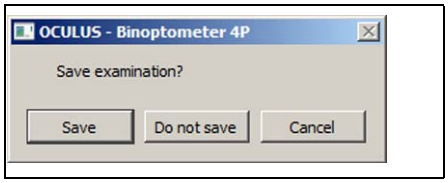
Then you can print the test results.

➔ To do so, press this button

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

If you do not have a printer connected, you can save the data on a USB stick and print them later from a different netbook, laptop or PC. The Binoptometer® 4P software must be installed on the other device. For more information, see *"Exporting Results via the Patient Data Management" page 41*.

9.6 Finishing the Exam



➔ Press the [Back] button.

➔ Press the appropriate button:
[Save], the examination is saved
[Do not save], the examination is not saved
[Cancel], return to the examination

The Binoptometer® 4P Overview menu is displayed.

You can start a new examination *(sec. 9.4, page 36)* or switch over to a new patient. To do this, press the button [Select patient].

➔ Clean and disinfect forehead rest after each exam, *sec. 11.1, page 43*.

➔ Set the viewing angle to 0 degrees, to perform the next examination.

9.7 Load Existing Examination

You can load an existing examination, e.g. in order to print it out.

If you are working with the OCULUS Patient Data Management, you can load an existing examination from there.

➔ Double click on the desired examination in the list of examinations, *fig. 9-1, page 23, Pos. 2*.

The examination is displayed in the examination menu

If you are not working with the OCULUS Patient Data Management, you can nevertheless load an existing examination. To do so, you must have activated the appropriate button in the settings, *(fig. 9-5, page 26, item 9)*.

➔ Press the button (1).

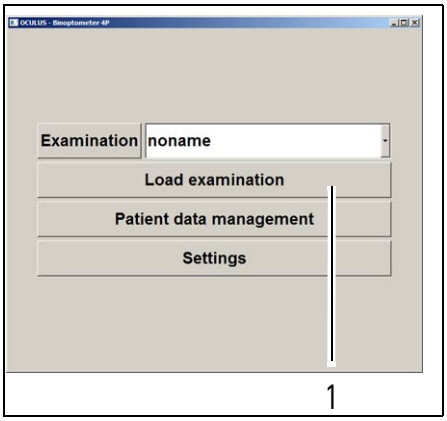


Fig. 9-20: "Load examination" button

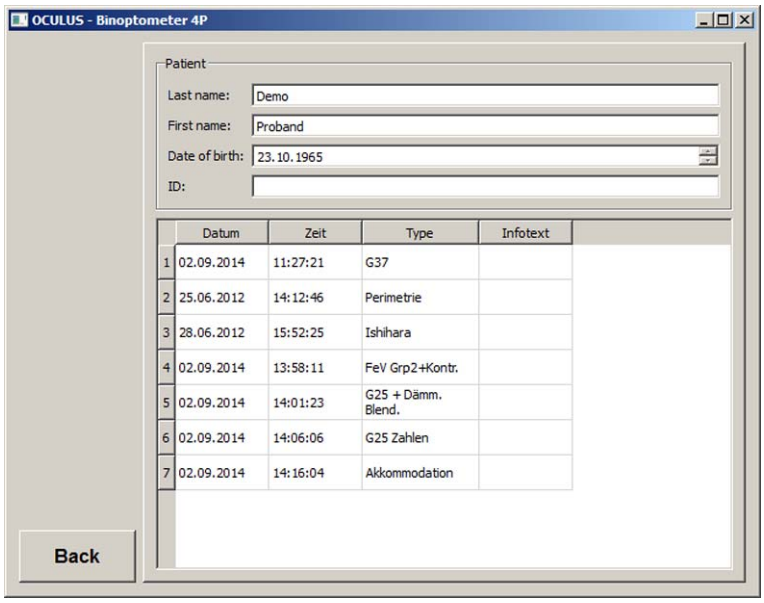


Fig. 9-21: Loading an examination without using the OCULUS Patient Data Management

➔ Move the cursor to the desired examination.

➔ Double-click on that examination.

The examination is displayed in the examination menu.

If you do not want to load any of the examinations, press the [Back] button. This returns you to the Binoptometer® 4P menu.

9.8 Turning Off

➔ Finish the current exam.
➔ Close the Binoptometer® 4P program.
➔ Shut down the computer.
➔ Turn off the Binoptometer® 4P with the On / Off switch.

If you want to transport or store the Binoptometer® 4P after an exam, you must proceed in the proper manner.

➔ Proceed as described in *sec. 12, page 47*.

Caution

Risk of electric shock if the Binoptometer® 4P is not completely disconnected from the mains for transport, cleaning, maintenance, disinfection and repair

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

10 Exporting Results via the Patient Data Management

Note:

Risk of loss of data due to computer viruses

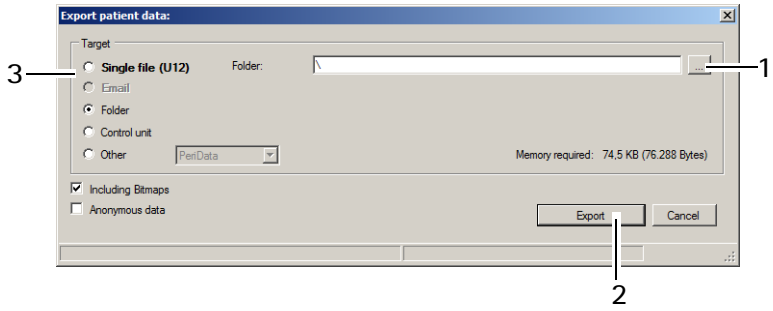
➔ Run a virus check before importing data from the USB stick.

10.1 Exporting Patient Data

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

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

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



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

Fig. 10-1: "Export patient data" dialog

The default options for import and export of data are configured in the "settings" field. See also *User Guide*. Depending on the settings, you may not have to perform all of the following steps (for example selection of the directory).

Recommendation: Export the patient data using the "Individual file (U12)" option.

For more information on patient data management, refer to the *User Guide*.

➔ Select the option for exporting the data in "Target" (3).

➔ Press the [...] button. (1).

➔ In the dialog that appears, select the folder or the file to which the patient data should be exported.

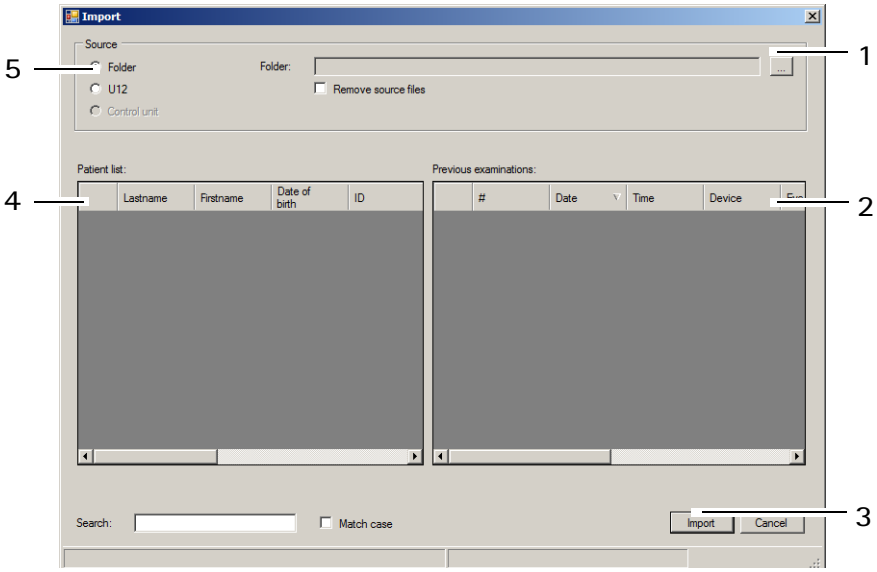
➔ Confirm your selection with [OK] or [Save].

➔ To export the data, press the [Export] button (2).

10.2 Importing Patient Data

If you receive patient data, for example, on a USB stick, you can import these data. To do this, the version of the Binoptometer® 4P program which you would like to import data into must match the version from which the data has been exported.

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



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

Fig. 10-2: Function "Import"

The default options for import and export of data are configured in the "settings" field. See also *User Guide*.

Depending on the settings, you may not have to perform all of the following steps (e.g. selection of the directory).

➔ Select the option (5) which contains the source data ("Folder" or "Single file (U12)").

➔ Press the [...] button. (1).

➔ In the dialog box, select the directory or the file where the patient data are located.

➔ Confirm your selection with [OK] or [Open].

The patients and the associated examinations that are found are displayed in the lower part of the dialog.

➔ To import the data, press the [Import] button (3).

The data will then be available in the patient data management system.

11 Cleaning, Disinfection and Maintenance

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

To ensure satisfactory and reliable operation, we recommend that you: Have the Binoptometer® 4P checked every two years by our service department or an authorized dealer.

If an error occurs that you can not resolve label the damaged Binoptometer® 4P as "out of order" and report the damage to OCULUS Service or your authorized dealer.

➔ Use only undamaged Binoptometer® 4P devices.

➔ Always heed the product descriptions and directions for use of products you use to care for, clean, and disinfect the unit and/or its accessories.

➔ Do not clean the Binoptometer® 4P with aggressive, chlorinated, abrasive or sharp cleaning agents.

11.1 Cleaning

Caution

Risk of electric shock if the Binoptometer® 4P is not completely disconnected from the mains

➔ Turn the Binoptometer® 4P off, *sec. 9.8, page 40*.

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

Materials needed:

- Cleaner for plastic surfaces with anti-static effect
- Cleaner for painted surfaces: Mixture of equal parts of alcohol and distilled water, possibly with a few drops of commercial detergent
- Soft cloth or lens brush
- Alcohol or lens cleaner

Cleaning intervalls:

➔ Wipe the forehead rest after each examination, and the housing as required.

Proceed as follows:

➔ Turn the Binoptometer® 4P off, *sec. 9.8, page 40*.
➔ Unplug the power cord.
➔ When cleaning, use a damp cloth and make sure that no liquid enters the Binoptometer® 4P.
➔ Clean the plastic surfaces and painted surfaces with appropriate cleaning agents.
➔ Clean the lenses with a soft cloth or lens brush, and, if necessary, with alcohol or a lens cleaner.

11.2 Disinfection

Materials needed:

- Disinfection and cleaning kit (included),
  Alternative:
  Mikrozid sensitive wipes premium
  Make: Schülke & Mayr
  Softpack 48 pcs
  Art.No. 165711

➔ Wipe the forehead rest after each examination, and the housing as required.

Note:

Equipment damage caused by disinfectant solution

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

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

11.3 Care and Maintenance

To ensure satisfactory and reliable operation, we recommend that you:

➔ Have the Binoptometer® 4P checked every two years by our service department or an authorized dealer.

Caution

Risk of electric shock if the Binoptometer® 4P is not completely disconnected from the mains

➔ Turn the Binoptometer® 4P off, *sec. 9.8, page 40*.

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

Note

Faulty examinations due to damaged equipment

If an error occurs that you can not resolve

➔ Label the damaged Binoptometer® 4P as "out of order".

➔ Report the damage to OCULUS Service or your authorized dealer.

➔ Use only undamaged Binoptometer® 4P devices.

11.3.1 Forehead Rest Replacement

When the forehead rest (1) is worn or soiled, you can replace it (order 07 59860 01 007).

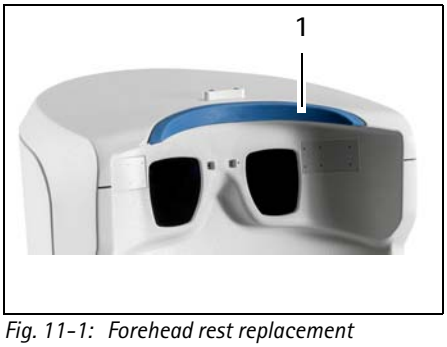


Fig. 11-1: Forehead rest replacement

➔ Pull off the forehead rest.

➔ Insert the new forehead rest.

11.3.2 Replacing the Fuse

You can replace a blown fuse.

Note:

Function loss due to incorrect fuse

➔ Only use the fuse specified in the parts list (order 05100171).

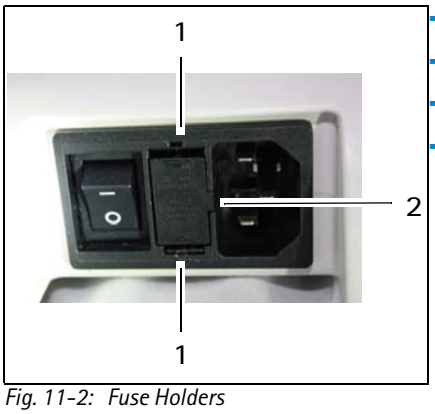


Fig. 11-2: Fuse Holders

➔ Turn the Binoptometer® 4P off, *sec. 9.8, page 40*.
➔ Unplug the power cord.
➔ Unplug the power cord from the Binoptometer® 4P.
➔ Press the latches on the sides (1) together.

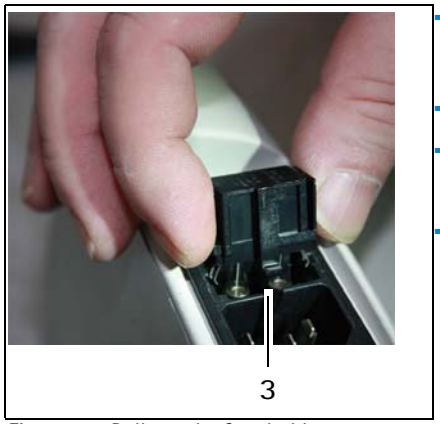


Fig. 11-3: Pull out the fuse holder

➔ Pull the fuse holder (3) out.
➔ Replace the blown fuse.
➔ Insert the fuse holder (3). Make sure it fits properly. The pin (2) must fit in the recess.
➔ Connect the Binoptometer® 4P to the mains.
You can now turn on the Binoptometer® 4P and start doing exams.

12 Transport and Storage

Before storing or transporting the Binoptometer® 4P, you have to dismantle and pack it properly.

12.1 Disassembly and Packing

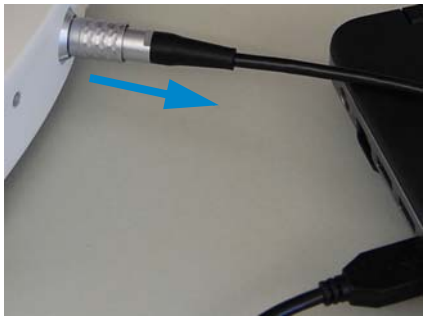


Fig. 12-1: Disconnect the cable

- ➔ Finish the current exam.
- ➔ Turn off the Binoptometer® 4P with the On / Off switch.
- ➔ Unplug the power cord.
- ➔ Disconnect the cable from the netbook / laptop / PC.
  To do so, take hold of the plug itself. Pull the thicker end gently backwards somewhat to release the lock. That way, the cable and plug are not damaged.
- ➔ Remove the lightproof viewer, if applicable.

Fig. 12-2: Packing the Binoptometer® 4P (Example with trolley)

- ➔ Pick up the Binoptometer® 4P with the handhold, and insert it into the transport box / bag so that the knob for adjusting the viewing angle is pointing up.
- ➔ Place the accessories in the corresponding sections.

Note:

Damage to the external light shield due to incorrect insertion.

If you bend or buckle the external light shield, the reinforcement could break.

- ➔ Do not bend or buckle the external light shield.
- ➔ Insert the external light shield with care.

12.2 Transport and Storage

Storage conditions

Ambient temperature	-30 – +70°C
Relative humidity, including condensation	10 – 90%
Air pressure	500 – 1060 hPa

Transport conditions

Ambient temperature	-30 – +70°C
Relative humidity, including condensation	10 – 90%
Air pressure	500 – 1060 hPa

➔ Wait approx. 3-4 hours after transport before operating the Binoptometer® 4P for the first time. In the event of extreme temperature changes from cold areas to warm rooms, the optical components can become fogged.

Note:

Equipment damage due to improper transport and storage

➔ Avoid shocks, vibration and dust.

➔ Avoid high temperatures and moisture.

➔ Transport the Binoptometer® 4P in a compliant manner.

➔ Store the Binoptometer® 4P in accordance with the storage conditions.

➔ Keep away from heating elements and moisture.

➔ Check the Binoptometer® 4P for damage every time it has been transported.

13 Disposal

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

➔ Transport the Binoptometer® 4P in a compliant manner.

14 Troubleshooting

Caution

Risk of personal injury or equipment damage due to improper troubleshooting

➔ If an error occurs which you are unable to correct by following the instructions below, label the device as "out-of-order" and contact our service department or an authorized dealer.

Error	Possible source	Remedy
The Binoptometer® 4P program doesn't start after the On/Off switch is pressed	There is no power.	Check that ■ the power cord is plugged in correctly. ■ the power cord is not defective. ■ the netbook/laptop/PC is correctly connected. ■ the fuse is not defective. If so, replace the fuse, *sec. 11.3.2, page 46*.
The following error message is displayed: "Binoptometer® 4P could not be found. Error code = -1"	The Binoptometer® 4P is not properly connected to the netbook / laptop / PC.	Check the connection from the device to the netbook / laptop / PC.

15 Terms of Warranty and Service

15.1 Terms of Warranty

If software is included with the deliverable items, it has been tested by us and meets the technical standards. Observe the following warranty requirements:

- It is important that you follow the User Instructions, the User Guide and the Safety Instructions before and during use of the equipment.
- In accordance with legal regulations, you are entitled to a warranty for the Binoptometer® 4P.
- If modifications are made to the Binoptometer® 4P by unauthorized persons, all warranty claims shall be voided. Improper modifications and repairs may result in considerable hazards to users and patients.
- Any entitlement to a warranty shall also be void if unauthorized persons interfere with the PC hardware and software supplied.
- Report any transport damage to the shipper immediately upon delivery. Have the damage confirmed on the bill of lading so that an orderly handling of the complaint for damages is possible.
- In general, our Business and Shipping Terms applicable on the date of purchase shall apply.

15.2 Assumption of Liability for Functions and Damage

OCULUS will only accept responsibility for the safety, reliability and serviceability of the Binoptometer® 4P if the unit is used in compliance with the following terms:

- Use the device in accordance with these instructions and the accompanying User Guide.
- There are no parts on or in the Binoptometer® 4P that require maintenance or repair by the user (except replacing the forehead rest and fuse). If assembly work, modifications, adjustments, repairs, changes or service is performed by unauthorized personnel, or if the Binoptometer® 4P is improperly maintained or handled, then any liability by OCULUS is voided.

- If the above-referenced work is performed by authorized persons, then a certification of the work shall be requested from this service technician which shall state any changes to factory defaults or to operating ranges. This certification must contain the date of performance and statement of the performing firm, with signature.
- On request, and for this purpose, OCULUS will supply authorized persons with spare parts lists and additional descriptions.
- Make certain that only original OCULUS parts are used.

15.3 Manufacturer and Service Address

Supplemental information is available from our service department or from our authorized representatives. Manufacturer and Service address:

Germany:

OCULUS Optikgeräte GmbH
Münchholzhäuser Straße 29
35582 Wetzlar
GERMANY
Tel.: 0641/2005-0
Fax: 0641/2005-255
E-mail: sales@oculus.de
www.oculus.de

USA:

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

16 Technical Data

Test distances	300 mm to infinity
Viewer setting	adjustable up to approximately 35 °
Viewing height	Optionally electrically adjustable, using either the rocker switch on the device or with the control unit or PC / Laptop / Netbook
Operation	with software via a PC / laptop / netbook.
Electric height adjustment (optional)	Rocker switch on the device. The measuring head can be adjusted by motor via the software.
Eye cover	LCD shutter
Test field luminance	approximately 130 – 300cd/m^2 - Corresponding to standard illumination D65 (D55 color test)
Eye test generation	Micro colour display, 800 x 600 pixels
Lighting	LED
Max. power consumption	30 VA
Voltage	100 – 240 VAC
Frequency	50/60 Hz
Fuses	2 x 1,25A H 250 V
Interfaces	USB
Recommended computer specifications	4 GB RAM, 320 GB HDD, 1.8 GHz, Windows® 8, 64bit
Lifecycle expectancy	Up to 10 years

Ambient Conditions

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

Storage Conditions

Ambient temperature	-30°C to +70°C
Relative humidity, including condensation	10% to 90%
Air pressure	500 hPa to 1060 hPa

Transport Conditions

Ambient temperature	-30°C to +70°C
Relative humidity, including condensation	10% to 90%
Air pressure	500 hPa to 1060 hPa

Definition according to DIN EN 60601-1

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

Dimensions

Binoptometer® 4P (59862) (W x D x H))	224 x 220 x 455 mm (8.8 x 8.7 x 17.9 in)
Binoptometer® 4P (59860) - with height adjustment	224 x 220 x 455 - 560 mm (8.8 x 8.7 x 17.9 - 22.0 in)

Weight

Binoptometer® 4P (59862)	4.8 kg including power cables
Binoptometer® 4P (59860) - with height adjustment	5.6 kg including power cables

CE in accordance with directive 93 / 42 / EWG for Medical Devices

The unit is a Class I product.

CE

Conformity assessment: Directive 93/42 / EEC: annex VII

17 Appendix

17.1 Electromagnetic Compatibility

Medical electric equipment is subject to special precautionary measures regarding EMC and must be installed and operated according to the EMC instructions contained in the accompanying paperwork.

Devices and systems from OCULUS 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 equipment may interfere with electrically operated medical devices.

The device was manufactured taking into account the permissible decline in performance during or resulting from the EMC test, without compromise to overall safety.

Caution

The use of accessories, converters, and cables that do not meet OCULUS specifications can result in increased emissions or a reduced interference immunity of the Binoptometer® 4P.

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

The use of OCULUS-specified accessories, converters and cable with any devices other than the Binoptometer® 4P can result in increased emissions or a reduced interference immunity of the other devices.

➔ Do not use the OCULUS-specified accessories, converters and cables for any device other than the Binoptometer® 4P.

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

Order Number	Description	
59860	Binoptometer® 4P with height adjustment	
59862	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
025986000002	USB connection cable	0.8m
025986000004	Alternative: USB connection cable	3 m
025986000005	Alternative: USB connection cable	1.8 m

17.2 Guidelines and Manufacturer's Declaration Electromagnetic interference emissions

Guidance and manufacturer´s declaration electromagentic emmissions IEC 60601-1-2: 2015, based to table 1		
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.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Binoptometer® 4P uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
HF-emissions CISPR 11	Class B	
Harmonics emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	complies	

Electromagentic immunity, IEC 60601-1-2: 2015, based on table 4			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV ± 15 kV	Floors should be made of wood or concrete or covered with ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Electromagentic immunity, IEC 60601-1-2: 2015, based on table 5, 8			
Electrical Fast transient/bursts IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/ output lines	± 2 kV ---------- ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 6100-4-5	± 1 kV kine(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% U_τ; 1/2 period at 0, 45, 90, 135, 180, 225, 270 and 315 degree 0% U_τ; 1 period and 70% U_τ; 25/30 periods Single-phase: at 0 degree 0% U_τ; 250/300 periods	0% U_τ; 1/2 period at 0, 45, 90, 135, 180, 225, 270 and 315 degree 0% U_τ; 1 period and 70% U_τ; 25/30 periods Single-phase: at 0 degree 0% U_τ; 250/300 periods	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Binoptometer® 4P requires continued operation during power mains interruptions, it is recommended that the Binoptometer® 4P be powered from an uninterruptible power supply or battery.
Note: U_τ is the a.c. mains voltage prior to application of the test level.			

Electromagentic immunity, IEC 60601-1-2: 2015, based on table 4, 5

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – Guidelines
Conducted RF IEC 61000-4-6	3 V_{eff} 150 KHz to 80 Mhz 6 V in ISM- and amateur radio frequency bands between 150 kHz and 80 MHz 80% AM to 1 kHz	V_{eff} = 3 V	Portable and mobile RF communications equipment should be used no closer to any part of Binoptometer® 4P, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{(V_1)}\right]\sqrt{P}$ $d = \left[\frac{3,5}{(E_1)}\right]\sqrt{P}$ 80MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz 80% AM at 1 kHz		$d = \left[\frac{7}{(E_1)}\right]\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range (b). Interface may occur in the vicinity of equipment marked with the following symbol: 

Note 1:	At 80 Hz and 800 MHz, 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 Binoptometer® 4P is used exceeds the applicable RF compliance level above, 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 150 KHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Binoptometer® 4P, IEC 60601-1-2:2007, table 6

The Binoptometer® 4P in intended for us e in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Binoptometer® 4P can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Binoptometer® 4P as recommended below, according to the maximum output power of the communications equipment.

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

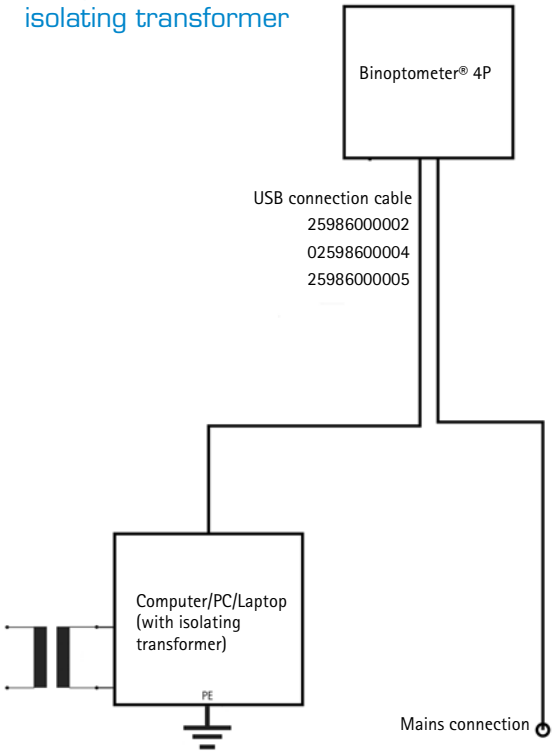
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

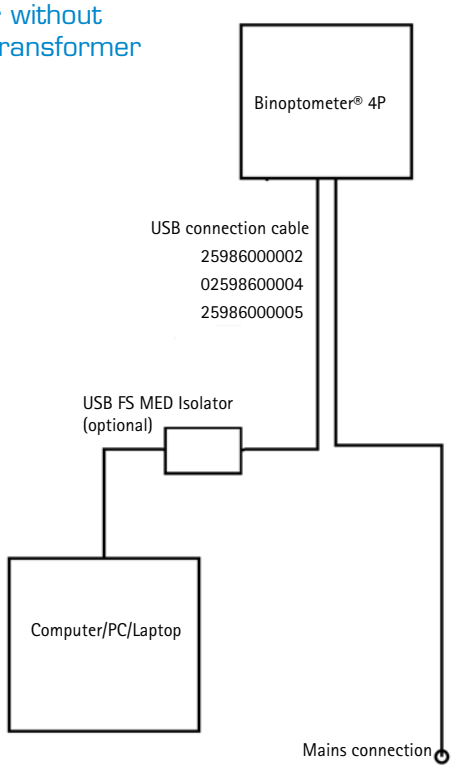
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

17.3 Description of the Connection

Computer with isolating transformer



Computer without isolating transformer



Manufacturer and Service Address

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OCULUS Optikgeräte GmbH
Münchholzhäuser Straße 29
35582 Wetzlar
GERMANY

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