OCULUS
Mesotest

INSTRUCTION MANUAL

OCULUS®

Foreword

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

The Mesotest II is used for testing the mesopic visual acuity of the human eye.

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

Article number G/62800/XXXX/EN
Revision: 02
Release: 02.12.2024

Table of Contents

1 Scope of Delivery

Components	Order number
■ Mesotest II	62800
or	
■ Mesotest II konkav (minus lenses can be swung in), with eye occluder	62801
■ Mains cable	05200320
■ Test block (100 sheets)	62850
■ Dust protection cover	026010005001
■ Cover for back pane of the viewer	016280000002
■ Instruction Manual Mesotest II	G/62800/xxxx/en
Optional:	
■ Control pad with LCD module and panel illumination	62811
■ Software module for Windows®-compatible computers for patient data acquisition and for control of the Mesotest II, incl. interface cable, USB 2.0 adapter and floating license key	62803
■ Carrying bag	62802

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

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

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

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

2 Pictograms

2.1 On the device / type plate

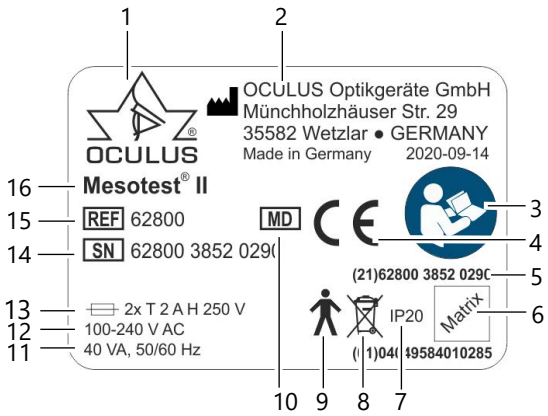


Fig. 2-1: Type plate

Nr.	Beschreibung	Nr.	Beschreibung
1	Manufacturer's logo	9	Applied parts
2	Manufacturer's address	10	Medical device
3	Observe instruction manual	11	Voltage
4	CE marking	12	Power supply
5	UDI number	13	Fuse
6	Matrix for device identification	14	Serial number
7	Protection class	15	Type number
8	Disposal in household trash is prohibited	16	Name of device

2.2 On the packaging

Figure legend	Notes	Figure legend	Notes
Transport 	Permitted temperature range for transport	**Storage** 	Permitted temperature range for storage
	Keep dry		Limit of humidity
	This way up		Limit of air pressure
	Fragile		

3 Information about the Documentation

A folder containing a set of documentation is supplied with your Mesotest II:

- **Instruction Manual:** The design of the unit is described in detail in this document. The instruction manual also gives you general information about working with the Patient Data Management system and all safety-related instructions for use of the Mesotest II.
- **Software Installation:** The introduction to the Software Installation describes how to install the Mesotest II software and the associated drivers.

If you work with a floating license key, the respective instruction manual explains how you can use the Mesotest II within a network.

4 Safety Instructions

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

- ➔ Carefully read through the Instruction Manual.
- ➔ Keep the Instruction Manual in good condition near the device.
- ➔ If the scope of delivery includes a netbook: Read the operating manual for the netbook.
- ➔ Observe the legal regulations with regard to accident prevention.

4.1 Pictograms in this manual

Attention
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.

Identifies important information about the product and its use, which require special attention.

> This symbol denotes menu paths and screen shots. Example for starting an examination:
Mesotest II > Examination > Load
which means:

- ➔ Select the “Examination” menu from the menu bar.
- ➔ Select the menu item “Load”.

4.2 Safety Instructions for Use

Attention

Personal injury or property damage due to improper operation

➔ Observe the following safety instructions.

Attention

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

➔ This equipment may not be modified without the permission of the manufacturer. Changes or modifications may only be made by OCULUS Service and authorized dealers.

Any serious-incident that has occurred in relation to the device should be reported to the manufacturer (vigilance@oculus.de) and the competent authority of the region in which the user and/or patient is established.

4.3 Instructions for operating personnel

➔ Make certain that the Mesotest II is used exclusively by personnel that have the training and practical experience to safely and properly operate the equipment *(sect. 5.5, page 16)*.

4.4 Transport and Storage Information

Refer to the notes in *sect. 15, page 80*.

4.5 Instructions for setup and connection

➔ Do not use or store the Mesotest II in rooms that are humid.

➔ Keep the Mesotest II away from water that may drip, surge or splash on it, and make sure that no liquids can enter the Mesotest II. Do not place any containers holding liquids in the vicinity of the Mesotest II.

➔ Germany: Only operate the Mesotest II 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 Mesotest II 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.

➔ Make sure that the power cord has no contact with hot surfaces (for example heater).

➔ Use only a mains cable that meets the requirements of IEC 60227-1, Type 53, min. 0.75 m^2 and of IEC 60320-1.

➔ Do not use excessive force when connecting the electrical plug, but make sure that the mains plug is completely plugged into the socket.
If a connection is not possible, check whether the plug fits the jack.
If you find damage to the plug connector, have the damage corrected by our service department.

4.6 Information about patient environment

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.
Use devices in the patient environment which are in conformity with the IEC 60601-1 standard. If you use a multiple socket extension cord or a device which do not comply with the IEC 60601-1 standard, use an isolation transformer

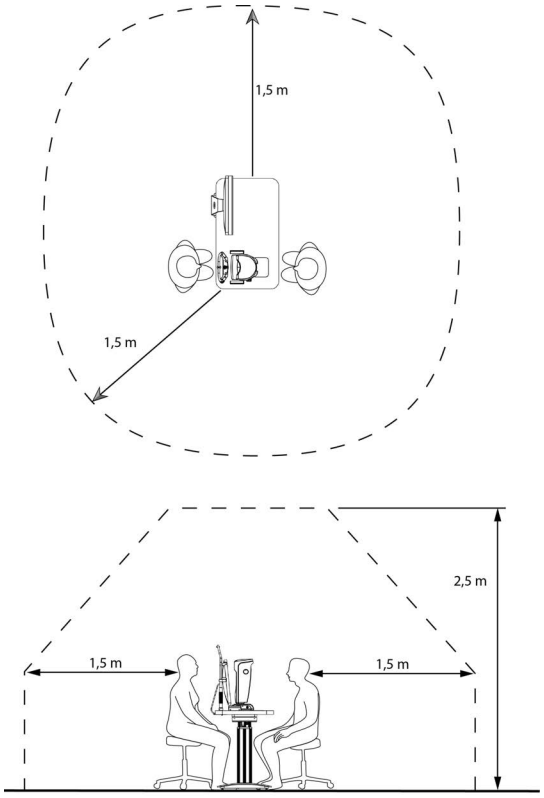


Fig. 4-1: Patient environment

4.7 Instructions to us a ME system

The Mesotest II and a connected computer are a medical electrical system (ME system) according to IEC 60601-1. If you want to connect further devices, for example a printer, these devices will be part of the ME system.

➔ Make sure that all devices of the ME system are in accordance with IEC 60601-1 or IEC 62368-1.

4.8 Instructions for operation

- ➔ Never put a damaged Mesotest II into operation.
- ➔ Only operate the Mesotest II 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 Mesotest II.
- ➔ Only operate the equipment after you have read and understood the Instruction Manual.
- ➔ 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 cover the ventilation openings.
- ➔ Do not place any heavy objects or the device itself on top of the connecting cable.

4.9 Instructions for maintenance

To ensure satisfactory and reliable operation, we recommend that you have the Mesotest II checked every two years by our service department or an authorized dealer. If an error occurs which you are unable to correct, label the Mesotest II as "out of order" and contact our service department or an authorized dealer.

4.10 Instructions for disassembly and disposal

- ➔ When disconnecting electrical connections, pull on the respective plug instead of the cable itself.
- ➔ Dispose of the equipment in compliance with the corresponding legal requirements.

4.11 Note on electrical safety

Attention

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

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

- ➔ Ensure that connections with non-medical devices are made correctly.
- ➔ Use only a computer that meets the specifications given in this instruction manual, *sect. 18, page 85*.

Attention

Use of a multiple socket extension cord

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

If you are using a multiple socket extension cord to connect the Mesotest II to the power supply, you must heed the following information:

- ➔ Use a multiple socket extension cord that complies with the requirements of IEC 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 Mesotest II 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 Mesotest II: Check the electrical safety.

- ➔ Call OCULUS Service for this purpose.

Attention

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 *sect. 19, page 87*.

- ➔ Make sure that portable and mobile RF communications equipment do not cause interference.
- ➔ Recommendation: Maintain a minimum distance (*please refer chap. "Electromagnetic Compatibility" on page 87*). If the distance is shorter, you must ensure that the Mesotest II functions correctly.

4.12 Cybersecurity Instructions

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

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

Data responsibility

The device itself is not designed to connect with the internet, but only with a computer. It does not require Internet access for regular use.

Do not connect with the internet while using the device. It is considered misuse.

If you elect to connect the computer to the internet for other purposes you are responsible for ensuring data security.

Device Security

It is the responsibility of the authorized user to ensure that the Mesotest II device is not left unlocked, or otherwise unsecured when not in use, to ensure that non-authorized medical, professional, or otherwise unapproved personnel are not exposed to, or gain access to, ePHI.

User Responsibility

User names or passwords must not be shared with colleagues or others, even if they are permitted by law and provider policy to view the same type of information (e.g. two operators reviewing the same patient samples).

Operators have access to patients' ePHI and must not take snap-shots, screenshots or pictures (e.g. using another device) of any information viewed through the device.

Operators should not enter identifying data into the device. All the data on the device should be de-identified and relate to the sample id and not to the patient.

Reporting Device Security or Privacy Breaches

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

Recovering from Compromised Accounts or Devices

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

Unavailable Service

Users should report unavailable service or prohibited access to information to their local Healthcare Organization's IT department.

Precautions

➔ 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 “Mesotest”).
- ➔ 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 reentering 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

- ➔ If you elect to connect the computer to the LAN or internet, you are responsible for ensuring data security.
- ➔ 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.
- ➔ Heed the instructions for integration into an IT-Network *(sect. 19.3, page 92).*

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

5 Intended Use

5.1 Intended purpose

The Mesotest® II is used for testing the mesopic visual acuity of the human eye.
The Mesotest II is only intended for the use described in these instructions for use.

➔ Observe the safety instructions.

5.2 Intended medical indication

- Assessment of night driving ability
- Pre- and post-operative testing of patients with intraocular lenses
- Prescription of tinted lenses

5.3 Contraindication

None known

5.4 Possible side effects

None known

5.5 Intended users

The Mesotest II is only intended for use:

- in optometrist practices
- in clinics
- by opticians or optometrists
- by occupational physicians

Mesotest II is intended to be used by trained personnel:

- who can ensure proper handling due to their expertise, training and practical experience.
- who have been trained accordingly by OCULUS personnel or an authorised dealer prior to operating the equipment.

5.6 Patient group

Children from 3years up to not limited.
No restrictions on weight and health.
The patient must be able to sit and follow the instructions.

6 Device Description

6.1 Components,

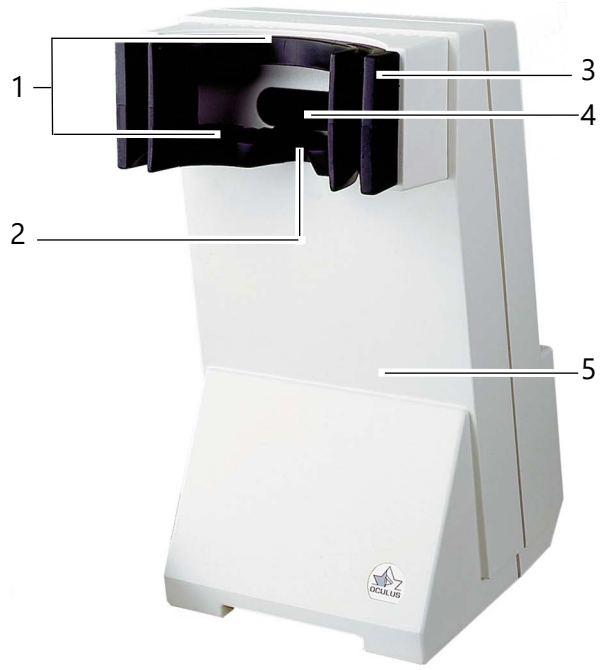


Fig. 6-1: Front view

Fig. 6-2: Back view

No.	Description	No.	Description
1	Viewer enclosure	7	Control pad
2	Device viewer	8	Device plug with fuse holder
3	Housing	9	Serial interface port
4	Yoke spring	10	On/Off switch
5	Air vents	11	Nameplate
6	Back of the viewer with grey pane		

6.2 Applied Parts

The viewer enclosure is an applied part of type B.

Fig. 6-3: Apllied parts

6.3 Mesotest II Functionality

6.3.1 Description

The Mesotest II is a PD-independent, freespace instrument for testing mesopic vision and glare sensitivity.
Freespace means that the tests are conducted under natural visual conditions in an open space.
The device myopia is more or less eliminated, as the eyes accommodate and converge in the same way as for natural vision.
The flexible viewer enclosure facilitates relaxed viewing and provides an optimal fit for every patient. The enclosure completely shuts out all extraneous light, thus allowing correct examinations to be conducted, even in just moderately dark room conditions.
The air vents in the enclosure prevent the patient's glasses or the unit's viewer glass from fogging.

6.3.2 Use

In Germany: The Mesotest II is used for testing mesopic vision and glare contrast sensitivity as required by driver's license issurance regulations and it meets the requirements of DIN 58220, Part 7.
Testing of mesopic vision and glare contrast sensitivity is an important supplement to photopic vision testing, especially for the assessment of night driving ability. Pre- and post-operative testing of the mesopic vision and glare sensitivity of patients with intraocular lenses, or those who have undergone refractive surgery is recommended, as well as for prescription of tinted lenses.
The device is dimensioned such that the patients' differing inter-pupillary distance does not affect the results.

6.3.3 Setup

The focussing screen of the test field is viewed through a lens via a semi-reflector viewer mirror. The optotypes are presented in front of this focussing screen. Their virtual image appears 5 meters away from the eye.
The optotypes are vapour-deposited on a glass substrate.
The glare light is located at the left of the test field at a visual angle of 3°. Depending on the test that has been selected, this is activated automatically.
The glare light simulates the glare situation of an oncoming vehicle with dimmed headlights. The glare illuminance at pupil level is 0.35 lux.
White light emitting diodes are used as the light source. It is thus unnecessary to change lamps.
The ambient light and the glare light are illuminated separately by one light emitting diode each.

6.3.4 Controls

You can operate the Mesotest II either via the control pad or via a computer/laptop.

Control pad: The integrated panel illumination allows testing to be done in a darkened room, also see *sect. 9.1, page 29*.
Operation via **computer/laptop**: You can also operate the Mesotest II via a computer/laptop. You then need the Mesotest II software (available as an optional extra), also see *sect. 10, page 35*.

6.3.5 Testing wit landolt rings

Testing is conducted under natural vision conditions, without device accommodation.
Testing is done with a Landolt ring of the visual acuity level 0.1 in acc. with DIN 58220, Part 1 (in Germany). The Landolt ring can be presented in six different positions. Four contrast levels without glare (ambient luminance 0.032 cd/m^2) and four contrast levels with glare (ambient luminance 0.10 cd/m^2) are tested.
The optotypes can be presented in six different positions, whereby one position is prespecified at the beginning of the test.
Four different contrast levels are available:
1:23 / 1:5 / 1:2.7 / 1:2
The contrast level 1:23 is the strongest contrast, i.e. this level is the easiest to see.
Contrast 1:23 is the ratio of Ambient luminance: Luminance of the optotype.

6.3.6 Glare light

The glare light is located on the test field.

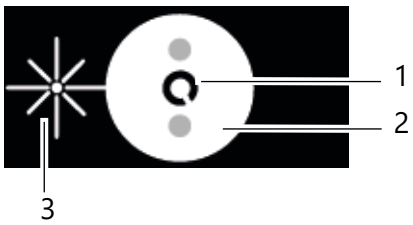


Fig. 6-4: Glare light

1 Landolt ring
2 Ambient light
3 Glare light

The glare light simulates the glare situation of an oncoming vehicle with dimmed headlights in the twilight (glare sensitivity). The glare illuminance at pupil level is 0.35 lux.
White light emitting diodes are used as the light source. It is thus unnecessary to change lamps.
The ambient light and the glare light are illuminated separately by one light emitting diode each.
A stand-by function switches off the illumination after a certain time if no entries are made by the operator.

6.3.7 Fixation aid

A projection device for a fixation aid is located over the test field. Two red dots can be projected onto the test field with this device, if necessary.

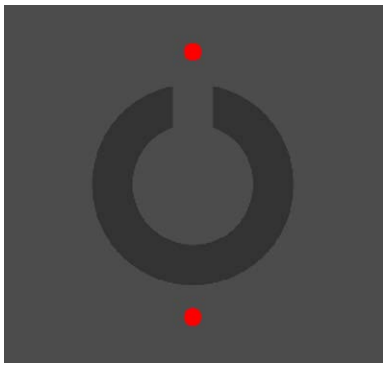


Fig. 6-5: Fixation aid

If the patient looks directly into the glare light when the switch-over to mesopic vision is made, he will no longer be able to see the optotypes, to begin with. This can lead to a delay in the examination procedure, as he needs some time (approx. 10-30 seconds) to readapt.

6.3.8 Test procedure

Control Pad:
The contrast levels are each presented with and without glare. As such, a total of eight consecutive tests are conducted.

Test no.	1	2	3	4	5	6	7	8
Contrast	1:23	1:5	1:2.7	1:2	1:23	1:5	1:2.7	1:2
Glare light	off	off	off	off	on	on	on	on
Prespecified position of the Landolt ring	TL	TR	T	B	BR	B	BL	T
Function	Test mesopic vision				Test mesopic vision with glare			

The visual requirement is deemed to be met when the patient has recognised at least 3 of 5 positions of the Landolt ring (60% criterion). Mark this accordingly on the test sheet.

Computer/Laptop:
With the examination program “Mesopic vision bin”, you can examine mesopic vision binocularly. It consists of 10 test steps.
Test 1 and Test 6: Facilitate the fixation, as here the fixation marks are displayed
Test 2-5: Are used to test mesopic vision
Test 7-10: Are used to test mesopic vision with glare.

With the examination program “Mesopic vision mono” (optional with Mesotest II konkav), you can examine mesopic vision monocularly, for the right and for the left eye. It consists of 20 test steps.
Test 1, 6, 11 and 16: Facilitate the fixation, as here the fixation marks are displayed.
Test 2-5 and 12-15: Are used to test mesopic vision
Test 7-10 and 17-20: Are used to test mesopic vision with glare.
5 Landolt rings are presented for each contrast level. The visual requirement is deemed to be met when the patient has recognised at least 3 of 5 positions of the Landolt ring (60% criterion). Mark this in the software accordingly *(sect. 10.1.2, page 37)*. The results are saved and you can print them out. You can also compile your own tests.

6.4 Twilight (Mesopic) Vision

Tests for determining mesopic visual acuity and glare contrast sensitivity were developed, among other things, to test the visual functions that a driver must have for driving at night.

How do we see in twilight?

The transition between daytime (photopic) vision and night (scotopic) vision is referred to as twilight vision (mesopic vision).
Twilight vision has considerable differences compared to daytime vision.
Daytime vision and cone vision (also known as photopic vision) are the terms used for luminances greater than 3 cd/m^2, night vision and rod vision (also known as scotopic vision) for luminances below 0.03 cd/m^2, and mesopic vision for luminances in the range between 0.03 and 3 cd/m^2.

Testing mesopic vision

To adapt the test conditions to the luminance conditions prevailing on roads at night, the Landolt ring is presented on a test field with a luminance of 0.032 cd/m^2, and for the test with glare, on a test field with a luminance of 0.1 cd/m^2.
During the function test, unlike in the visual acuity test, the size of the Landolt ring is not reduced, but rather the contrast that it has to its surroundings. The size of the Landolt ring corresponds with a visual acuity of 0.1. Four different contrast levels are available for reducing the contrast.

- 1:23
- 1:5
- 1:2.7
- 1:2

The contrast level 1:23 is the strongest contrast, i.e. this level is the easiest to see.

Testing mesopic vision with glare

Testing of mesopic vision can also be conducted with additional glare. The glare comes from the left, just as it would in a road traffic situation.

Thresholds according to DOG (German Ophthalmological Society)

The following thresholds for assessment of fitness for driving in road traffic are recommended by DOG and the German Association of Ophthalmologists:

- Classes D, D1, DE, D1E: Contrast 1:2.7
- Classes C, C1, CE, C1E and taxi drivers: Contrast 1:5
- Classes A, A1, A2, B, BE, AM, L and T: Contrast 1:23

A stop criterion similar to that described in DIN 58220 (visual acuity test) must be established as the test criterion: 3 out of 5 of the different optotypes presented must be correctly recognised. This means that for the critical contrast levels 1:23 to 1:2.7, at least 5 different optotypes must be presented.

7 Initial Operation

7.1 Before Initial Operation

Before the Mesotest II is operated for the first time, you must complete the following actions:

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

Attention

Risk of incorrect measurements/equipment damage due to improper setup

➔ Before first use, make sure the installation and connection of the Mesotest II are completed by our service or by a professional authorized by OCULUS.

7.2 Information on the installation room

The Mesotest II should be set up in a moderately bright or darkened room (room brightness between 2 and 5 lux).

Attention

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.

Note:

Falsified examination results if the room is too bright

If you set up the Mesotest II in a bright room, you must occlude the back pane of the viewer with the supplied cover.

➔ Insert the cover, see *sect. 7.3, page 23*

7.3 Insert Cover

Occlusion of the back pane of the viewer, however, increases the risk of device myopia.
Take this into account in your examination results.

➔ Insert the cover into the slot between the back pane and the housing at one side.

➔ Keep hold of the cover at the recessed grips with one hand.

➔ With the other hand, bend the cover and let it snap into the opposite slot.

Fig. 7-1: Insert cover

➔ Removing the cover:
Pull out the cover at the recessed grips.

7.4 Set up and Connection

Note:

Risk of damage to the device if not handled correctly

➔ Do not expose the Mesotest II to any vibrations, shocks, contaminants, moisture, or high temperatures.

➔ Handle the optical device with care.

The ambient conditions for operation are given in *"Ambient conditions" on page 85*.

➔ Remove the Mesotest II from the packaging.

➔ Place the Mesotest II on a level surface.

➔ Set up the Mesotest II 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.

➔ Plug the control pad into the jack *(fig. 7-2, page 25)*.

Attention

Electrical safety hazard

➔ Do not use the Mesotest II immediately adjacent to other devices and do not stack it with other devices.

➔ If you use a multiple socket extension cord to connect the Mesotest II: Use a multiple socket extension cord that complies with the requirements of IEC 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 Mesotest II 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.

If you are going to operate the Mesotest II via a computer/laptop, connect the latter in the same way as the control pad, *fig. 7-2, page 25*.

➔ Connect the unit to the mains with the supplied power cable, *(fig. 7-2, page 25)*.
Make sure that the mains voltage is the same as the voltage specified on the rating plate.

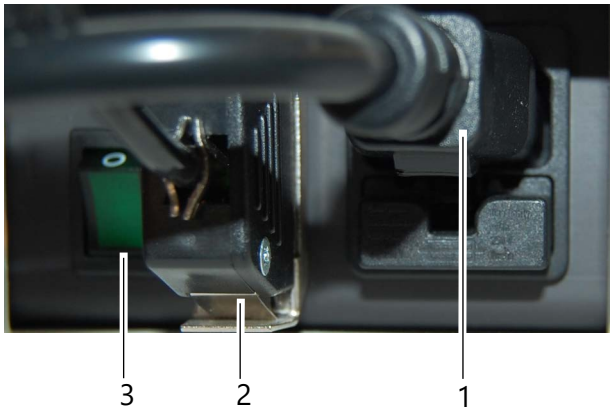


Fig. 7-2: Mesotest II Connection

1 Mains connection
2 Jack for connection of the control pad/laptop/computer
3 On/Off switch

➔ Switch on the Mesotest II at the On/Off switch.
After a short, automatic self-test, the device is ready for operation. The On/Off button lamp lights up for control purposes. If you are working with the control pad, the LCD module and the panel illumination also light up here.

7.5 Software Installation

Before first use, you must install the Mesotest II software on your laptop or PC. Proceed as described in the *Software Installation*.
Use a computer which is in conformity with the IEC 62368-1 *(sect. 18, page 85)*.

You can only conduct the examination with the computer when you use the supplied floating license key and the current version of the device software has been installed on the computer.

➔ Plug the floating license key into one of the computer's USB ports.
The software then installs itself.

7.6 Switching the Device On and Off

➔ Switch the Mesotest II on or off at the On/Off switch at the unit *(fig. 7-2, page 25)*.
If the Mesotest II is connected with a control pad, the unit starts automatically.
If the Mesotest II is connected with a netbook, laptop or PC, you must start the software, *sect. 10.3.1, page 43*.

8 Before Conducting the Examination

8.1 Prepare the Unit for Routine Operation

To start the Mesotest II for daily operation, you must:

- Check the connections, *sect. 7.4, page 24*
- Check whether the viewer is dirty

➔ If impurities are found: Clean the viewer, also refer to *sect. 13.2, page 75*.

➔ Disinfect the viewer enclosure after every examination and the housing whenever necessary, *sect. 13.3, page 75*.

8.2 Prepare the Patient for the Examination

Prepare the patient for the examination, as follows:

➔ Check to be sure that any adaptation disorder has been resolved, *sect. 8.3, page 28*.

➔ Check the patient's glasses for damage or dirt.

➔ Explain the procedure and the optotypes to the patient.
Use the following figure to explain to the patient how to describe the gap in the ring:

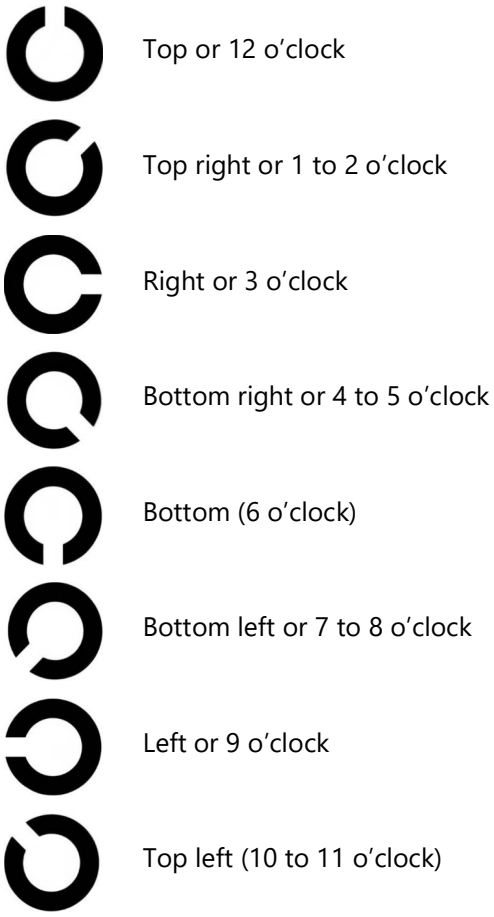


Fig. 8-1: How to explain the Landolt rings

➔ Make sure that the viewer enclosure remains in contact with the patient's head during the entire examination. Interfering incidence of light and impairment of the adaptation state associated with it can thus be avoided.

8.3 Patient Adaptation

Before the examination, the patient's eyes need about 5 minutes to adapt to the darkness.
When the Mesotest II is set up in a darkened room, this is not a problem. If the unit is set up in a bright room, adaptation of the patient must be done by having him look into the unit for the required length of time prior to starting the examination.

In a darkened room

➔ Let the patient's eyes adapt for about 5 minutes.

In a bright room

➔ Let the patient look into the unit for about 5 minutes.

9 Examination Using the Control Pad

This chapter explains:

- The control pad, *sect. 9.1, page 29*
- How to fill out a test sheet, *sect. 9.2, page 32*
- How to start an examination, *sect. 9.3, page 32*
- How to test mesopic vision, *sect. 9.4, page 33*
- How to test mesopic vision with glare, *sect. 9.5, page 33*

9.1 Control pad

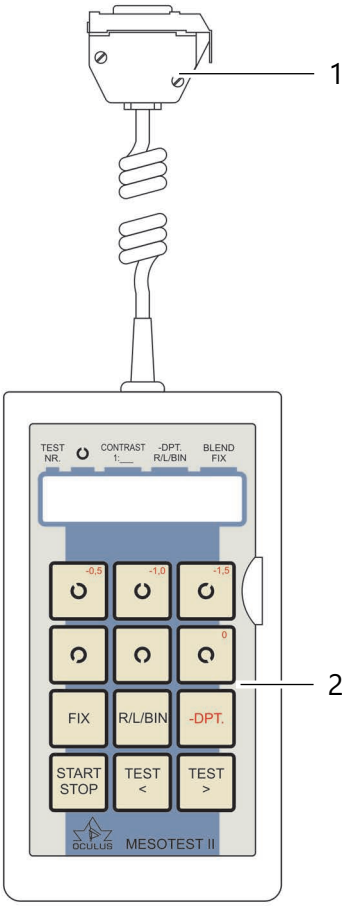


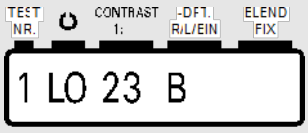
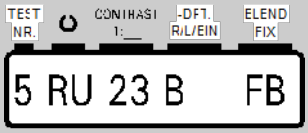
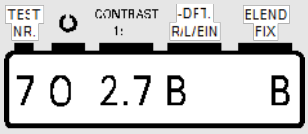
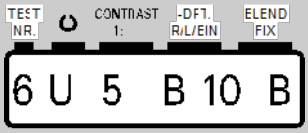
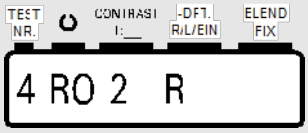
Fig. 9-1: Control pad

1 Mains connection

2 Control pad

Control pad user interface

Button	Meaning
	Landolt ring position: Top Left (LO) 2nd function: interpose -0.5 D minus lenses (option)
	Landolt ring position: Top (O) 2nd function: interpose -1.0 D minus lenses (option)
	Landolt ring position: Top Right (RO) 2nd function: interpose -1.5 D minus lenses (option)
	Landolt ring position: Bottom Left (LU)
	Landolt ring position: Bottom (U)
	Landolt ring position: Bottom Right (RU) 2nd function: reset minus lenses to 0 D (option)
	Turns Fixation Assistance on and off
	Select an eye for examination (option)
	Activitates 2nd function (minus lenses) (option)
	Next patient, or stop current tests andreturn to beginning Return to previous test
	Proceed to next test
	Control pad user interface

Display		Meaning
	Test no. 1 Optotype: LO CONTRAST 1:23 -DPT. R/L/BIN: B BLEND FIX: (empty)	Display after switch-on Landolt ring gap at top left Presented contrast level 1:23 Binocular examination, without minus lens Glare and fixation aids are not switched on
	Test no. 5 Optotype: RU CONTRAST 1:23 -DPT. R/L/BIN: B BLEND FIX: FB	Fifth programme step Landolt ring gap at bottom right Presented contrast level 1:23 Binocular examination, without minus lens Glare and fixation aids are switched on
	Test no. 7 Optotype: O CONTRAST 1:2.7 -DPT. R/L/BIN: B BLEND FIX: B	Seventh programme step Landolt ring gap at top Presented contrast level 1:2.7 Binocular examination, without minus lens Glare is switched on and fixation aids are switched off
	Test no. 6 Optotype: U CONTRAST 1:5 -DPT. R/L/BIN: B 10 BLEND FIX: B	Sixth programme step Landolt ring gap at bottom Presented contrast level 1:5 Binocular examination, minus lens -1.0 dpt is swung in (option) Glare is switched on and fixation aids are switched off
	Test no. 4 Optotype: RO CONTRAST 1:2 -DPT. R/L/BIN: R BLEND FIX: (empty)	Fourth programme step Landolt ring gap at top right Presented contrast level 1:2 Monocular examination of the right eye (option), without minus lens Glare and fixation aids are switched off

9.2 Filling In the Test Sheet

➔ Prepare a test sheet before every examination.

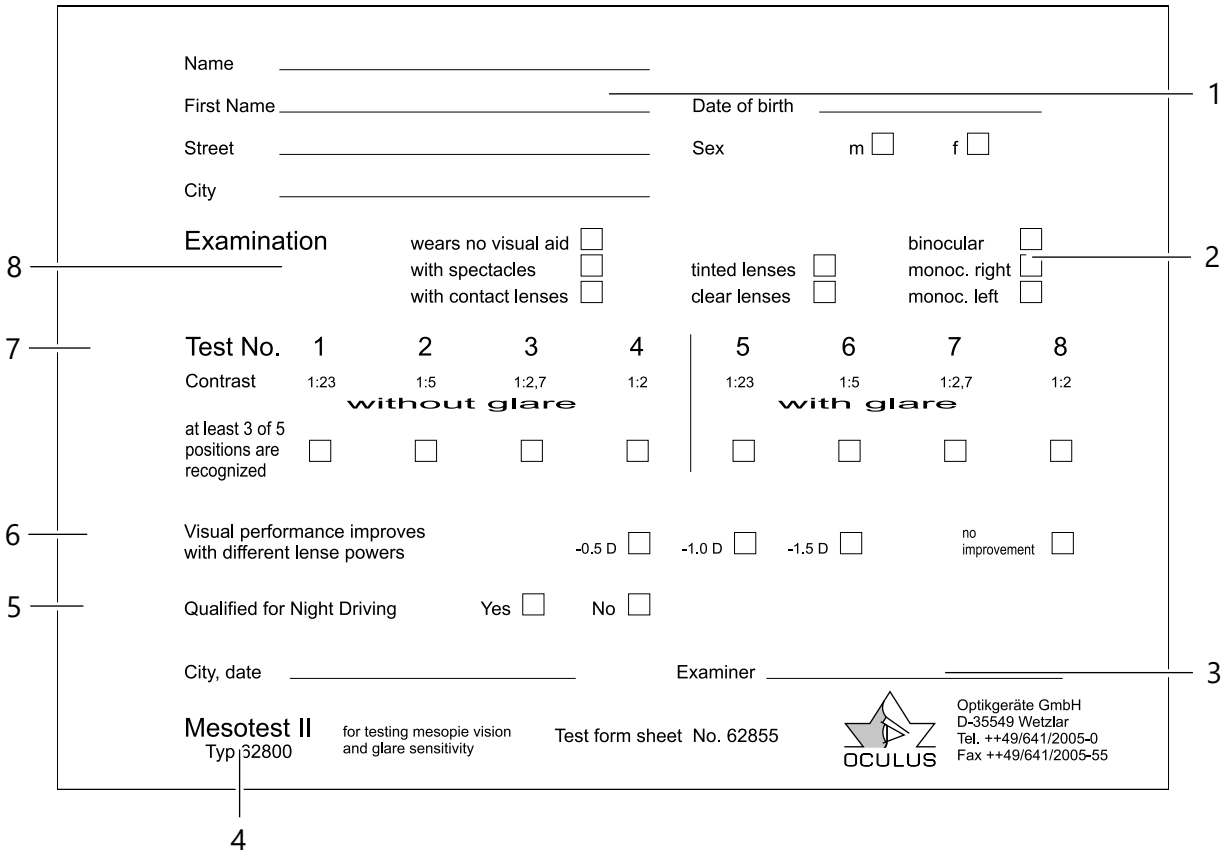


Fig. 9-2: Test sheet

1 Patient data
2 Examined eyes
3 Information about the place, date of the examination and the person conducting the test
4 Information about the device used for the examination
5 Assessment of the night driving ability
6 Use of concave lenses
7 Results of the individual tests
8 Information about any visual aids used

If the patient wears glasses or contact lenses for distance vision, the examination is conducted with the glasses or contact lenses.

➔ Mark this on the test sheet (including tinting, etc.), *fig. 9-2, page 32*.

9.3 Starting the Examination

➔ New start: Switch on the unit.
After automatic calibration of the Mesotest II, test no. 1 is presented.

➔ After an examination: Press this button.
The programme begins with test no. 1

Instruct the patient

➔ Instruct the patient with the help of test no. 1 (contrast level 1:23), as this test is the easiest to recognise.

9.4 Test Mesopic Vision

TEST >

➔ Press this button.
Test no. 2 is requested.
➔ Present five different Landolt ring positions to the patient.
You can select these randomly with the Landolt ring buttons.

The visual requirement is deemed met when the patient has recognised at least 3 of 5 positions of the Landolt ring (60% criterion).

➔ Mark this down on the test sheet accordingly, see *fig. 9-2, page 32*.
➔ Conduct the tests, nos. 3 and 4 in the same way.

9.5 Test Mesopic Vision With Glare

When you proceed to test steps 5-8, the glare is automatically switched on in order to test the patient's mesopic vision with glare.

If the patient looks directly into the glare light when you switch over to the test for mesopic vision with glare, he may no longer be able to recognise any optotypes to begin with. This can lead to a delay in the examination procedure, as he needs some time (approx. 10-30 seconds) to readapt.

To avoid an adaptation problem, proceed as follows:

FIX

➔ Before you switch to test no. 5: Press this button to switch on the fixation aid.
➔ Tell the patient to focus on the red fixation mark. Explain to the patient that he must keep looking in that direction and must not, under any circumstances, look directly at the glare light during any of the subsequent tests.
➔ Press this button again to switch off the fixation aid.
Or, the fixation aids are automatically switched off for the next test or optotype, to prevent falsification of the examination results.

TEST >

➔ Press this button.
➔ Conduct the remaining tests, nos. 5 through 8 in the same way as described above, *sect. 9.4, page 33*.
➔ Fill out all of the other required items on the test sheet.

9.5.1 Test for Night Myopia (optional)

If your Mesotest II is equipped with minus lenses (Mesotest II konkav), you can conduct these additional examinations. With the minus lenses, you can determine whether the patient suffers from night myopia.

➔ Swing in the minus lenses for the last test number that the patient just recognised.

➔ Press this button to swing in a minus lens.

➔ Press the button with the desired lens power.

If the visual acuity of the patient improves, he may suffer from night myopia. This should be corrected with suitable visual aids.

You can determine the extent of the night myopia by swinging in lenses of different powers (-0.5/-1.0/-1.5 D).

9.5.2 Monocular Examinations (optional)

If your Mesotest II is equipped with an eye occluder (Mesotest II konkav), you can conduct the following additional examinations. Monocular examinations can be conducted with the eye occluder.

This is very important, for example for patients with intraocular lenses or who have undergone excimer laser surgery, to assess the visual function of one eye.

➔ Press this button to swing in the eye occluder.

➔ Press the button again to advance the cover.

The information (R / L / BIN) shown in the display relates to the eye that is to be examined.

10 Conducting the Examination with a Computer/Laptop

Here, you will find information about:

- How to use the examination menu, *sect. 10.1, page 35*
- How to change settings, if necessary, *sect. 10.2, page 38*
- How to conduct an examination, *sect. 10.3, page 43*

10.1 Using the Examination Menu

The general use of the examination menu is explained in this chapter.

➔ Start the Patient Data Management, *sect. 10.3.1, page 43*.

➔ If necessary, press the [Mesotest II] button to start the Mesotest II programme.

➔ Press the button [Examination] (1) to start the examination.

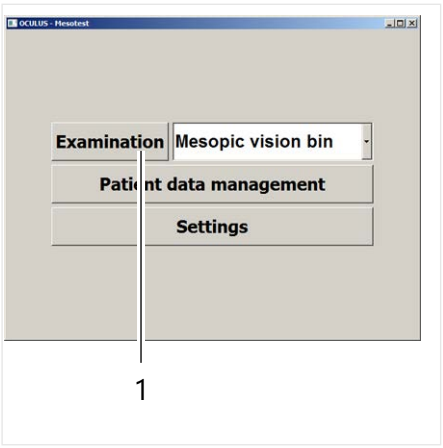


Fig. 10-1: Menu “Mesotest II“

The following components are available:

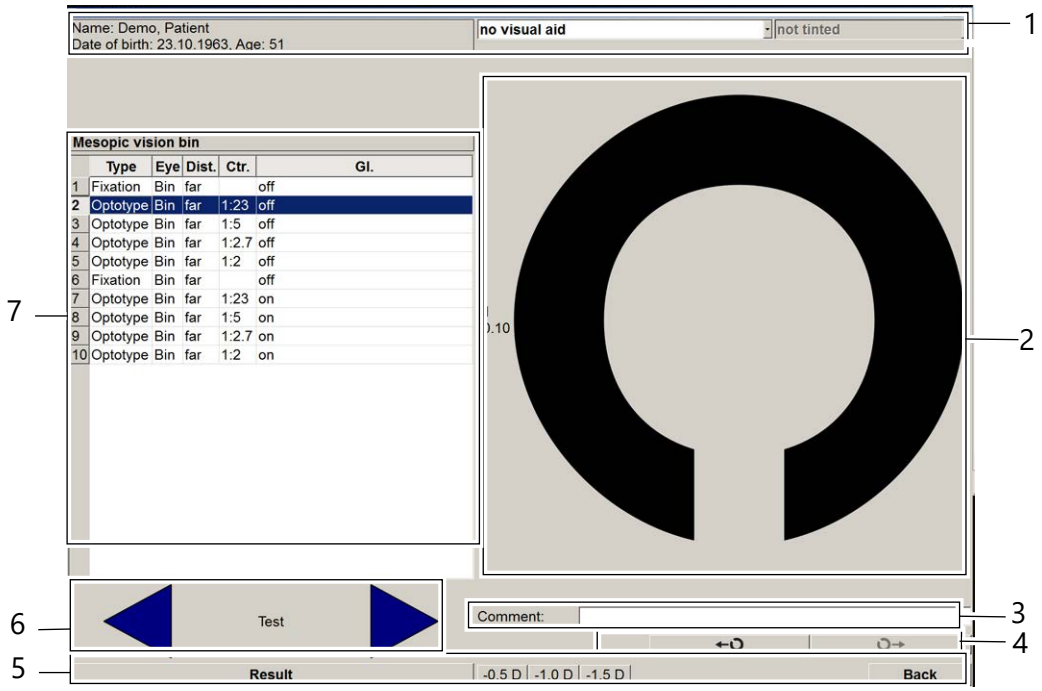


Fig. 10-2: Examination menu Example “Mesopic vision bin”

1 Header with information about the patient and “vision aid” selection field.
2 Optotype display
3 Input field “Comment”
4 Button: Change Landolt ring position
5 Task bar with the buttons [Back] and [Result], as well as minus lenses for myopia test (Mesotest II konkav)
6 Arrow keys for steps: “back” and “next”
7 Display the exam programme with test steps

10.1.1 View the Patient’s Information and Enter any Visual Aid

The name, date of birth and age of the patient are displayed in the header *(fig. 10-2, page 36)*. If the patient wears visual aids, you must select these here before conducting the examination.
A drop-down list appears with the following options.

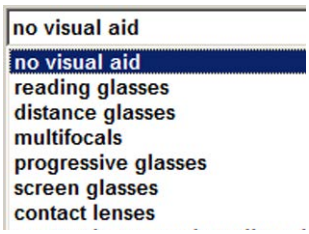


Fig. 10-3: Selection of visual aids

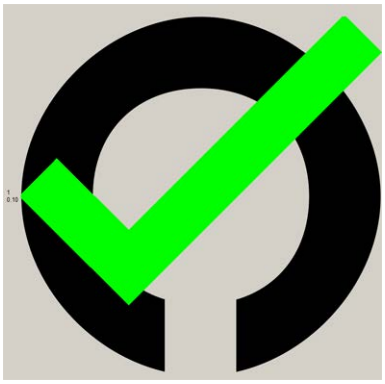
➔ Select the visual aid(s) worn by the patient.
➔ Specify whether the visual aid is tinted or not.
When you select a visual aid at the beginning of an examination, it is applied to all subsequent test steps.

If you select a different visual aid in a later test step, then that is applied to all subsequent test steps.

10.1.2 Marking the Results in the Test Image Display

The test image (optotype) that the patient is presently seeing is shown to you in the test image display *(fig. 10-2, page 36)*. Here, you have to mark the individual test results so that the examination can be subsequently evaluated. Here, you can mark which optotypes the patient has recognised or not recognised. The following shows you how to mark the results.

➔ Click on the optotype if the patient has recognised it.
The recognised optotype is marked with a green tick.
If the patient does **not** recognise the optotype, click twice on the optotype.



Recognised optotype

Not recognised optotype

Fig. 10-4: Marking the results

10.1.3 Present the Next Optotype

After you have marked the results, you must present another optotype to the patient. A number beside the optotype (here: 1) indicates the first position of the optotype. You can present 5 different Landolt ring positions per contrast level to the patient, see *fig. 10-2, page 36*.
The visual requirement is deemed met when the patient has recognised at least 3 of 5 positions of the Landolt ring (60% criterion).

➔ Press this button to present the next optotype.

➔ Press this button to display the previous, marked optotype.

10.1.4 Swing in Minus Lenses

You can swing in minus lenses to determine whether the patient suffers from night myopia.

You can only use the myopia test if your Mesotest II has this function (Mesotest II konkav), and the myopia test has been activated in the "Settings", see *sect. 10.1.4, page 37*.

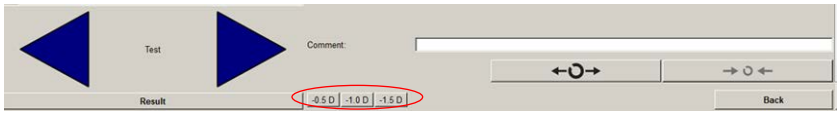


Fig. 10-5: The buttons for minus lenses are activated

➔ Swing in the minus lenses for the last test that the patient just recognised.

➔ Press the button with the desired lens power.

If the visual acuity of the patient improves, he may suffer from night myopia.

You can determine the extent of the night myopia by swinging in lenses of different powers (-0.5/-1.0/-1.5 D).

10.2 Change Settings

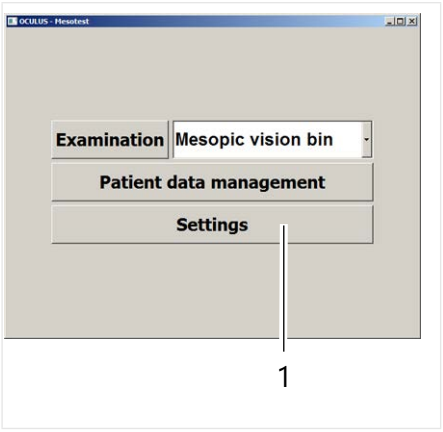


Fig. 10-6: Menu "Mesotest II"

If necessary you can make some basic adjustments in the Mesotest II programme (1). If you do not want to change any settings, proceed as described in *sect. 10.3, page 43*.

➔ Select a patient from the list of patients and double-click on the selected patient to start the Mesotest II programme. The "Mesotest II" menu is displayed.

The following settings can be changed:

- Set the language, *page 39*
- Set the date format, *page 39*
- Change the visual acuity data, *page 40*
- Adjust font, *page 40*
- Activate the myopia test, *page 40*
- Enable the option to allow the patient's gender to be entered in the patient data management, *page 40*
- Enable to load an existing examination without using the OCULUS patient data management, *page 40*
- Enable full screen mode when the programme is started, *page 41*
- Activate Demo mode, *page 41*
- Edit examination programme, *page 41*
- Personalise the results printout, *page 41*

Proceed as follows:

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

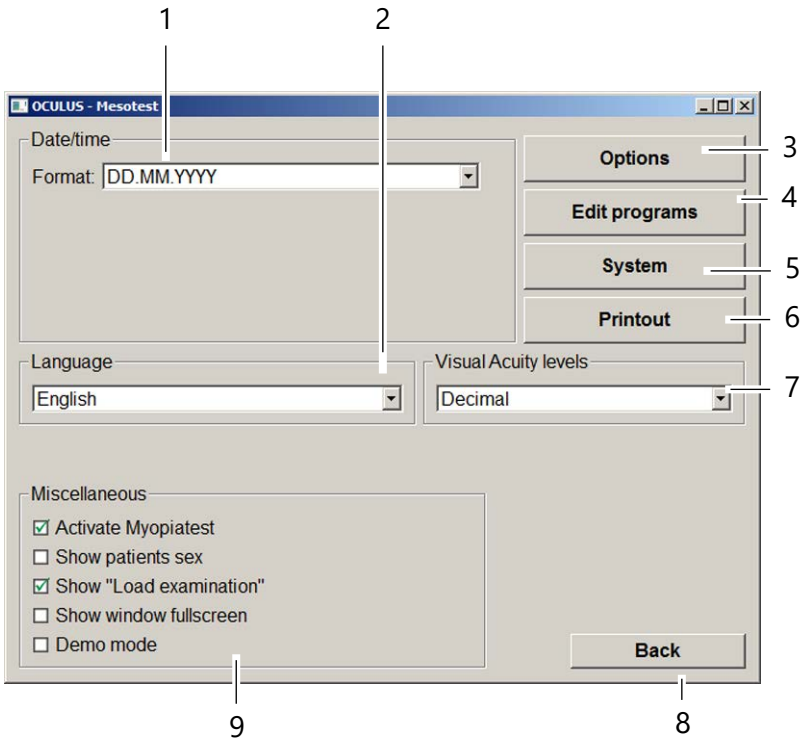


Fig. 10-7: "Settings" screen

1 "Date / Time" box
2 "Language" box
3 [Options] button
4 [Edit programs] button
5 [System] button
6 [Printout] button
7 "Visual acuity data" box
8 [Back] button
9 "Miscellaneous" box

10.2.1 Change date format

"Date / Time" box *(fig. 10-7, page 39)*:

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

10.2.2 Language settings

"Language" box *(fig. 10-7, page 39)*:

➔ Select the desired language from the drop-down list.
The selected language will be active after the next start of the Mesotest II programme.

10.2.3 Change visual acuity data

"Visual acuity data" box *(fig. 10-7, page 39)*:

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

10.2.4 Activate myopia test

"Miscellaneous" box *(fig. 10-7, page 39)*:
This test is useful for determining whether the patient suffers from night myopia.

You can only use this test if your Mesotest II has this function (Mesotest II konkav).

Fig. 10-8: The buttons for minus lenses are activated

➔ Activate the checkbox [Activate Myopiatest].
Three additional buttons, -0,5 D / -1,0 D / -1,5 D, now appear on the user interface.

10.2.5 Show patients sex

"Miscellaneous" box *(fig. 10-7, page 39)*:

➔ Activate the [Show patients sex] checkbox.
The patient's gender is displayed in the examination menu. Prerequisite: The feature "Patient's sex" was entered and activated in the Patient Data Management *(sect. 12.5.1, page 65)*.

10.2.6 Display: 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. 10-7, page 39)*:

➔ Enable the [Show "Load examination"] checkbox.
The according button will added in the "Mesotest II" menu.

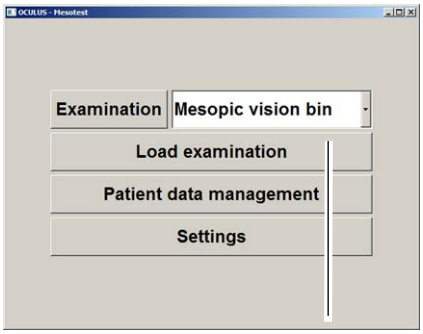


Fig. 10-9: [Load examination] button

10.2.7 Show window fullscreen

"Miscellaneous" box *(fig. 10-7, page 39)*:
➔ Activate the [Show window fullscreen] checkbox.

10.2.8 Activate "Demo" mode

This function is for demonstration purposes only, if a Mesotest II is not connected to your laptop/netbook/PC.
"Miscellaneous" box *(fig. 10-7, page 39)*:
➔ Activate the [Demo mode] checkbox.

10.2.9 Edit examination programme

➔ Press the [Edit programs] button *(fig. 10-7, page 39)*.
You can
- change the order in which the examination programmes are displayed
- copy and edit an existing examination programme
- create and edit a new examination programme

You will find more detailed information in *sect. 11, page 55*.

10.2.10 Personalise the results printout

➔ Press the [Result] button *(fig. 10-7, page 39)*. On this screen, you can enter data about yourself or your office address, and add your own logo to the results printout.

10.2.11 Options screen

This screen is for information purposes.

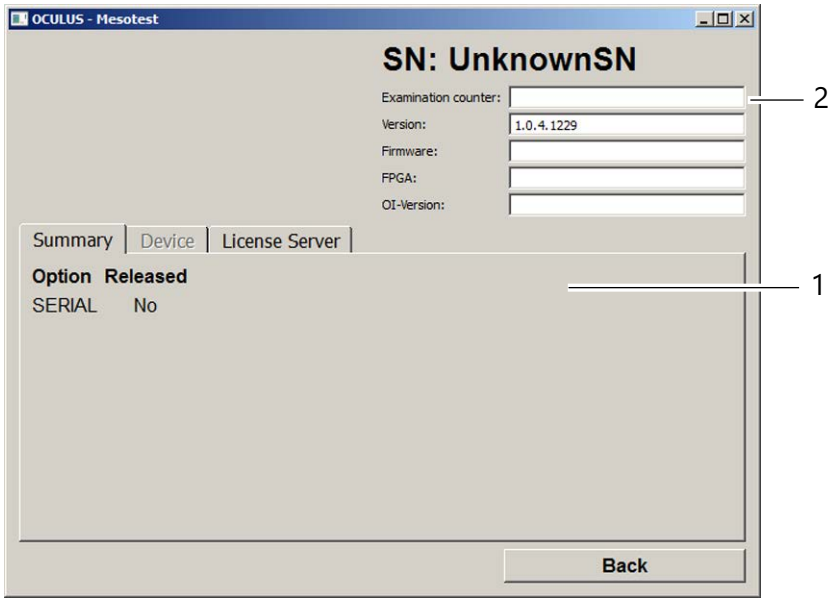


Fig. 10-10: "Options" screen

1 Device information
2 Connection status to the floating license key

10.2.12 System screen

You can activate the interface to external office management programmes here.

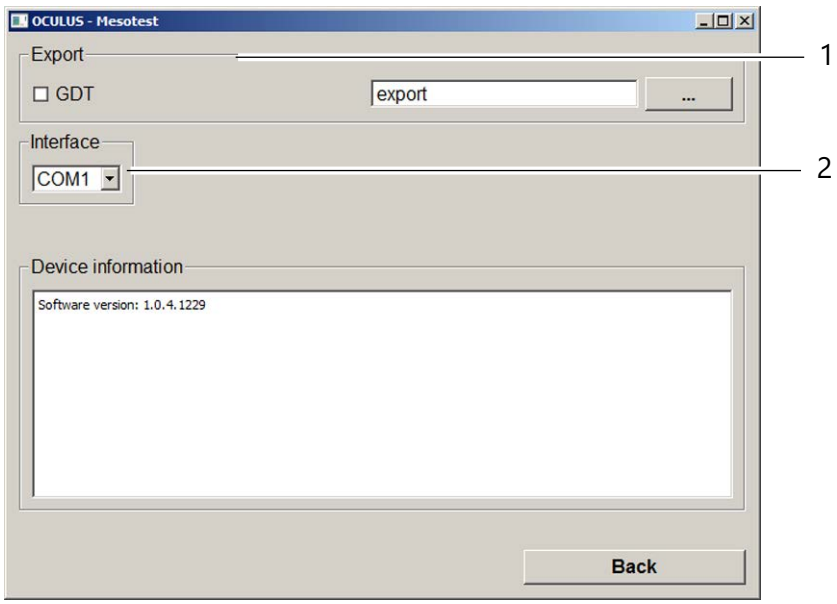


Fig. 10-11: "System" screen

➔ Activate the checkbox [GDT] in the "Export" box (1).
➔ Press the button [...] in the "Export" box (1).

➔ In the dialogue box, select the location to which the data are to be saved.

This interface (2) is used to establish a connection between the Mesotest II and the computer.

➔ Select the appropriate interface port.
Refer to the Operating Manual for your computer to find your computer's COM port numbers.
A notebook generally has only one port: COM1. A desktop computer generally has two: COM1 and COM2.

➔ Save your selection.

10.2.13 Switch to the Mesotest II programme

➔ Press the [Back] button *(fig. 10-7, page 39)*.
The settings will take effect immediately, except for the language change.

10.3 Conduct the Examination

To conduct an examination:

- Start the Patient Data Management, *sect. 10.3.1, page 43*
- Select and start an examination, *sect. 10.4, page 46*
- Test mesopic vision, *sect. , page 50*
- Test mesopic vision with glare, if applicable, *sect. , page 50*

You can display and print out the results, *sect. 10.5, page 52*.

➔ Prepare the patient for the examination, *sect. 8, page 27*.

10.3.1 Starting Patient Data Management

You can enter patient data in the Patient Data Management and then use it.
After you have switched on the computer, it first loads the operating system.
If the Windows desktop is displayed, you have to start the Patient Data Management programme from there.

➔ If necessary, click on the Mesotest II icon:  .

The user interface for the Patient Data Management is displayed

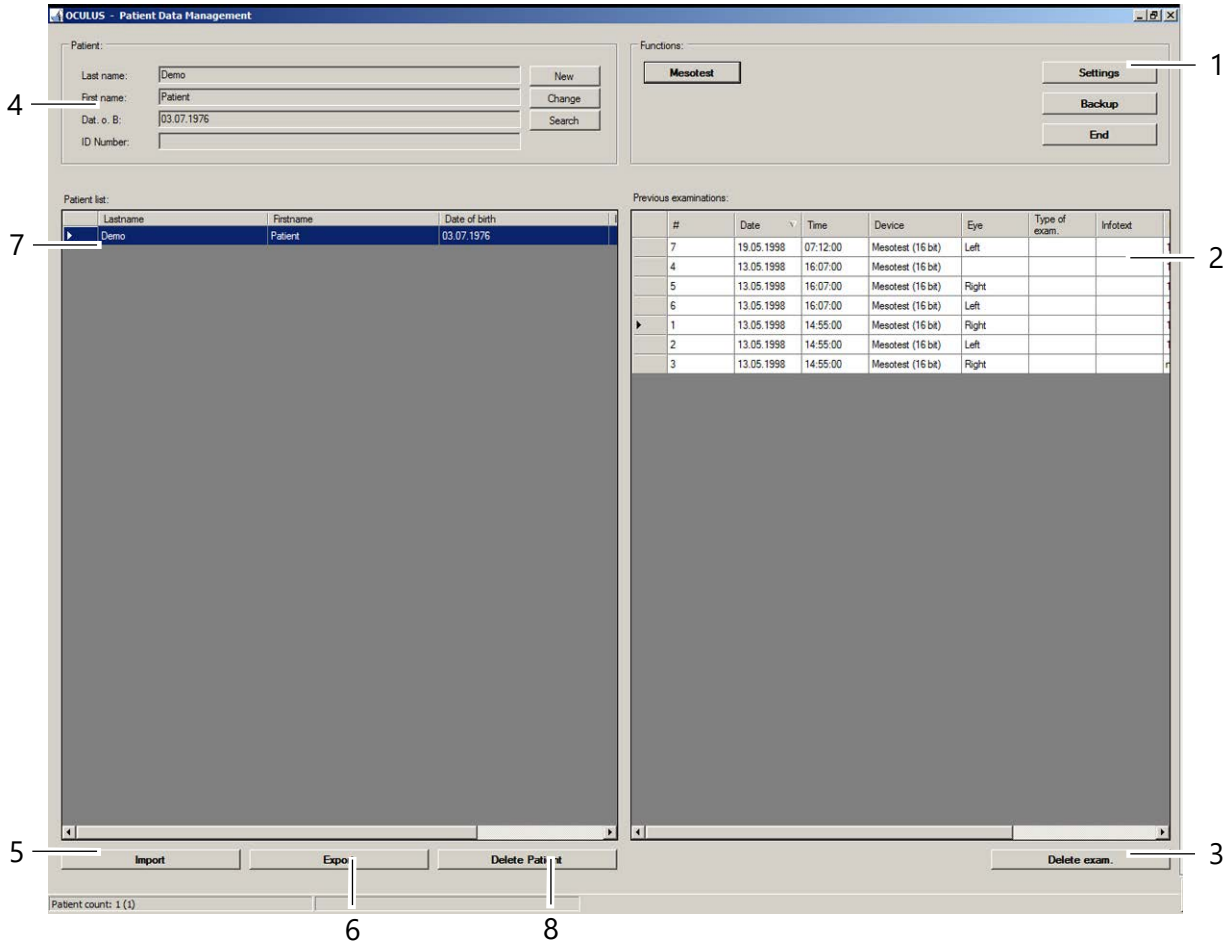


Fig. 10-12: User Interface for Patient Data Management

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

To start the Mesotest II programme, first enter a new patient (8) , or select an existing patient from the list of patients (7). For more information on Patient Data Management, refer to the *sect. 11, page 55*.

10.3.2 Entering a New Patient

➔ Press the [New] button to enter a new patient in the Patient Data Management system.

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

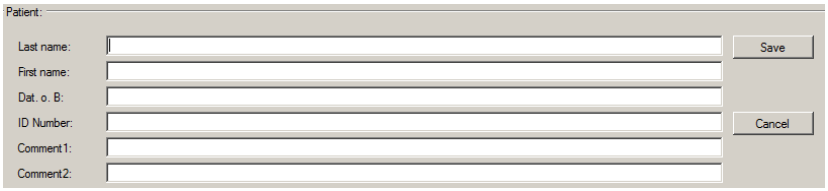


Fig. 10-13: Entering patients

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.

10.3.3 Selecting an Existing Patient

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

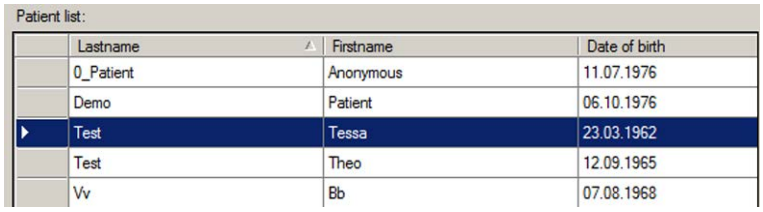


Fig. 10-14: Patient list

➔ Choose [Search] to quickly find the patient you are looking for in the list.

➔ Enter the patient's name or the first letter of the name in the "Last name" field.
Alternatively, you can search for the patient using an ID number, first name or date of birth, assuming that one was assigned when the patient was first recorded.

➔ 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.

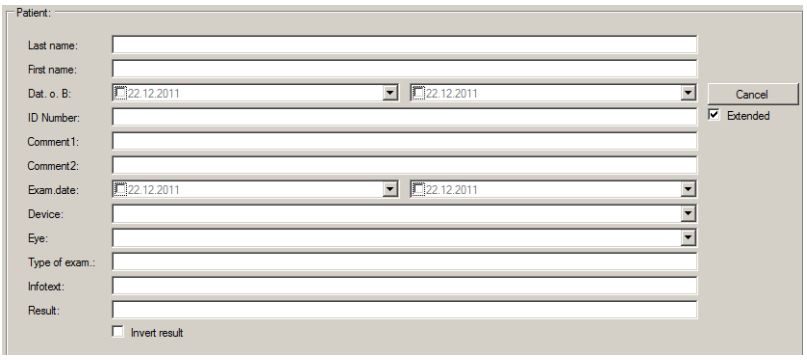


Fig. 10-15: Advanced search

➔ Enter a search parameter.
The respective patient is highlighted in the list.
➔ Press the button [End search].
➔ Proceed as for entering a patient name.

10.4 Select and Start Exam

➔ If necessary, press the [Mesotest II] button to start the Mesotest II programme.
The following dialogue is displayed:

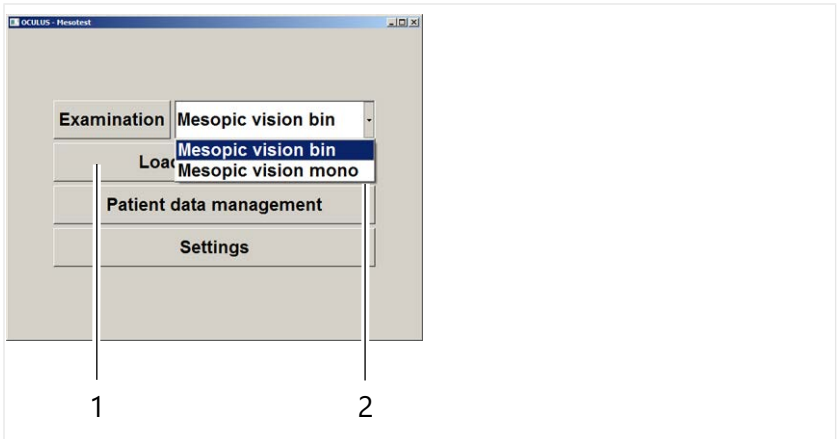


Fig. 10-16: Menu “Mesotest II“

➔ Select a program.
You can choose between “Mesopic vision bin” and “Mesopic vision mono”.
If you have created your own programs, a drop-down list showing all programs is displayed here, *sect. 11, page 55*.
➔ Press the button [Examination] to start the examination.
The selected programm appears:
- Mesopic vision bin, *sect. 10.4.1, page 47*
- Mesopic vision mono, *sect. 10.4.2, page 48*

10.4.1 Conduct the Programm “Mesopic vision bin”

With the examination program “Mesopic vision bin”, you can examine mesopic vision binocularly, at different contrast levels, with and without glare. It consists of 10 test steps.

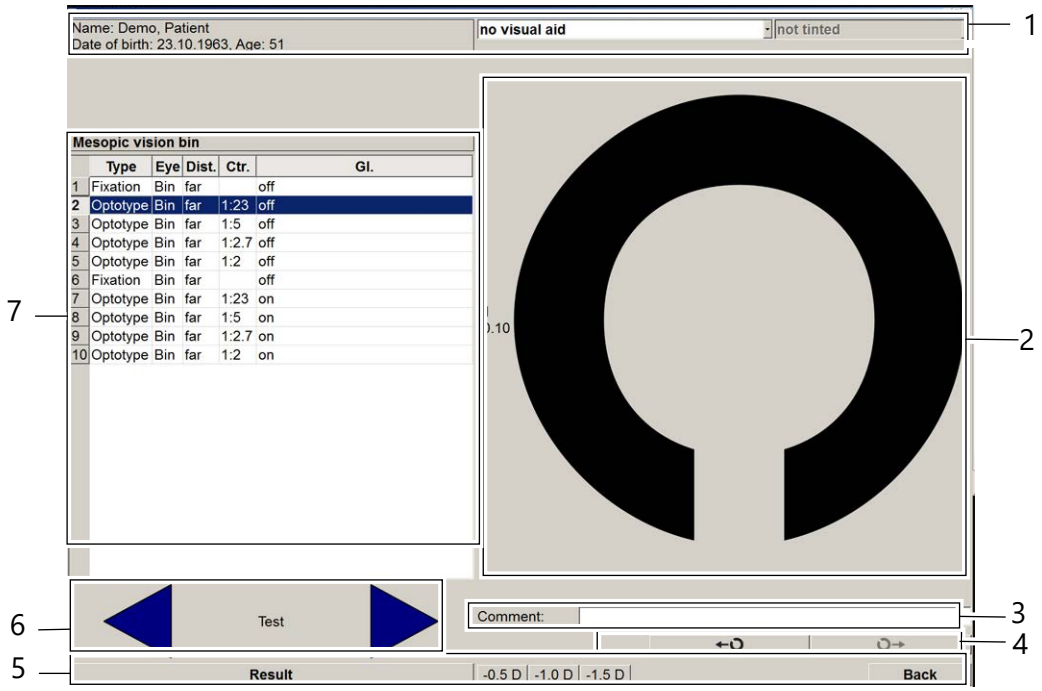


Fig. 10-17: Examination menu

1 Header with information about the patient and “vision aid” selection field.
2 Optotype display
3 Input field “Comment”
4 Button: Change Landolt ring position
5 Task bar with the buttons [Back] and [Result], as well as minus lenses for myopia test (Mesotest II konkav)
6 Arrow keys for steps: “back” and “next”
7 Display the exam programme with test steps

Test 1 and Test 6: Facilitate the fixation, as here the fixation marks are displayed
Test 2-5: Are used to test mesopic vision
Test 7-10: Are used to test mesopic vision with glare.

Enter a visual aid

If the patient wears glasses or contact lenses, the examination is conducted with the glasses or contact lenses.

➔ Enter whether the patient wears visual aids (including any tinting, etc.), *sect. 10.1.1, page 36*.

Instruct the patient

➔ Select test step 1
➔ Tell the patient to focus between the red fixation marks.
➔ Instruct the patient with the help of displayed Landolt ring.

Test mesopic vision

➔ Select test step 2.
➔ Present the optotype to the patient in 5 different positions, *sect. 10.1.3, page 37*.
➔ Mark the results, *sect. 10.1.2, page 37*.

The visual requirement is deemed met when the patient has recognised at least 3 of 5 positions of the Landolt ring (60% criterion).

➔ Conduct test steps 3 through 5 in the same way.

Test mesopic vision with glare

➔ Select test step 6.
➔ Tell the patient to focus on the red fixation mark. Explain to the patient that he must keep looking in that direction and must not, under any circumstances, look directly at the glare light during any of the subsequent tests.
➔ Conduct test steps 7 through 10 in the same way as described above, *sect. , page 50*.

The visual requirement is deemed met when the patient has recognised at least 3 of 5 positions of the Landolt ring (60% criterion).

10.4.2 Conduct the Programm “Mesopic vision mono”

With the examination program “Mesopic vision mono” (optional with Mesotest II konkav), you can examine mesopic vision monocularly, for

the right and for the left eye, at different contrast levels, with and without glare. It consists of 20 test steps.

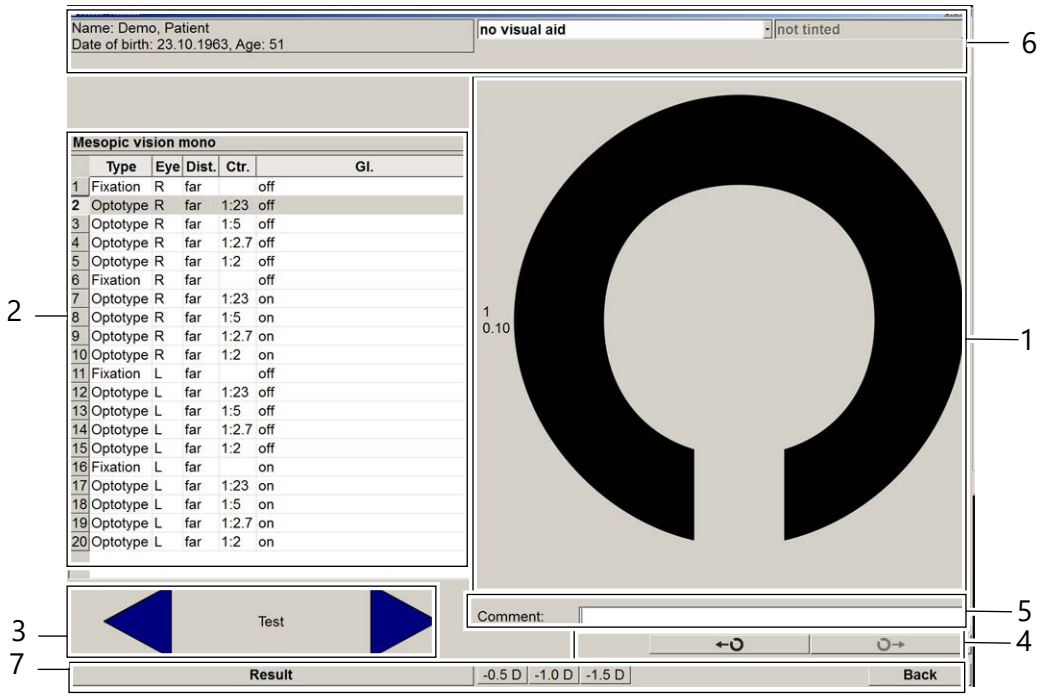


Fig. 10-18: Examination menu

1 Header with information about the patient and “vision aid” selection field.
2 Optotype display
3 Input field “Comment”
4 Button: Change Landolt ring position
5 Task bar with the buttons [Back] and [Result], as well as minus lenses for myopia test (Mesotest II konkav)
6 Arrow keys for steps: “back” and “next”
7 Display the exam programme with test steps

Test 1, 6, 11 and 16: Facilitate the fixation, as here the fixation marks are displayed
Test 2-5 and 12-15: Are used to test mesopic vision
Test 7-10 and 17-20: Are used to test mesopic vision with glare.

Enter a visual aid

If the patient wears glasses or contact lenses, the examination is conducted with the glasses or contact lenses.

➔ Enter whether the patient wears visual aids (including any tinting, etc.), *sect. 10.1.1, page 36*.

Instruct the patient

➔ Select test step 1
➔ Tell the patient to focus between the red fixation marks.
➔ Instruct the patient with the help of displayed Landolt ring.

Test mesopic vision for the right eye

➔ Select test step 2.
➔ Present the optotype to the patient in 5 different positions, *sect. 10.1.3, page 37*.
➔ Mark the results, *sect. 10.1.2, page 37*.

The visual requirement is deemed met when the patient has recognised at least 3 of 5 positions of the Landolt ring (60% criterion).

➔ Conduct test steps 3 through 5 in the same way.

Test mesopic vision with glare for the right eye

➔ Select test step 6.
➔ Tell the patient to focus on the red fixation mark. Explain to the patient that he must keep looking in that direction and must not, under any circumstances, look directly at the glare light during any of the subsequent tests.
➔ Conduct test steps 7 through 10 in the same way as described above, *sect. , page 50*.

The visual requirement is deemed met when the patient has recognised at least 3 of 5 positions of the Landolt ring (60% criterion).

Test mesopic vision for the left eye

➔ Select test step 11.
➔ Tell the patient to focus between the red fixation marks.
➔ Present the optotype to the patient in 5 different positions (step12), *sect. 10.1.3, page 37*.
➔ Mark the results, *sect. 10.1.2, page 37*.

The visual requirement is deemed met when the patient has recognised at least 3 of 5 positions of the Landolt ring (60% criterion).

➔ Conduct test steps 13 through 15 in the same way.

Test mesopic vision with glare for the left eye

➔ Select test step 16.
➔ Tell the patient to focus between the red fixation marks. Explain to the patient that he must keep looking in that direction and must not, under any circumstances, look directly at the glare light during any of the subsequent tests.
➔ Conduct test steps 17 through 20 in the same way as described above, *sect. , page 50*.

The visual requirement is deemed met when the patient has recognised at least 3 of 5 positions of the Landolt ring (60% criterion).

10.4.3 Test for Night Myopia (optional)

If your Mesotest II is equipped with minus lenses (Mesotest II, konkav), you can conduct these additional examinations. With the minus lenses, you can determine whether the patient suffers from night myopia.
The myopia test must be activated, *"Activate myopia test" on page 40*.

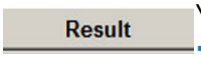
➔ Swing in the minus lenses for the last test that the patient just recognised.

Fig. 10-19: The buttons for minus lenses are activated

➔ Press the button for the desired lens power.

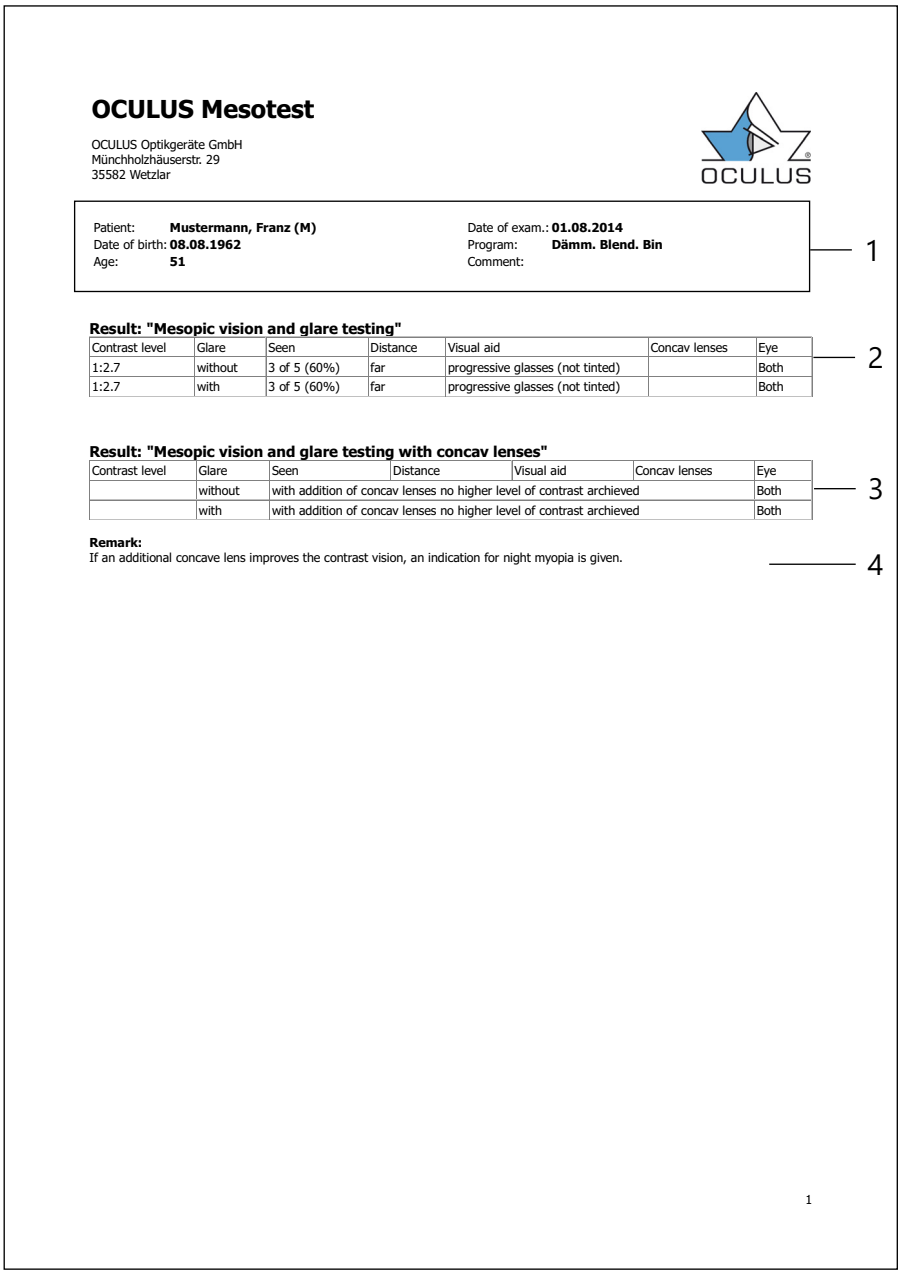
If the visual acuity of the patient improves, he may suffer from night myopia.
You can determine the extent of the night myopia by swinging in lenses of different powers (-0.5/-1.0/-1.5 D).

10.5 Display and Print Results



You can view the test results.
➔ To do so, press this button.

Then you can print the test results.
➔ To do so, press this button.



OCULUS Mesotest

OCULUS Optikgeräte GmbH
Münchholzhäuserstr. 29
35582 Wetzlar

OCULUS

Patient: **Mustermann, Franz (M)**
Date of birth: **08.08.1962**
Age: **51**
Date of exam.: **01.08.2014**
Program: **Dämm. Blend. Bin**
Comment:

1

Result: "Mesopic vision and glare testing"

Contrast level	Glare	Seen	Distance	Visual aid	Concav lenses	Eye
1:2.7	without	3 of 5 (60%)	far	progressive glasses (not tinted)		Both
1:2.7	with	3 of 5 (60%)	far	progressive glasses (not tinted)		Both

2

Result: "Mesopic vision and glare testing with concav lenses"

Contrast level	Glare	Seen	Distance	Visual aid	Concav lenses	Eye
	without	with addition of concav lenses no higher level of contrast archieved				Both
	with	with addition of concav lenses no higher level of contrast archieved				Both

3

Remark:
If an additional concave lens improves the contrast vision, an indication for night myopia is given.

4

1

Fig. 10-20: Results printout

1 Header with information about patients
2 Test results “Mesopic vision and glare testing”
3 Test results “Mesopic vision and glare testing” when testing was done using a Mesotest II konkav
4 Remark

➔ To return to the examination: Press the “Close” X.

10.6 Finishing the Exam

➔ Press the button [Back] to end the examination.
➔ In the dialogue, select whether the data are to be saved or not.
You are then returned to the Mesotest II main menu. You can now
- Start a new examination *(sect. 10.4, page 46).*
- Change patients. To do this, press the button [Select patient].

➔ Clean and disinfect viewer enclosure after each exam, *sect. 13.2, page 75*.

10.7 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. 10-12, page 44*.
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, *page 40*.
➔ Press the [Load examination] button.

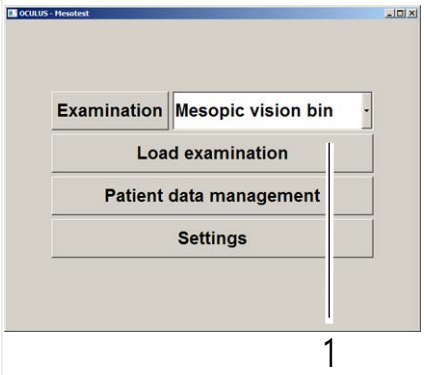


Fig. 10-21: [Load examination] button

➔ Move the cursor to the desired examination.

➔ Double-click on that examination.

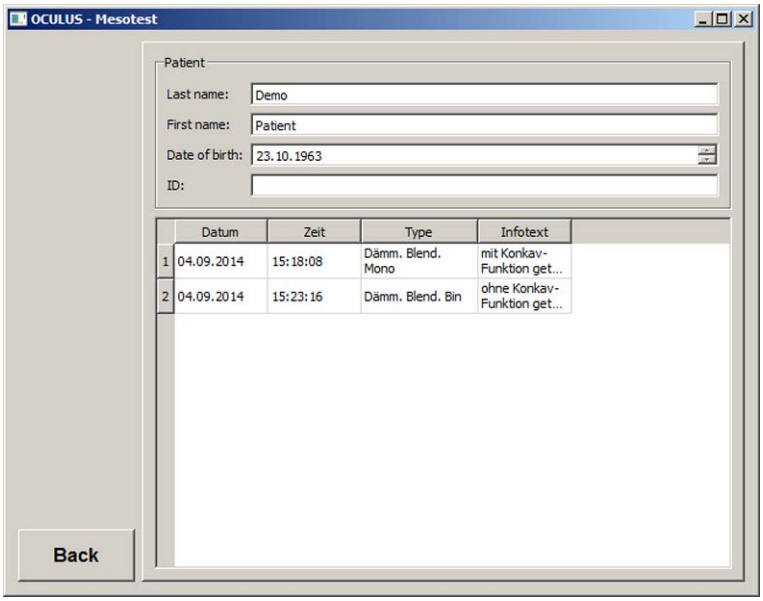


Fig. 10-22: Loading an examination without using the OCULUS Patient Data Management

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 Mesotest II menu.

11 Editing the Examination Programmes

With the Mesotest II, you can

- Compile a custom selection list of examination programmes, *sect. 11.1, page 55*
- Create a new, custom examination programme, *sect. 11.2, page 56*
- Edit an examination programme that you created, *sect. 11.3, page 59*

11.1 Compilation of a Custom Selection List of Examinations

Mesotest II > Settings > Edit programmes

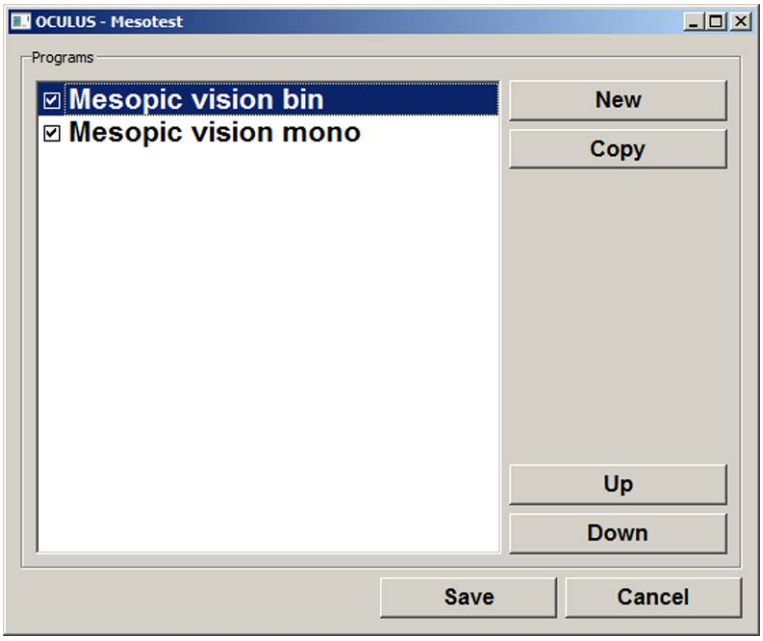


Fig. 11-1: Activation of an examination programme

This function acts on the display in the selection list for the examination programmes.
You can activate and deactivate the wanted examination programmes and can change the order in which they are displayed here.

11.1.1 Activate/deactivate examination programme

➔ Activate/deactivate the checkbox for the wanted examination programme.
➔ Press the [Save] button.
The selection list is adapted accordingly.

11.1.2 Change order

➔ Select an examination
➔ Press the [Up] or [Down] button as many times as necessary until the examination has moved to the wanted position.

➔ Press the [Save] button.
The selection list is adapted accordingly.

11.2 Create A New Examination Programme

Mesotest II > Settings > Edit programmes

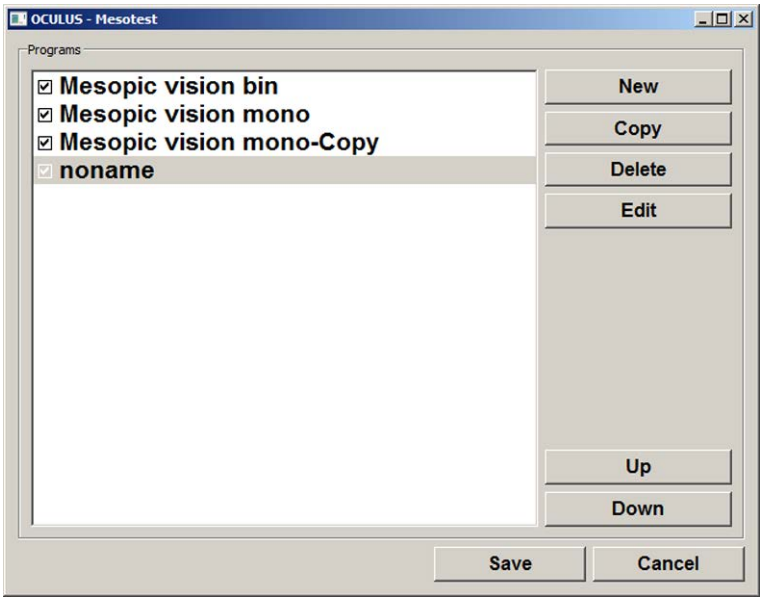


Fig. 11-2: List of activated/deactivated examination programmes.

➔ Press the [New] button.
A new programme appears at the end of the list under the name “noname”. The [Delete] and [Edit] buttons appear.

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

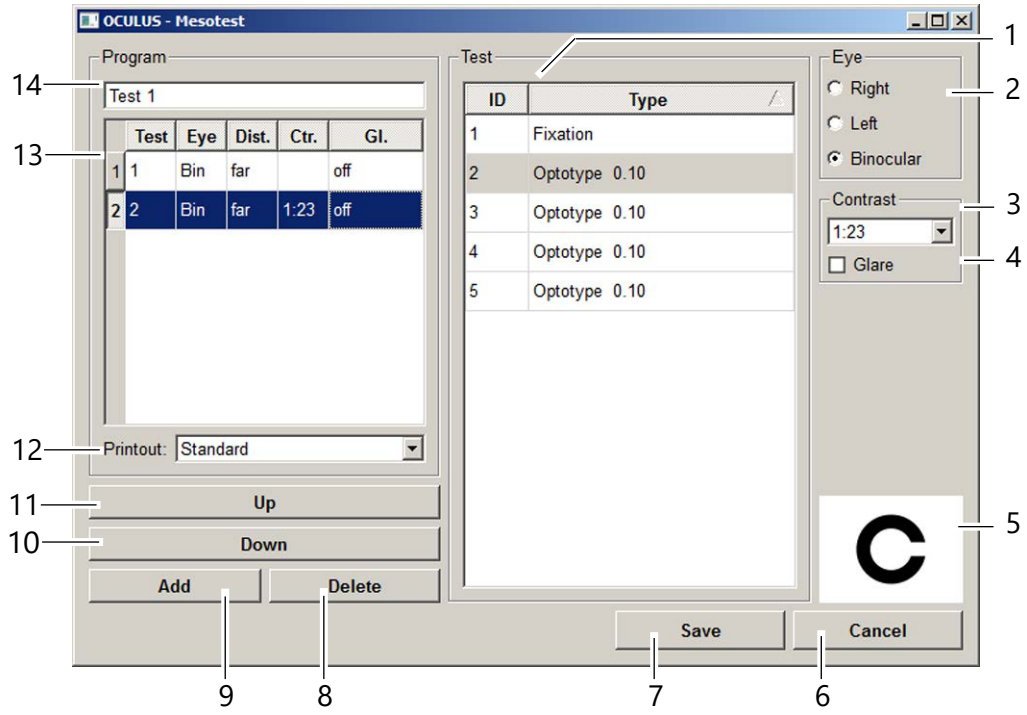


Fig. 11-3: Editing a new examination programme

1 List of test presentation variants
2 [Eye] box for eye selection
3 Drop-down list for contrast selection
4 [Glare] checkbox
5 Display of the optotype
6 [Cancel] button
7 [Save] button
8 [Delete] button
9 [Add] button
10 [Down] button
11 [Up] button
12 Presetting for the printout: Presently without function
13 List of the test steps of the examination programme
14 Name of the examination programme

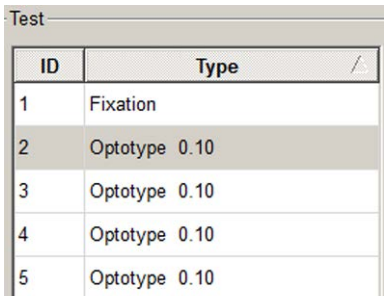
11.2.1 Assign a name

You can assign a new name to the examination programme in the field for the “name of the examination programme” (14).

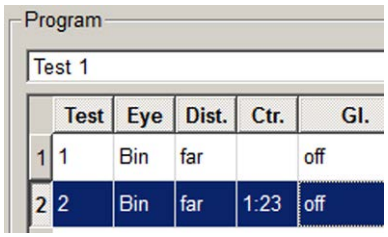
➔ To do this, move the cursor into that field and enter the new name.

11.2.2 Change test step settings

➔ In the list of test steps (13), highlight the test step for which you want to change the settings.

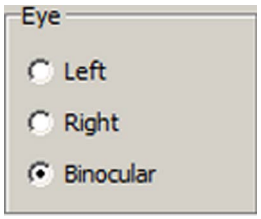


➔ Select a test presentation variant from the list (1).



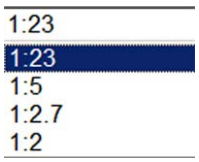
This is taken over into the table for the highlighted test step. The test number is shown in the first column (“Test”).

11.2.3 Select the eye to be examined (2)



➔ Activate the checkbox for the eye that is to be examined (2).
All test steps can be conducted binocularly, or at option monocularly (only possible with device type Mesotest II konkav).
The selection is displayed in the list of test steps for the examination programme (13).

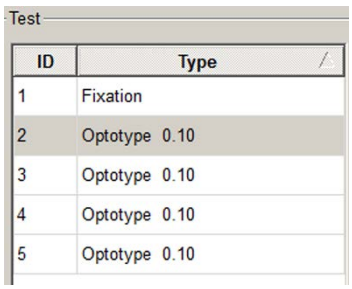
11.2.4 Select the contrast (3)



You can select any of the contrast levels shown here.

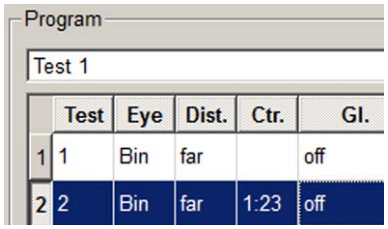
To test mesopic vision with glare:
➔ Activate the checkbox [Glare].

11.2.5 Add a test step



To add another test step to the examination programme:
➔ Press the [Add] button.
You can now edit the added test step in the described manner.

11.2.6 Save examination programme



➔ Enter a name for the created examination programme.
➔ Press the button [Save] to save your examination programme.
The newly created examination programme is displayed in the list of activated and deactivated examination programmes. It is automatically set to active, *sect. 11.1, page 55*.

11.3 Edit Examination Programme

Mesotest II > Settings > Edit programmes

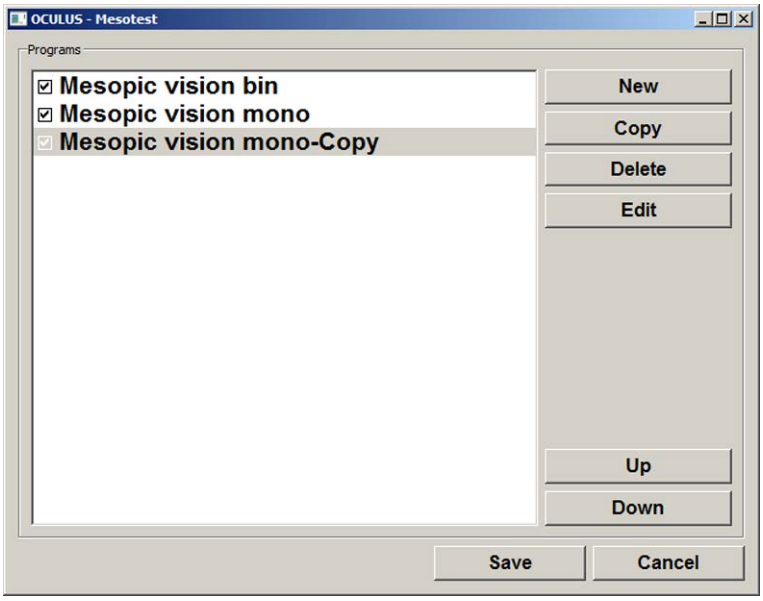


Fig. 11-4: List of activated/deactivated examination programmes.

You can only edit or delete those examination programmes that were created as user-defined ones.

➔ Select an examination programme.

When you select an examination programme that has already been edited or a newly created programme, the buttons [Edit] and [Delete] are displayed.

➔ Press the [Edit] button.
➔ Proceed as described in *sect. 11.2, page 56*.

If you select a preset (default) examination programme, the buttons [Edit] and [Delete] are not displayed.

Proceed as follows.

➔ Press the [Copy] button.
The examination programme is copied and is displayed with the suffix "Copy" at the end of the list of programmes.
The buttons [Edit] and [Delete] appear.
➔ Press the [Edit] button.
➔ Proceed as described in *sect. 11.2, page 56*.

12 Patient Data Management

You can do the following to the patient data

- rename, *sect. 12.1, page 60*
- export, *sect. 12.2, page 60*
- import, *sect. 12.3, page 61*
- save, *sect. 12.4, page 62*

You can also change the Patient Data Management settings, *sect. 12.5, page 64*.

12.1 Rename Patient Data

Patient data can be changed retroactively after it has been added.

➔ Press the [Change] button.
The input boxes for patient data are now enabled, and the cursor jumps to the "Last name" field.

➔ Change the entries in the individual boxes.

➔ Press the [Save] button.

12.2 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.

➔ Press the [Export] button below the patient list. The following dialog appears:

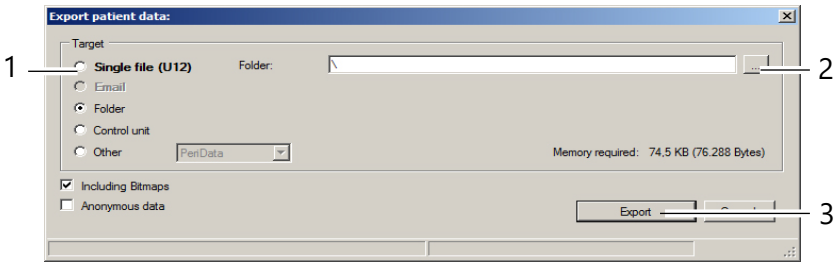


Fig. 12-1: "Export patient data" dialog

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

The options for import and export of data are set as defaults in the "settings" field, see also *sect. 12.5, page 64*.

Depending on the settings you may not have to perform all of the following steps (for example selection of the directory).

➔ Select the "Target" (1) where you would like to export the data.

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

➔ Press the [...] button (2).
➔ 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 (3).

12.3 Importing Patient Data

If you keep patient data on a USB stick, you can import this data.

Note
Loss of data due to computer viruses
Computer viruses can cause loss of data.
➔ Run a virus check before importing data from the USB stick.

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

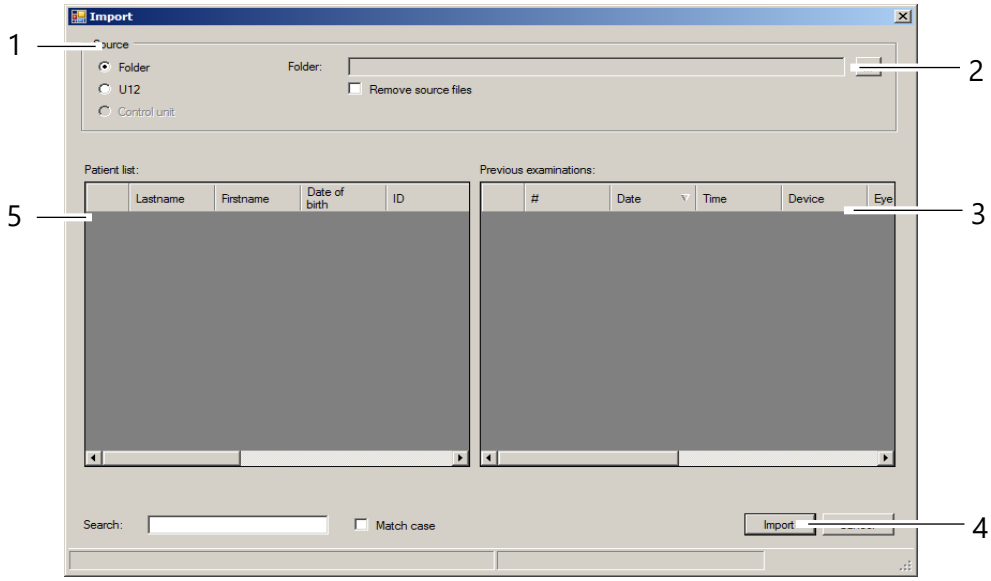


Fig. 12-2: “Import” dialog

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

The options for import and export of data are set as defaults in the “settings” field, see also *sect. 12.5, page 64*.

➔ Depending on the settings you may not have to perform all the following steps (for example selection of the directory).

➔ Select the option (1) which contains the source data (“Folder” or “Single file (U12)”).

Recommendation: Import the patient data using the “Single file (U12)” option.

➔ Press the [...] button (2).
➔ In the dialog box, select the directory or the file where the patient data is located.
➔ Confirm your selection with [OK] or [Save].
The patients that are located and the associated examinations are displayed in the lower part of the dialog.
➔ To import the data, press the [Import] button (4).
The data will then be available in the patient data management system.

12.4 Data Backup

You should carry out a backup of patient and examination data at regular intervals. In case of a loss of data, you can reconstruct the data from a previously created backup with the help of this function. Since data backup takes several minutes depending on the scope of the database and the data to be backed up, a backup should be carried out when the computer and the device will not be needed.

Note

Loss of data due to computer viruses

Computer viruses can cause loss of data.

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

The general rules for security backups apply to backup copies created with the help of the Patient Data Management user interface. Storage of backup files should always be done on a separate system (for example on a USB flash drive with adequate capacity).

12.4.1 Backup data

➔ Press the [Backup] button on the upper right part in the Patient Data Management user interface. The following dialog appears:

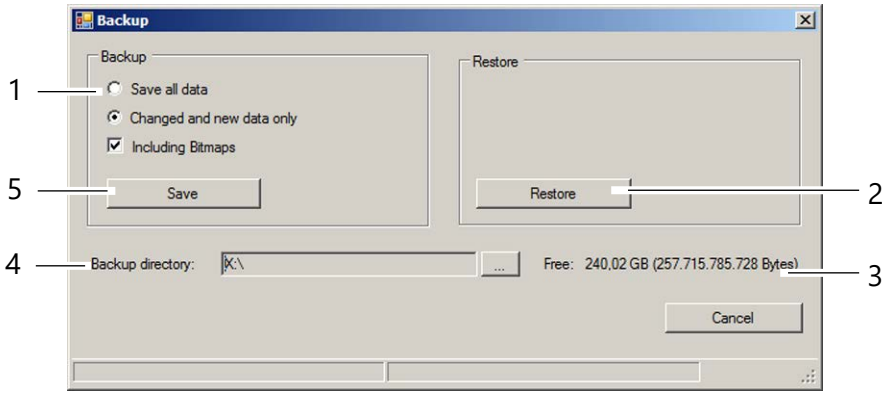


Fig. 12-3: "Backup" dialog

1 Backup data selection
2 [Restore] button
3 Display free storage space
4 Backup folder and button [...]
5 [Save] button

➔ Select whether all of the data or only changed data should be backed up.

The Patient Data Management function internally tags all saved data records.
If you selecting the option "Changed and new data only", only the data records that were not saved during a previous backup will be backed up.

➔ Press the [...] button to the right of the "Backup directory" box (3).
➔ In the dialog that appears, select the folder to which the data should be backed up.
➔ Confirm your selection with [OK].
➔ To back up the data, press the [Save] button (4). The previously selected data will then be backed up to the corresponding folder.

12.4.2 Reconstruct data

If a loss of data occurs, the data from a previous backup can be re-imported into the Patient Data Management user interface.
➔ Press the [...] button to the right of the "Backup directory" box (3).
➔ In the dialog that appears, select the folder which contains the backup data.
➔ Confirm your selection with [OK].
➔ To import the data, press the [Restore] button (2). All data in the appropriate directory are copied to the Patient Data Management software.

12.4.3 Automatic backup

In addition to the manually performed backup, it is also possible to automatically run a backup when exiting the Patient Data Management program. The settings required for this can be made in the "Settings" area, see *sect. 12.5.3, page 68*.

12.5 Change settings

Basic specifications for working with the Patient Data Management user interface can be made in the "Settings" area.

➔ Press the [Settings] button in the upper right portion of the Patient Data Management user interface.

The "Settings" menu page will be displayed. The "Main" tab will appear in the foreground.

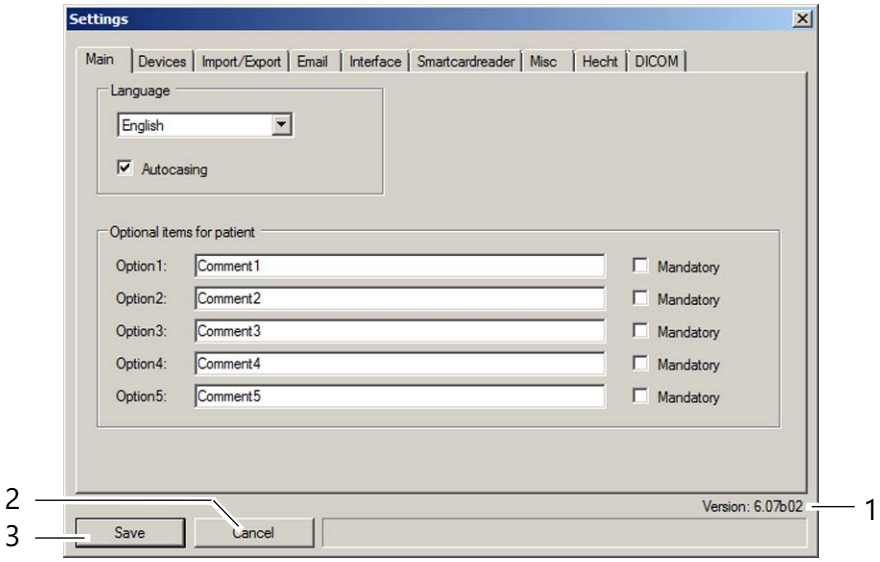


Fig. 12-4: "Settings" screen

1 [Save] button
2 [Cancel] button
3 Program version of Patient Data Management

The following information and buttons are available to you on all tabs:

- The version of the Patient Data Management program appears on the lower right (3).
- There are two buttons below and to the left for saving (1) or discarding (2) the changes that have been made. **All** changes are always saved or discarded, and then the screen is closed.

12.5.1 "Main" tab

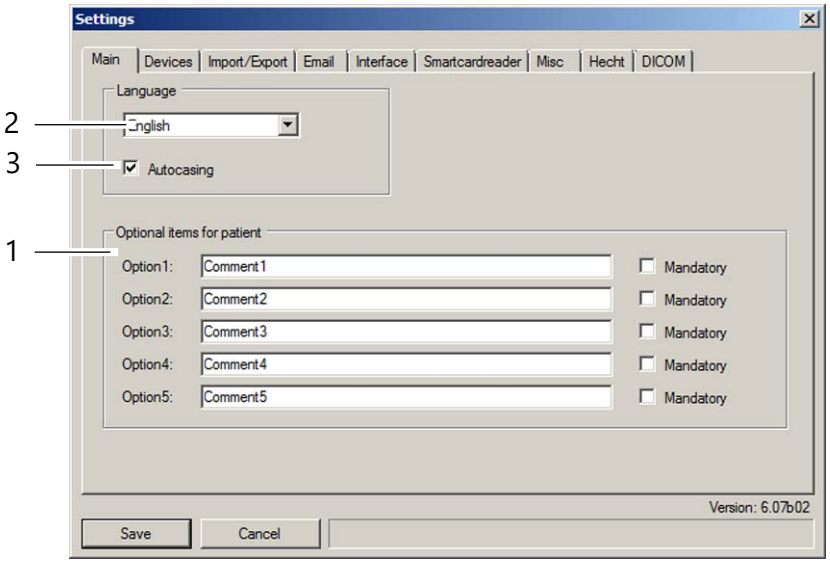


Fig. 12-5: "Settings" screen, "Main" tab

1 "Language selection" drop-down list
2 Checkbox [automatic upper case/ lower case]
3 Optional patient entries

"Language" box

➔ Select the language to be used to display the Patient Data Management user interface from the "Language" drop-down list (1).

➔ Enable the [Autocasing] checkbox (2) as required. If the checkbox is active, the first letter of a patient's first and last name are **always** converted to capital letters.

"Optional items for patient" box

Besides the five standard attributes of first name, last name, date of birth, gender, and ID, up to five additional attributes can be freely defined.

➔ Enter the identifiers for the attributes in the fields Option 1 to 5, for example, "Comment".

To be able to carry out entries for the newly defined attributes, proceed as follows:

➔ Click with the right mouse button on the patient list and open the associated context menu.

➔ Select the desired attribute, for example “Comment2” [2].

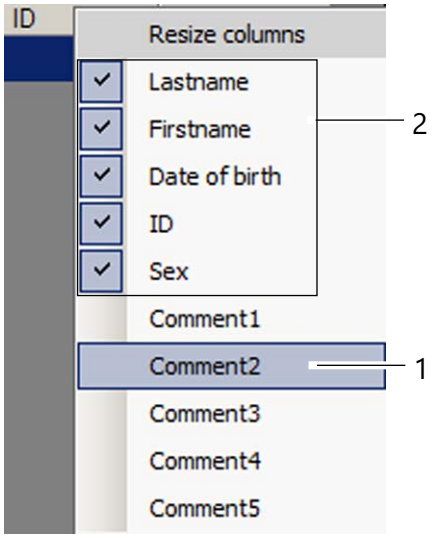


Fig. 12-6: New attribute enabled

1 Previously enabled attributes 2 New attribute selected

The context menu will close, and the attribute “Comment2” will be displayed in the upper section of the entry fields for patient data (1) as well as in the patient list (2).

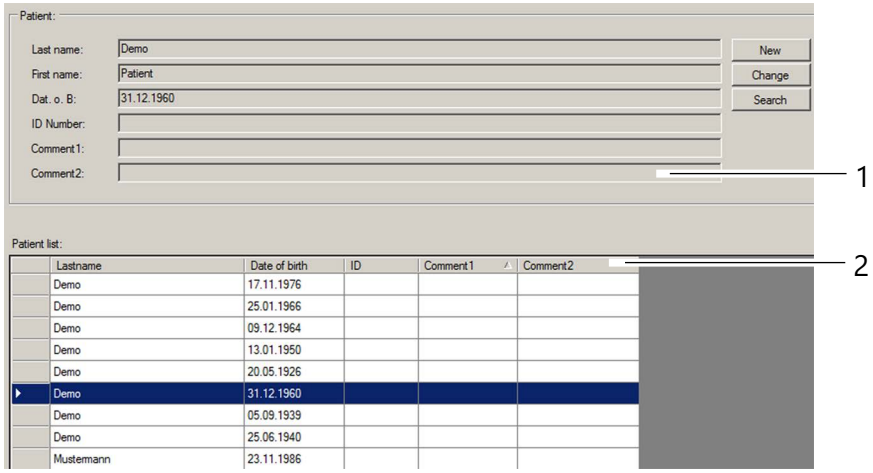


Fig. 12-7: Custom attribute “Comment”

1 Attribute “Comment2” as an input field
2 Attribute “Comment2” in the patient list

The deselection of attributes in the context menu is done in the same manner. The currently selected attributes are marked with a check.

12.5.2 “Devices” tab

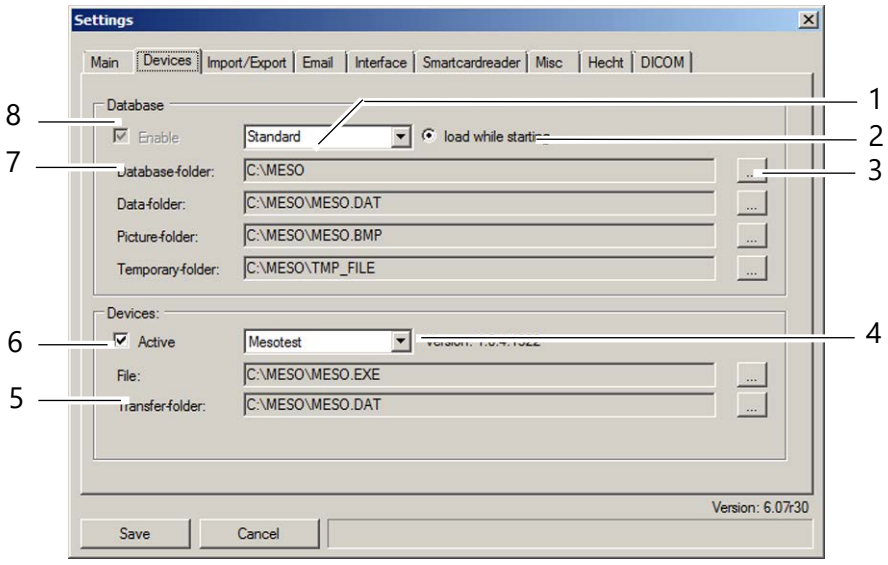


Fig. 12-8: “Devices” tab

1 Drop-down list for selecting a database
2 “Load while starting” radio button
3 Folder selection
4 Drop-down list for selecting a device
5 Path for the currently selected device
6 Checkbox for activating a device
7 Path for the database
8 Checkbox for activating a database

“Database” box

Different users can be set up for different databases.

➔ In the drop-down list for selecting a database (1), choose the entry (User) that you would like to edit.

➔ Choose the corresponding path for the database, data, and images using the individual buttons for folder selection (3).
Normally, two different folders are created for data and images during installation, as shown here (8).

- **For data:** Name of the device plus the .DAT identifier
- **For images:** Name of the device plus the .BMP identifier

➔ For each user, enable whether the associated database should be enabled or not (8).

If more than one database is enabled, an additional drop-down list appears on the main page of the Patient Data Management user interface. You can enable a user (or the assigned database) in this list. The patient list and the associated examinations are updated when the active user is changed.

➔ You can also select the “load while starting” option (2) for exactly one user. The associated database is loaded by default when the Patient Data Management user interface is started, and is selected accordingly.

“Devices” box

Make settings for the connected devices in this box.

➔ In the drop-down list, select the desired device (4).

➔ If the device is in fact connected, then mark the checkbox [Active] (6).

➔ Choose the path to the associated device’s application file using the folder selection button.

When you save patient and examination data in the database, it is initially placed in the so-called “Transfer folder”. This folder is always created locally on the computer.

➔ Choose the transfer folder using the folder selection button. This should correspond with the name of the device and the .DAT extension.

You can also specify settings for devices which are not connected to the computer.

12.5.3 “Import/Export” tab

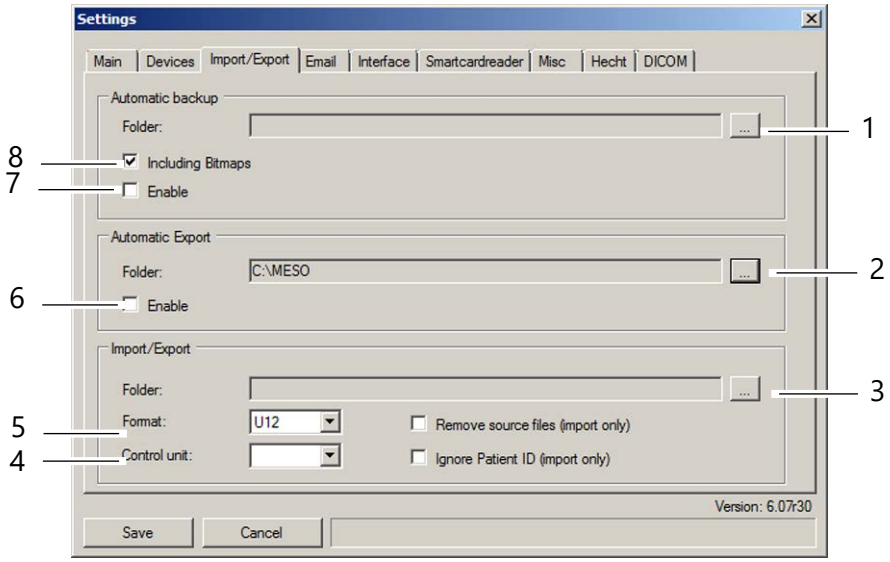


Fig. 12-9: “Import/Export” tab

1 Automatic backup folder
2 Select import/export folder
3 [Remove source files] checkbox
4 Interface for manual operating unit
5 Standard format for import and export
6 [Enable] checkbox for automatic export
7 [Enable] checkbox for automatic backup
8 [Including bitmaps] checkbox

“Automatic backup” box

In addition to the manually executed backup *(sect. 12.4, page 62)*, there is also the option to perform a backup when the Patient Data Manage-

ment user interface is closed. The settings required for this can be specified in the group box.

➔ Select the folder where the data should be saved during an automatic backup using the folder selection button (1).

➔ Select the checkbox [Including Bitmaps] (8) if camera images should also be backed up.

➔ If the automatic backup should be executed with the specified settings, enable the [Enable] checkbox (7).

"Automatic export" box

If you enable this checkbox, every examination will be exported automatically.

➔ Select the folder using the folder selection button (2) which should normally be preselected for the automatic export.

➔ If the automatic export should be executed, enable the [Enable] checkbox (6).

"Import/Export" group box

You can enter settings in this box to import and export Patient Data Management data.

Note

The settings specified in this tab for import and export of data can be overwritten. These are only default values.

➔ Select the folder using the folder selection button (1) which should normally be used as the default for import or export.

➔ In the "Format" drop-down list (5), select whether the default import or export should be done for a folder or a single file (U12).

The checkbox "Control unit" (4) is currently out of function.

12.5.4 "Email" tab

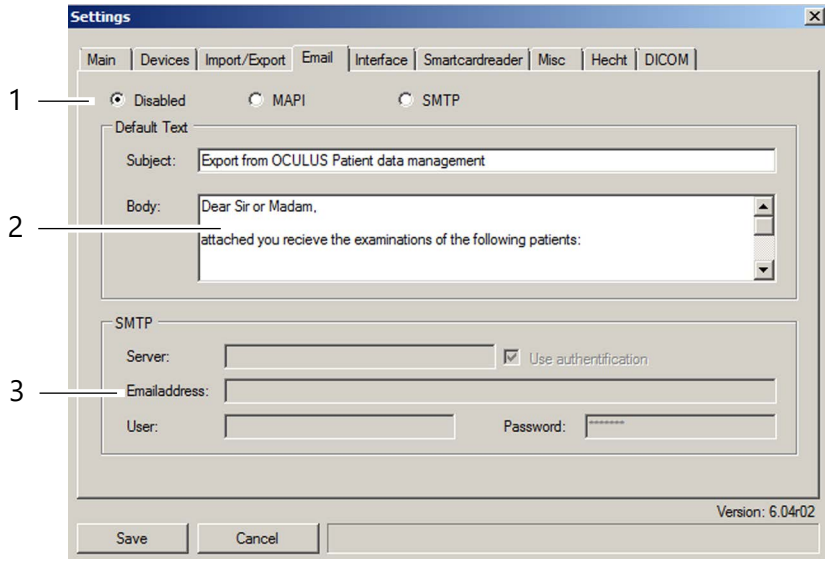


Fig. 12-10: "Email" tab

1 Select e-mail connection
2 Standard text for subject and body text
3 SMTP connection selection

With the three radio buttons in the upper part of the tab (1), you can determine whether the email connection is active, and if it is, how the transfer of data should take place.

➔ Enable the option "MAPI" if an email program (for example Microsoft Outlook) is installed on your computer and if data should be sent using this program.

➔ Enable the option "SMTP" if **no** email program is installed on your computer but you would still like to send the data by email. In this case, additional entries in the "SMTP" box are necessary.

"Default text" group box

➔ Enter the default text for sending emails in the "Subject" and "Body" (2) boxes. You can adjust this text before email is actually sent (for example particular to patients or examinations).

"SMTP" group box

If no email program is installed on the computer, several additional entries must be made here to be able to send emails.

➔ Contact your system administrator if you have questions about the individual entries.

12.5.5 "Interface" tab

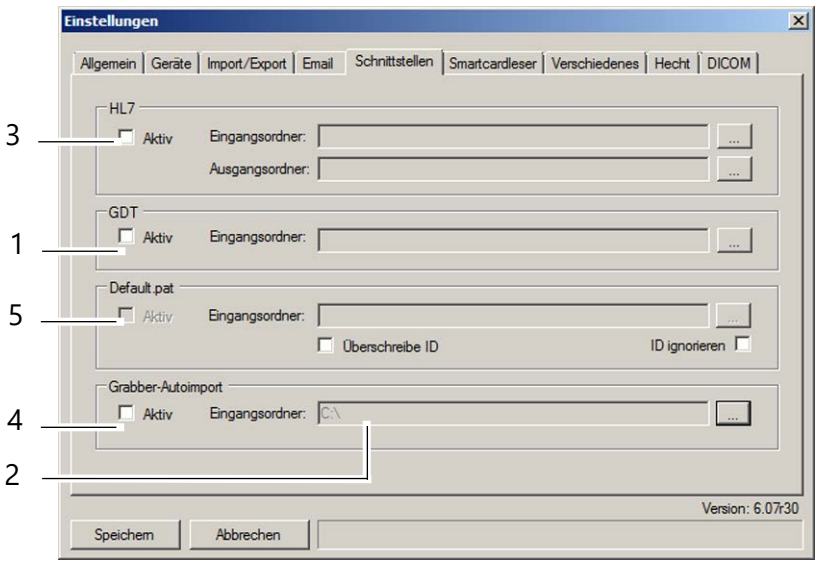


Fig. 12-11: "Interface" tab

1 Settings for HL7
2 Settings for GDT
3 Settings for Default.pat
4 Settings for Grabber Import
5 Inbox for Grabber import

Use this tab to enter the folder for different interface types and to enable or disable them.
The interface "Default.pat" (3) is used if the Patient Data Management user interface is launched by a third-party program.

➔ Add the interface "Default.pat" to the directory of the other program.

➔ Select the third-party program's folder as the "in" folder.

12.5.6 "Smartcardreader" tab

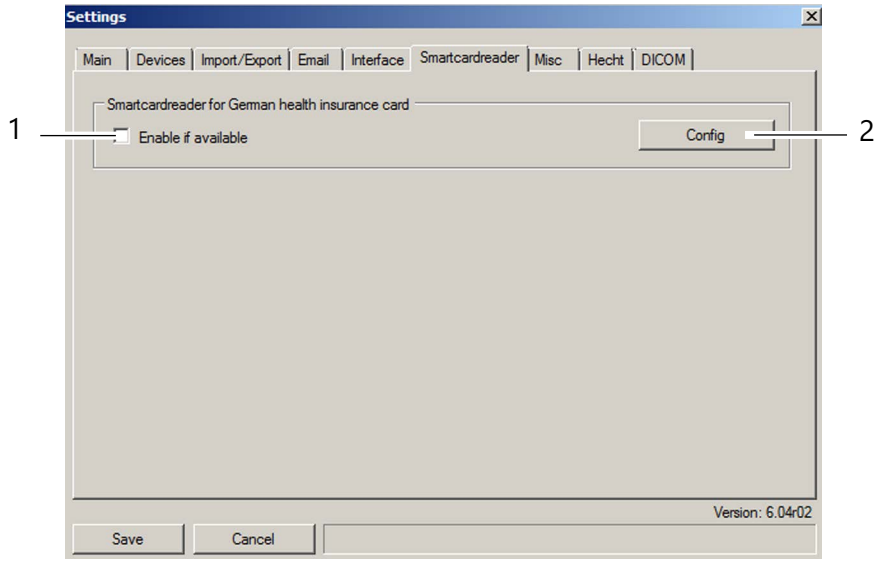


Fig. 12-12: "Smartcardreader" tab

1 [Enable] checkbox 2 [Config] button

You can configure a smartcard reader on this tab to be able to directly import patient data from the patient's insurance card into the Patient Data Management user interface. First, you have to configure the smartcard reader (usually only once).

➔ Press the [Config] button (2). A page appears for you to select the type of smartcard reader you are using.

➔ Select the [Enable if available] checkbox (1) to enable the smartcard reader.

12.5.7 “Misc” tab

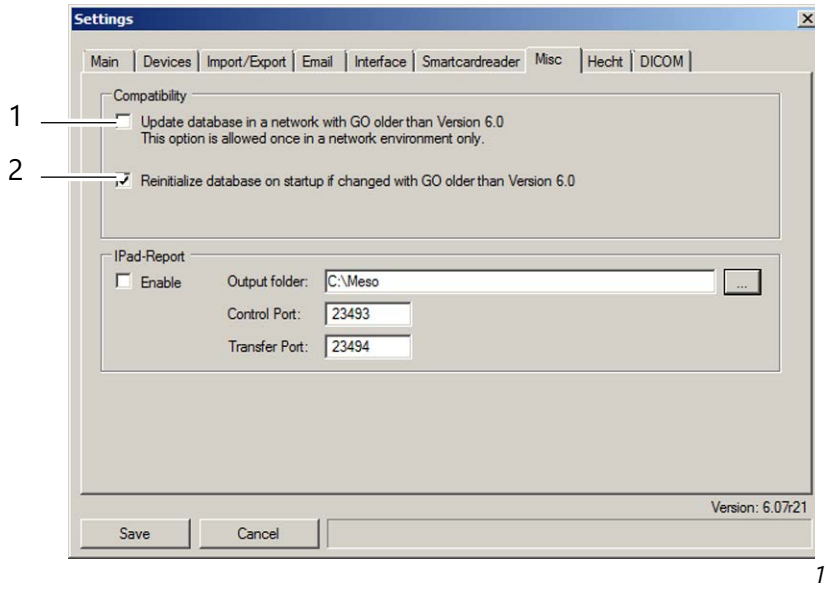


Fig. 12-13: “Misc” tab

1 Checkbox to manage the database

2 Check box to import the database

The Patient Data Management user interface is available in two different versions: V2.x and V6.x. In principle, implementing both versions on the same network should be avoided. In any case, if it is unavoidable due to the higher technical requirements of the new version V6.x, then the corresponding settings must be set on this tab.

- ➔ Enable the checkbox on this tab (1) on **exactly one** computer that has version V6.x installed.
- ➔ Make sure that this checkbox is **not** enabled on any other computer which has version V6.x of the Patient Data Management user interface installed.
- ➔ Enable Checkbox (2) so that data from the database will be read in again after the next start.

This ensures that the database is automatically updated when a patient is created on a computer with the older Patient Data Management V2.x.
The “IPad Report” field is currently disabled.

12.5.8 “Hecht” and “DICOM” tabs

“Hecht” and “DICOM” tabs are currently disabled.

13 Cleaning, Disinfection and Maintenance

This chapter describes how to clean and disinfect the Mesotest II and how to change the viewer enclosure, the fuses and the panel illumination lamp.
To ensure satisfactory and reliable operation, we recommend that you Have the Mesotest II checked every two years by our service department or an authorized dealer. If an error occurs which you are unable to correct, label the Mesotest II as "out of order" and contact our service department or an authorized dealer.

Attention

Risk of electric shock if the Mesotest II is not completely disconnected from the mains for these jobs.

➔ Turn the Mesotest II off, *sect. 7.6, page 26*.
➔ Unplug the power cord before cleaning, disinfection and maintenance, *sect. 13.1, page 74*.

➔ 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 Mesotest II with aggressive, chlorinated, abrasive or sharp cleaning agents.

13.1 Unplug the Equipment

➔ Turn off the unit with the On/Off (3) switch.

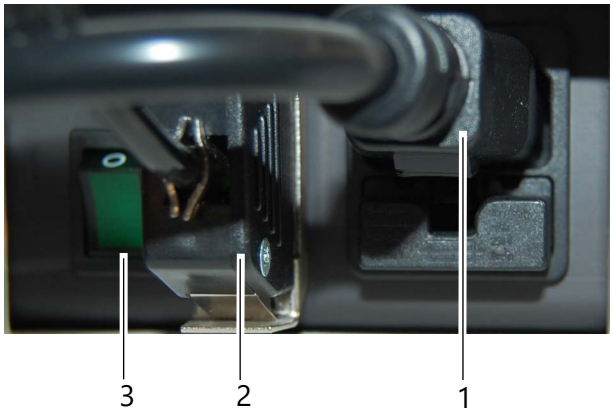


Fig. 13-1: Plug connections of the Mesotest II

1 Mains connection
2 Plug for the control pad/computer/laptop
3 On/Off switch

➔ Unplug the power cable from the socket.
➔ Push the button at the control pad plug and pull it out of the jack, or unplug the connecting cable to the computer/laptop.

13.2 Cleaning

Required Materials

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

Cleaning intervals: Wipe the viewer enclosure after each examination, and the housing whenever necessary.

➔ Turn the Mesotest II off, *sect. 7.6, page 26*.
➔ Unplug the power cord.
➔ When cleaning, use a damp cloth and make sure that no liquid enters the Mesotest II.
➔ 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.
➔ Clean the viewer enclosure with a mild soap solution.

13.3 Disinfection

Required Materials

To disinfect all surfaces (except the Plexiglas back pane of the viewer) we recommend the use of:

- Mikrozid sensitive wipes premium
  Make: Schülke & Mayr GmbH; Softpack 48x, Art.No. 165711

➔ Disinfect the viewer enclosure after every examination and the housing whenever necessary.

If the viewer enclosure is very dirty, you can exchange it, *sect. 13.4.1, page 76*.

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.

13.4 Care and Maintenance

To ensure satisfactory and reliable operation, we recommend that you

➔ Have the Mesotest II checked every two years by our service department or an authorized dealer.

Note

Faulty examinations due to damaged equipment

If an error occurs that you can not resolve

➔ Label the damaged Mesotest II as “out of order”.

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

➔ Use only undamaged Mesotest II devices.

13.4.1 Exchange Viewer Enclosure

If the viewer enclosure is worn or is very dirty, you can exchange it.

Required Materials

- Soft cloth as underlay
- New viewer enclosure (Order number 016280001003)

Proceed as follows:

➔ Turn the Mesotest II off, *sect. 7.6, page 26*.

➔ Unplug the power cord.

➔ Lay the Mesotest II on its back.

Note

Risk of damaging the viewer glass if the unit is put down incorrectly

➔ Lay the Mesotest II on its back only. Use the soft cloth as an underlay.

Removal:

➔ Remove the yoke springs:

- To do this, take hold of the yoke springs one after the other at the two round ends and unhook the spring ends from the rubber part by pulling them outwards.
- Then fully remove the yoke spring from the top guide groove.

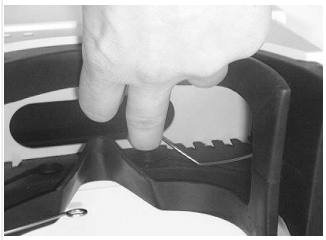


Fig. 13-2: Removing the yoke springs

➔ Then press the viewer enclosure out of its guide groove.

➔ Take hold of one side of the viewer enclosure and pull it out.

Fig. 13-3: Removing the viewer enclosure

Insertion:

➔ Compress the viewer enclosure vertically and insert it into the frame of the housing halfshell.

➔ Starting at one side, press the groove of the viewer enclosure into the frame.

Make sure that the small air ducts on the back are not folded over.

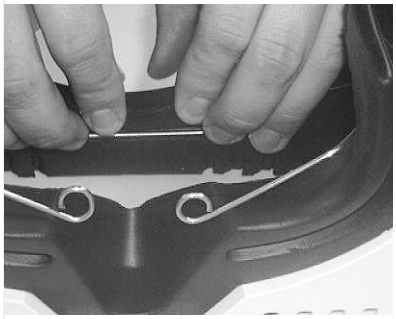


Fig. 13-4: Inserting the yoke springs

➔ First insert continuous yoke of the yoke spring into the top guide groove.

Make sure that the yoke sits fully in the groove.

➔ Then take hold of the two bent ends of the yoke spring, one after the other, and hook them back into place in the bottom groove.

13.4.2 Replacing the Fuse

The Mesotest II has two fuses. These are located in a small fuse box integrated in the mains power plug.
You can replace a blown fuse.

Note:

Function loss due to incorrect fuse

➔ Use only the fuse type that is specified on the rating plate, *sect. 2, page 7*.

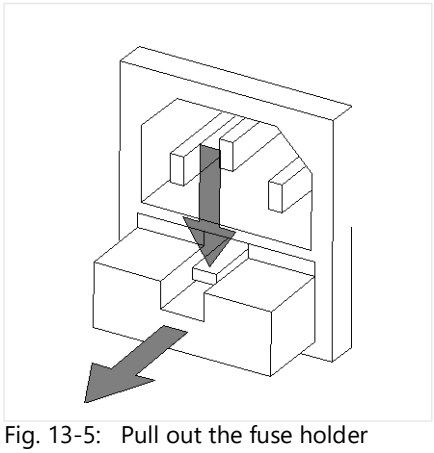


Fig. 13-5: Pull out the fuse holder

➔ Turn the Mesotest II off, *sect. 7.6, page 26*.

➔ Unplug the power cord.

➔ Open the drawer. To do this press on the lug on the top of the drawer.

➔ Pull out the drawer.

➔ Replace the blown fuse.

You can recognise a blown fuse by the burnt filament.

➔ Push the drawer back in until the lug snaps back into place.

➔ Connect the Mesotest II to the mains.

You can now turn on the Mesotest II and start doing exams.

13.4.3 Change the Lamp at the Panel Illumination

You can change a faulty lamp.

Note:

Risk of functional damage caused by wrong lamp.

➔ Use only genuine lamps from Oculus. Order number 016280006004.

Fig. 13-6: Changing the lamp

➔ The bulb is changed together with the plastic holder, which also acts as a glare shield.

➔ Simply pull the lamp up and remove it.

➔ Insert the lamp.
When inserting the new lamp, take care not to bend the pins (connecting wires) of the bulb.

➔ Push the lamp into its fixture.

14 Troubleshooting

Attention

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
Nothing happens when the power switch is turned on	The Mesotest II is not connected to the power supply	Plug the power cable into the socket or into the low heat device socket at the Mesotest II.
	Power failure or power socket is not active	Inform the in-house electrician
	The control pad or the serial cable of the computer is not connected properly	Check that the connector is plugged in properly
	The device fuses have blown	Change the fuses (see *sect. 13.4.2, page 77*)
	The unit has been switched off and back on again too quickly	Wait approx. 5 seconds before turning the unit back on again
Patient claims he cannot see anything	The unit is in stand-by mode	Press any button on the control pad
	The examination room is too bright	Darken the room or cover the back pane of the viewer with the supplied cover.
Panel illumination is not functioning	Lamp at the panel illumination is faulty	Change the lamp (see *sect. 13.4.3, page 77*)
R/L/BIN and -DPT. with corresponding minus lens powers are not working despite display in the LCD	Supplementary equipment is not installed in the device	

15 Transport and Storage

The Mesotest II, must be properly dismantled and packed before being transported or stored.

15.1 Transport and Storage Information

This device does not keep up with the temperature conditions for storage according to ISO 15004-1.

Storage conditions

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

Transport conditions

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

After storage and transport

➔ Wait approx. 3-4 hours after transport before operating the Mesotest II 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/improper storage

➔ Avoid shocks, vibration and dust.
➔ Avoid high temperatures and moisture.

➔ Transport the Mesotest II in a compliant manner.
➔ Store the Mesotest II in accordance with the storage conditions.
➔ Avoid placing near heaters and moisture.
➔ Check the Mesotest II and its accessories for damage after every transport.

15.2 Disassembly and Packing

➔ End the current session.
➔ Pull the power plug and disconnect the plug connectors.

Attention

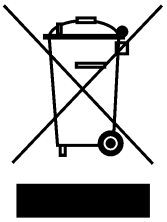
Equipment damage due to improper transport and storage

➔ Avoid knocks, vibrations, dirt, high temperatures and moisture.

➔ Transport the Mesotest II carefully.
➔ Avoid shocks, vibration and dust.
➔ Store the Mesotest II in accordance with the storage conditions. Avoid storing in the vicinity of heaters and moisture.

If you want to send the Mesotest II to OCULUS for repair, you can order an empty packaging box from OCULUS Service. That will help prevent potential transport damage.

16 Disposal



In accordance with Guideline 2012/19/EG of the European Parliament and of the Council dated 04 July 2012, 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.

➔ Dispose of the Mesotest II in a compliant manner.

17 Terms of Warranty and Service

17.1 Terms of Warranty

Note the following warranty provisions:

- Prior to and while operating the device it is important that you observe the instruction manual and safety instructions.
- The Mesotest II carries a warranty to which you are entitled in accordance with the legal provisions.
- If any unauthorized persons interfere with the Mesotest II, all warranty entitlements shall be void. Any inappropriate modifications or repairs can cause grave danger to the user and patient.
- Any entitlement to a warranty shall also be void if unauthorized persons interfere with the computer hardware and supplied software.
- Make transport damage claims to the shipping company during or immediately after delivery. Have the damage confirmed on the bill of lading, so that a proper claim settlement is possible.
- In general, the general terms and conditions of business and delivery apply as per the date of purchase.

17.2 Liability for proper function or damages

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

- Use the device in accordance with these instructions and the accompanying user manual.
- There are no user-serviceable parts either on or inside the Mesotest II. OCULUS shall not assume any liability if assembly, extensions, adjustments, changes or repairs are carried out by unauthorized personnel; if the Mesotest II is maintained improperly; or if it is handled incorrectly.
- If the work described above is carried out by persons authorized to do so, they must be required to supply a certification detailing the nature and scope of repairs, and, if applicable, to specify modifications to the rated data and area of work. The certificate must bear a date, a signature, specify who carried out the work, and contain company information.
- On request, and for this purpose, OCULUS will supply authorized persons with spare parts lists and additional descriptions.
- Make sure that only original OCULUS parts are used for service and maintenance.

17.3 Address of the manufacturer and service department

Our service department or authorized representatives will furnish you with additional information. Address of the manufacturer and service department:
Germany:

OCULUS Optikgeräte GmbH
Münchholzhäuser Straße 29
35582 Wetzlar, Germany
Tel.: 06412005-0
Fax: 06412005-255
E-mail: sales@oculus.de
www.oculus.de

18 Technical Data

Technical specifications

Dimensions (W x D x H)	246 x 377 x 464 mm (9.7 x 14.9 x 18.2 inches)
Weight (without control pad and power cable)	6.5 kg1(4.3 lbs)
Max. power consumption	40 VA
Voltage	100 -240 V AC
Frequency	50 / 60 Hz
Fuses	2x T 2A H 250V
Control pad: Dimensions (W x D x H) Weight	 82 x 152 x 45 mm (3.2 x 6.0 x 1.7 inches) 256 gr (0.6 lbs)
Expected service life	up to 10 years

Ambient conditions

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

Classification according to IEC 60601 - 1

Type of protection against electric shock	Protection class 1
Level of protection against electric shock	Type B
Level of protection against harmful penetration of water	IP 20

Lighting technology specifications

Ambient brightness without glare	0.032 ±0.003 cd/m^2
Ambient brightness with glare	0.10 ± 0.01 cd/m^2
Glare illuminance rating	0.35 ± 0.03 lux
Glare angle	3°

Computer

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

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

19 Appendix

19.1 Electromagnetic Compatibility

Medical electrical equipment is subject to special precautionary requirements with respect to EMC, and must be installed and operated according to the EMC-Instructions contained in the accompanying paperwork.
OCULUS devices and systems are suitable for use in professional healthcare establishments, e.g. doctor's practices or clinics; however, they may not be used in proximity to HF surgical units or inside of the HF shielded room of an ME system for magnetic resonance imaging.
Portable and mobile RF-communications devices can interfere with electrically operated medical devices.

Minimal performance quality and essential performance criteria

- A short flicker of the illumination of the device during the examination is permissible because it will not affect tthe functionality described in the intended use.
- A short interruption of the USB connection during the examination is permissible because it will not affect the functionality described in the intended use.

Attention

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

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

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

➔ Do not use the accessories, transducers and cables specified by OCULUS with devices other then the Mesotest II.

Attention

Recommended separation distances between portable and mobile RF communication devices and the device.

The Mesotest II is intended for use in an electromagnetic environment in which the radiated RF interference is uncontrolled. The customer or user can help prevent electromagnetic interference by maintaining a minimum distance, based on the maximum output of the communication equipment, between portable and mobile RF communication devices (transmitters) and the Mesotest II as recommended below. Portable RF communication devices (including peripheral devices such as antenna cables and external antennas) should not be any closer than 30 cm (12 inches) to any part of the Mesotest II device. Otherwise, the device performance may be affected.

To be in compliance with the requirements of the IEC 60601-1-2. 6.1 and 6.2 the following types of equipment, accessories, power adapters and cables must be used.

Order number	Description	
62800 62801	Mesotest II Mesotest II konkav	
05200320	Cable with plug, EU standard	2.5 m (8.2021 feet)
05200210 (110 Volt)	Cable with plug, US standard	2.5 m(8.2021 feet)

19.2 Guidance and Manufacturer's Declaration - Interference emission and interference immunity

Guidance and Manufacturer's Declaration - Electromagnetic Emmisssions

The OCULUS Mesotest II is intended for operation in the electromagnetic environment specified below. The user of the Mesotest II should ensure that it is being used in such an environment.

Emissions test	Compliance	Electromagnetic environment - Guidelines
RF emissions CISPR 11	Group 1	The Mesotest II 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.

Guidance and Manufacturer's Declaration - Electromagnetic Emmisssions	
HF-emissions CISPR 11	Class B
Harmonics emissions IEC 61000-3-2	Class A
Voltage fluctuations / flicker emissions IEC 61000-3-3	complies

Electromagnetic Interference Resistance			
Immunity test	**Test level**	**Compliance level**	**Electromagnetic environment - Guidelines**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV ± 15kV	Floors should be made of wood or concrete or covered with ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Power frequency (50/60Hz) 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.
Electrical Fast transient/bursts IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/ output lines	± 2 kV ---------- ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines per 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 Mesotest II requires continued operation during power mains interruptions, it is recommended that the Mesotest II be powered from an uninterruptible power supply or battery.
Note: U_τ is the a.c. mains voltage prior to application of the test level.			

Electromagnetic Interference Resistance			
Interference resistance tests	**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 Mesotest II, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{(V_1)}\right]\sqrt{P}$ $d = \left[\frac{3,5}{(E_1)}\right]\sqrt{P}$ 80MHz to 800 MHz $d = \left[\frac{7}{(E_1)}\right]\sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM to 1 kHz		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 Mesotest II is used exceeds the applicable RF compliance level above, the Mesotest II should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Mesotest II.
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 communication devices and the Mesotest II			
The Mesotest II in intended for us e in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Mesotest II can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Mesotest II as recommended below, according to the maximum output power of the communications equipment.			
	Separation distance according to frequency of transmitter m		
Rated maximum output power of transmitter W	150 KHz to 80 Mhz $d= 1.2 \sqrt{P}$	80 MHz to 800 MHz $d= 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d= 2.3 \sqrt{P}$
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.			

19.3 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.

It is essential that you follow the *"Cybersecurity Instructions" on page 14* section of "Safety Instructions" (*page 9*) in the device instruction manual.

Please note the following information for implementing an integration of 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
- Print
- Data export
- DICOM workflow

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

- Prefer wired LAN connection

- IPv4 network
- Fast-Ethernet (100 Mbit/s minimum)

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

- Licensing: Required opened 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 of data security:

- Refer to the cybersecurity section (*page 14*) of "Safety Instructions" (*page 9*) in the device instruction manual.
- Refer to the "Floating License Key - License management for software options" instruction manual (if applicable)
- Refer to device specific DICOM interface description (if applicable)

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

- License handling from local license server to PEMS and vice versa
- Storage and data export to local network storage and loading from local network storage
- Printout to local printer

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

- Loss of data
- Unsuitable data exchange
- Data corruption
- Unsuitable temporal data allocation
- Unexpected data reception
- Unauthorized 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 organization should identify, analyze, evaluate and control these risks.

Subsequent changes to the IT-Network could introduce new risks and require additional analysis.

Changes to the IT-Network include:

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

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