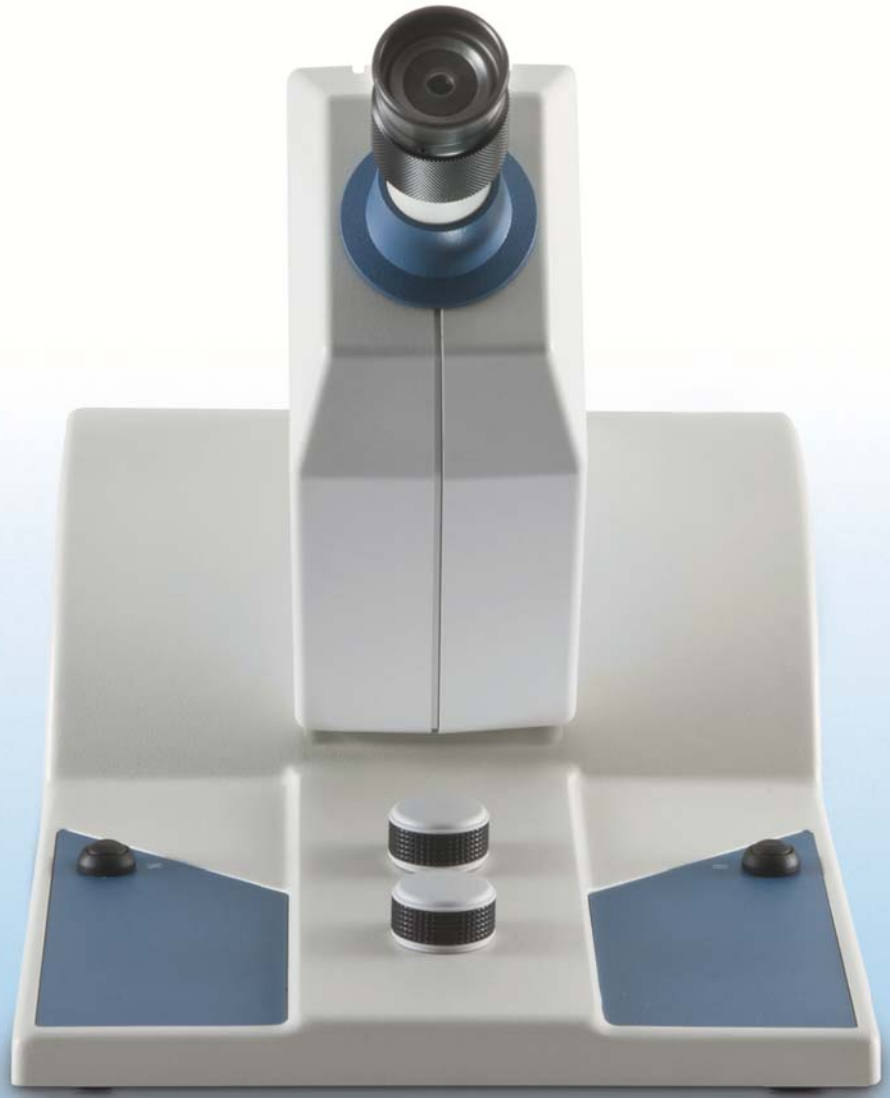
OCULUS | HMC-Anomaloskop



INSTRUCTION MANUAL

Examination of Colour Vision

OCULUS®

Notes on this Instruction Manual

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

The HMC-Anomaloskop is used to test colour vision.

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

If you have any questions or would like additional information about your device, please do not hesitate to contact us by mail or fax. Our team will be happy to assist you.

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

Table of Contents

1 Scope of Delivery

Components	Order Number
■ HMC-Anomaloskop MR (Moreland and Rayleigh), 230 V	47700
or ■ HMC-Anomaloskop R (Rayleigh), 230 V	47720
■ HMC-Anomaloskop MR (Moreland and Rayleigh), 115 V	47715
■ Mains cable	05200320
■ Software for patient data acquisition and evaluation of the HMC-Anomaloskop	47703
■ Instruction Manual HMC-Anomaloskop ■ Software installation instructions ■ User guide	G/47700/..../en SI/50000/.../en B/47700/..../en
■ Dust protection cover	026010005001
■ Replacement fuses, 0.2 A time-lag, for 230 V version)	05100060
■ Replacement fuses, 0.2 A time-lag, for 115 V version)	05100090
■ Floating License Key with manual	77900 SI/77900/.../en
HMC-Anomaloskop MR only:	
■ 4° add-on optics	47705

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

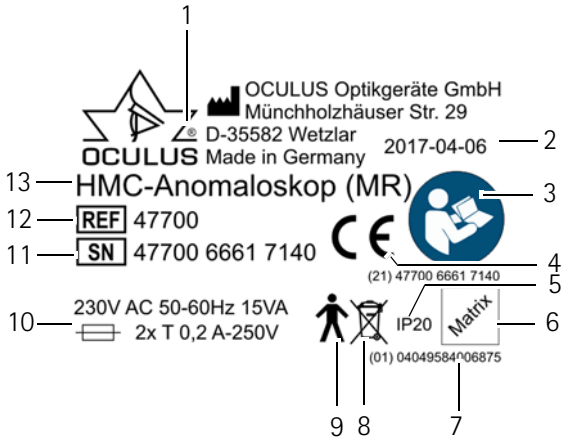
➔ If you find transport damage upon delivery, immediately file a claim with the transport company.

➔ 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 Graphic Symbols on the Equipment

Nameplate

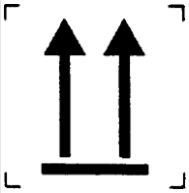


1	*Company logo + address*	*8*	*Do not dispose of the unit as household waste*
2	*Date of manufacturing*	*9*	*Applied part, type B*
3	*Heed Instruction Manual*	*10*	*Power supply and fuses*
4	*CE*	*11*	*Serial number*
5	*Protection class*	*12*	*Reference number*
6	*Matrix*	*13*	*Device name*
7	*UDI number*		

Fig. 2-1: Figure legend; example: HMC-Anomalsokop (MR)

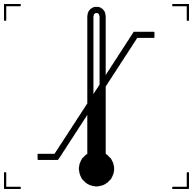
Graphic symbols on packaging


keep dry

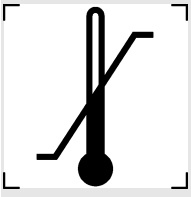

this way up


fragile

Transport


permitted temperature range: transport

Storage


permitted temperature range: storage

3 Information about the Documentation

3.1 Structure of the Documentation

A folder containing a set of documentation is supplied with your HMC-Anomaloskop:

- **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 HMC-Anomaloskop.
- **User Guide:** This document contains general information about colour blindness and the use of the HMC-Anomaloskop.
- **Software Installation:** The introduction to the Software Installation describes how to install the HMC-Anomaloskop software and the associated drivers.
- If you work with a floating license key, the respective instruction manual explains how you can use the HMC-Anomaloskop within a network.

3.2 Software Version

The instruction manual describes the following versions of the HMC-Anomaloskop software as well as the Patient Data Management system:

Laptop/Computer:

- HMC-Anomaloskop software: Version 2.0.0.x
- Patient Data Management: Version 6.08

Note

- The Patient Data Management software version is shown on the "Settings" screen **within the Patient Data Management program** *(sec. 11.5.2, page 62)*.
- The software version of the HMC-Anomaloskop program is shown on Help > About **within the HMC-Anomaloskop program**.

4 Safety Instructions

4.1 About this Manual

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

4.1.1 Used Graphic Symbols

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:

HMC-Anomaloskop > 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.

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.

Instructions for operating personnel

➔ Make certain that the HMC-Anomaloskop is used exclusively by personnel that have the training and practical experience to safely and properly operate the equipment.

Instructions for transport and storage

Heed the instructions in *sec. 14, page 77*.

Instructions for setup and connection

➔ Do not use or store the HMC-Anomaloskop in rooms that are humid.

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

➔ Germany: Only operate the HMC-Anomaloskop 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 HMC-Anomaloskop so that the power plug is easy to access. That way, you can easily disconnect it from the power supply for any repairs or maintenance work.

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

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

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

Patient environment information

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

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

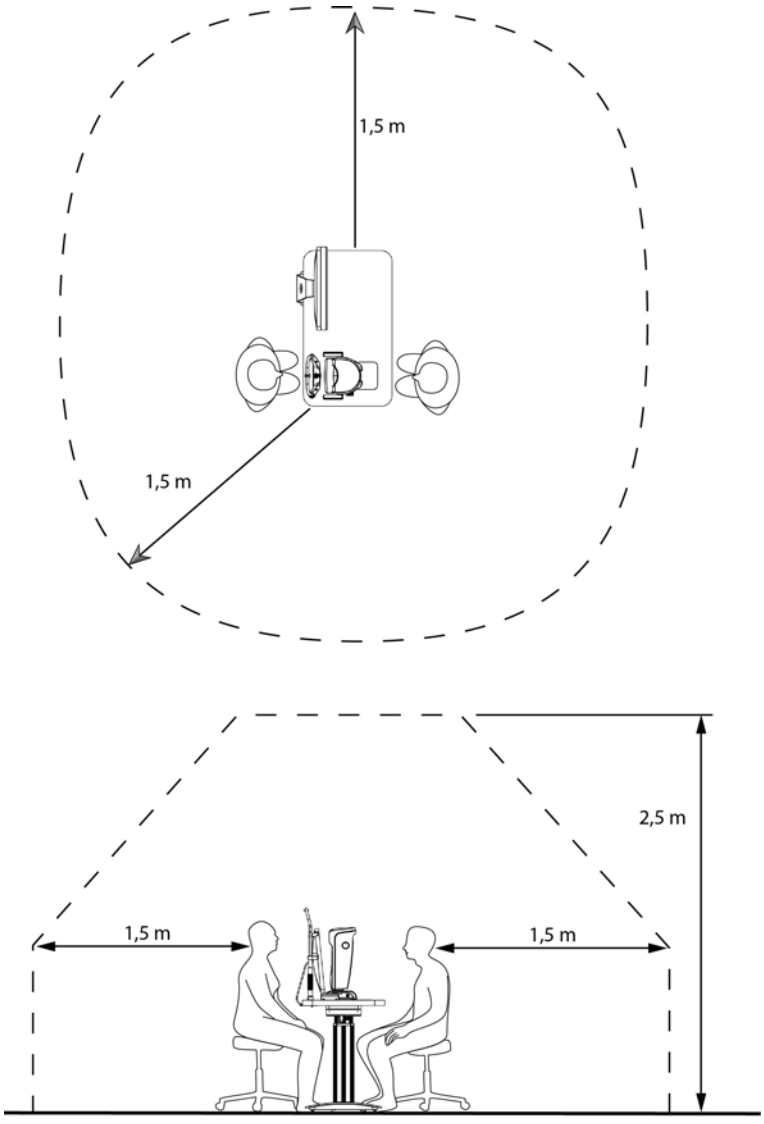


Fig. 4-1: Patient environment

Information about the operation of an ME system

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

➔ Make sure that all devices of the ME system meet the requirements of IEC 60601-1 or IEC 60950-1

Instructions for operation

➔ Before initial operation: Let OCULUS or an authorised dealer train you in the operation of the HMC-Anomaloskop.

➔ Never put a damaged HMC-Anomaloskop into operation.

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

➔ Only operate the equipment after your 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.

Instructions for maintenance

To ensure satisfactory and reliable operation, we recommend that you have the HMC-Anomaloskop checked every two years by our service department or an authorised dealer. If an error occurs which you are unable to correct, label the HMC-Anomaloskop as “out of order” and contact our service department or an authorised dealer.

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 applicable legal requirements.

Note on Electrical Safety

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

Connecting the HMC-Anomaloskop 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 DIN EN ISO 60601-1. If making this connection leads to the leakage current threshold being exceeded, protective measures including a circuit breaker must be in place.

- ➔ Ensure that connections with non-medical devices are made correctly.
- ➔ Use only a computer that meets the specifications given in this instruction manual, *sec. 18, page 82*.

Use of a multiple socket extension cord

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

If you use a multiple socket extension cord to connect the HMC-Anomaloskop to the power supply, you must heed the following information:

- ➔ Use an extension cord that complies with the requirements of DIN EN ISO 60601-1: 20005, section 16.
- ➔ Do not place the multiple socket extension cord on the floor.
- ➔ Do not use more than one multiple socket extension cord.
- ➔ Plug only the HMC-Anomaloskop 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 HMC-Anomaloskop, you must have the electrical safety checked. Call OCULUS Service for this purpose.

Electromagnetic compatibility (EMC / Cables)

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

Portable and mobile RF communications equipment can affect medical electrical equipment *sec. 19, page 84*.

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

5 Intended Use

This unit is intended for the use described in this instruction manual.

It is used for qualitative and quantitative assessment of colour vision of the human eye in the red/green area (HMC-Anomaloskop R) and in the red/green and blue/green areas (HMC-Anomaloskop MR).

This unit must only be operated by duly qualified people who have the required knowledge or practical experience to ensure the system is used in the proper manner.

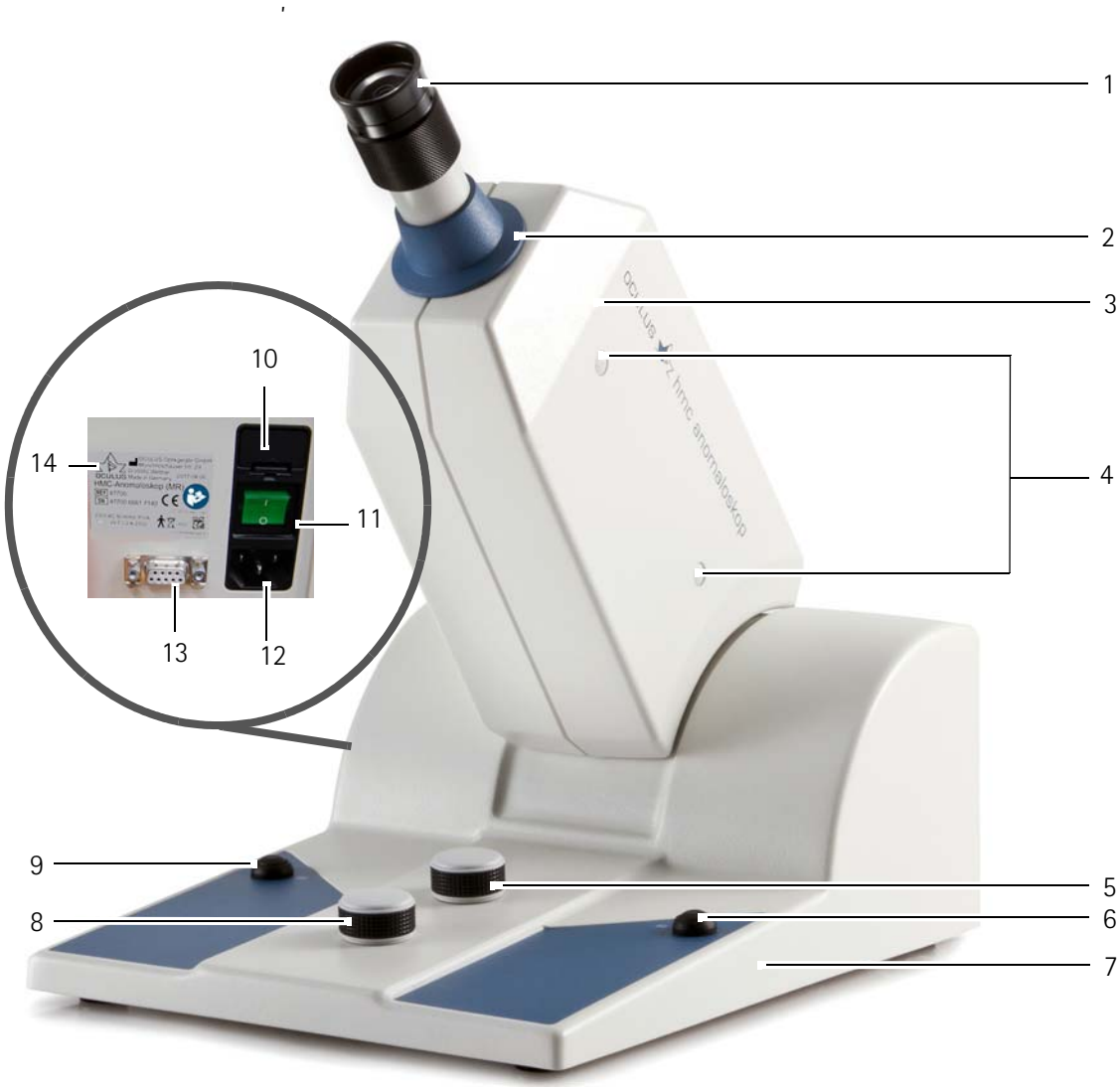
Displayed assessments must be checked individually, as incorrect assessment can occur due to adjacent and overlapping colour vision anomalies, or due to incorrect entries made by the patient.

➔ Heed the safety instructions listed above.

Contraindication

None known

6 Device Description



1	*Eyepiece*	8	*"Reference light" knob*
2	*Front bezel*	9	*"No Match" button*
3	*Tiltable top part of the housing*	10	*Fuse drawer*
4	*Caps*	11	*On/Off switch*
5	*"Mixed light" knob*	12	*Socket for power plug*
6	*"Match" button*	13	*Serial interface port*
7	*Housing base*	14	*Nameplate*

Fig. 6-1: Equipment overview of the HMC-Anomaloskop

6.1 Controls

Tiltable top part of the housing, *fig. 6-1, page 10, item 3*:

You can tilt the top part of the housing up and down. This enables you to seat the patient in a non-fatiguing manner and provide him with the optimal viewing angle during the examination.

Attention

Risk of finger injury

➔ Make sure that neither your nor the patient's fingers, or any other object is in the tilt range of the device.

➔ Keep hold of the base of the device *(fig. 6-1, page 10, item 7)* with one hand.

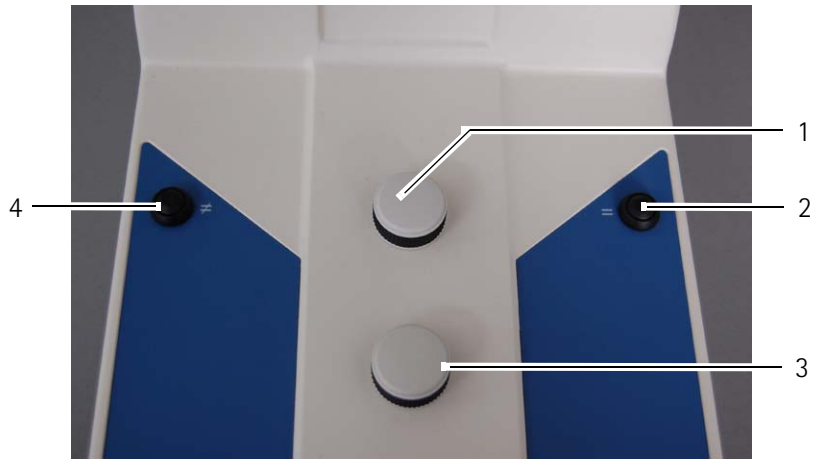
➔ Move the housing top part to the desired position.

Computer/Laptop:

To use the HMC-Anomaloskop software, you need a computer or laptop, also refer to *sec. 9, page 25*.

Controls for the patient

During the examination, the patient can use the following controls:



1 "Mixed light" knob
2 "Match" button
3 "Reference light" knob
4 "No Match" button

Fig. 6-2: Controls for the patient

"Mixed light" knob (1): Adjusts the mixed light (top test field)

"Reference light" knob (3): Adjusts the brightness of the yellow reference light (bottom test field)

Neither of the knobs have a limit stop. If the limit of a colour scale is reached, an acoustic signal sounds.

"Match" button (2): The patient presses this button if he sees the colours of the mixed and reference light in the top and bottom test fields as being the same.

"No Match" button (4): The patient presses this button if he sees the mixed and reference light in the top and bottom test fields as being different.

6.2 HMC-Anomaloskop Functionality

Use

The HMC-Anomaloskop enables qualitative and quantitative assessment of congenital colour vision deficiencies to be done. It also helps in the clarification of maculopathy or opticopathy, if bio-microscopic or perimetric findings do not lead to a conclusive diagnosis.

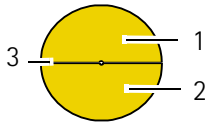
The HMC-Anomaloskop R (Rayleigh) is used for assessing red/green colour vision deficiencies.

The HMC-Anomaloskop MR (Moreland and Rayleigh) is used for assessing blue perception and red/green colour vision deficiencies.

Basis

The HMC-Anomaloskop utilizes the additive colour mixing and metamerism (colour theory) principles.

This can be seen in the test field, which actually consists of two parts.



1 Top test field (mixed light)
2 Bottom test field (reference light)
3 Line separating the two halves of the test field
Fig. 6-3: Test field (example Rayleigh)

Rayleigh Equation

The Rayleigh equation is used as the basis for assessing red/green colour vision deficiencies:

Green (549 nm) + Red (666 nm) = Yellow (589 nm)

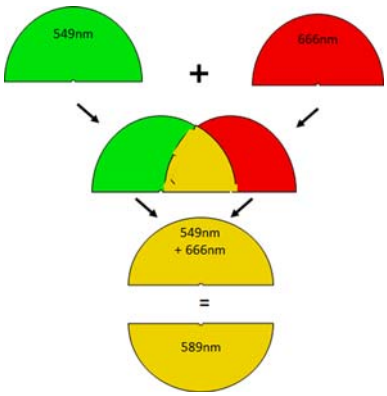


Fig. 6-4: Rayleigh equation (graphic by Prof. Krastel)

The red/green mixture is shown in the mixed light test field (at the top), the yellow reference light is shown in the reference test field (at the bottom). The purpose of the examination is to limit the mixture and brightness range so that the patient subjectively perceives both test fields

as having the same colour and brightness. A thin line separates the two halves of the test field from each other.

Moreland Equation

The Moreland equation is used to examine blue perception:

Blue (436 nm) + Green (490 nm) = Cyan (480 nm) + Yellow (589 nm)[1]

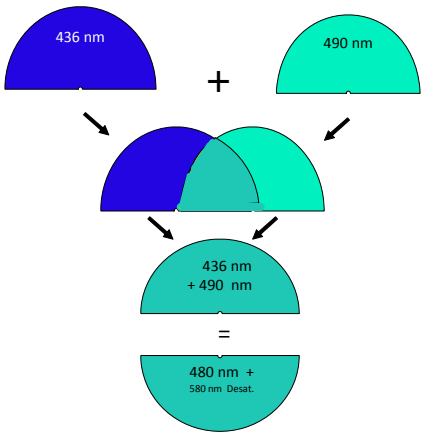


Fig. 6-5: Moreland equation (graphic by Prof. Krastel)

Here again, the additive colour mixing principle is used, this time with the colours blue and green.

Conditions and presentation modalities

To achieve reproducible and comparable results, the following conditions and presentation modalities were adhered to with the HMC-Anomaloskop:

- Presentation of the test field at an angle of 2° in a totally dark environment "unrelational colour", viewed through a tube
- Sharp focussing of the test field by adjusting the eyepiece *(fig. 6-1, page 10, item 1)*
- Germany: Adherence to the specifications for wavelengths, beam widths and bandwidths of the Rayleigh equation (in accordance with the description given in DIN 6160)
- Separation of the two halves of the test field with a thin line
- Homogenous colour fields by means of colour mixing in Ulbricht spheres
- Neutral adaption of the eye with white light
- Use of the diagram of the equation acc. to Moreland during the examination to document the findings

1. Here, the colour green is blue/green (turquoise), the colour blue is violet (in acc. with the CIE colour chart). The colour yellow is used here solely to desaturate cyan.

Neutral adaption

Neutral adaption of the patient's eye is an important condition for conducting the examination with the HMC-Anomaloskop. In this device, the neutral adaption takes place automatically by displaying white light, comparable to standard illuminant C (6750 K), instead of the test field. Depending on the matching range (absolute or relative), the neutral adaption appears at two different time intervals.

The neutral adaption is important because looking at the test field for extended periods causes accustoming ("adaption"), leading to falsified examination results.

Matching range

The matching range is a quantitative description of the sensitivity for differences in colour in the red/green or the blue/green area. The lower the matching range, the better the differences in colour are seen.

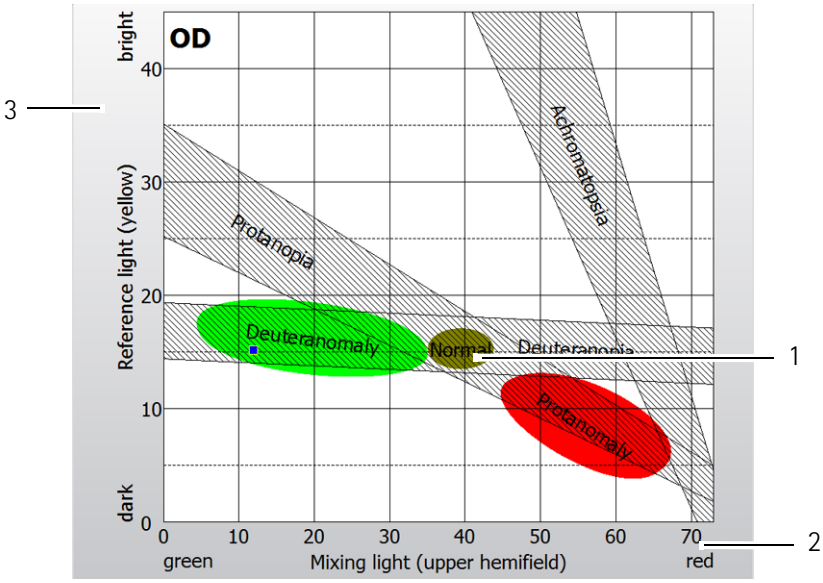
Rayleigh matching range

Determination of the matching range

The matching range comprises two threshold values.

To determine the threshold values, two different colour settings are used as the basis: Top test field starting with red or green.

Then during the examination, you gradually approach the threshold values of the mixture. This is done with the help of the Pitt diagram, which is stored in the examination program.



1 Position of the mean normal equation
2 X-axis: mixed light (top test field)
3 Y-axis: reference light (yellow)
Fig. 6-6: Example: Pitt diagram (Rayleigh)

The two extreme thresholds define the matching range.

Absolute matching range

The absolute matching range is decisive for aptitude assessments in reports and certifications. It is determined after neutral adaption of the eye, i.e. the observation of the colour test field takes place in 5 second cycles with intermittent neutral adaption of 3 seconds.

Relative matching range

The relative matching range is determined by viewing the colour test field for 15 seconds with intermittent neutral adaption of 3 seconds. It is generally higher than the absolute matching range, because the longer the test field is viewed, tuning takes place (accustoming, adaption to the colours), which affects the examination result.

The relative matching range is mainly needed for the diagnosis of acquired colour vision deficiencies, or for diagnosing "adapted" (accustoming) patients[1] with congenital colour blindness.

Rayleigh anomaly quotient

The anomaly quotient (AQ) defines the mixing ratio of the colours red and green as a numeric value. It is determined after the eye has been adapted to neutral. The yellow brightness is not taken into account here.

The anomaly quotient is calculated using the formula:

AQ=[(E-P):P]/[(E-M):M]

The abbreviations here mean:

- AQ: Anomaly quotient
- E: Upper limit (73) of the mixed light scale (x-axis) with 0% green content
- P: Patient's individual matching range on the mixed light scale (x-axis)
- M: Mean normal equation HMC-Anomaloskop
  40/15 = mixed light /reference light (colour setting of an observer with normal colour vision)

The results of an examination are output in the form of a pair of numbers, as the anomaly quotient alone does not draw any conclusions about the luminance of the reference field. In each pair of numbers, the first number represents the anomaly quotient and the second, separated by a semi-colon, represents the corresponding reference field value (for example 0.9;14).

The anomaly quotient must be determined after the eye has been adapted to neutral, i.e. during the examination step for the absolute matching range. Neutral adaption takes place every 5 seconds for 3 seconds.

Example:

The AQ of the mean normal equation is 1.0:

AQ=[(73-40):40]/[(73-40):40]

1. An adapted patient has become accustomed to the colours.

AQ=1.0

Assessment acc. to the German Colour Standards Committee (FNF):

Anomaly quotient	Comment
0.7 to 1.4	Normal range
< 0.7 to 0.1	Protanomaly
> 1.4 (mostly up to 20 max.) to ∞	Deuteranomaly
Up to ∞ or up to 0 or includes the normal match	Extreme anomaly

Mean normal equation acc. to Rayleigh

The colour setting of the test field for a colourmetric normal observer at an angle of 2^{o} is referred to as the mean normal equation (Germany: in acc. with DIN 5033-2).

For the red/green test, this setting is (55±5)% of the upper limit of the scale 73, i.e. 40/15 (mixed light/reference light); also refer to *fig. 6-6, page 14, item 1)*.

The ±5% here means the permissible matching range of a normal observer.

The number 15 refers to the scale value of the brightness setting of the reference light.

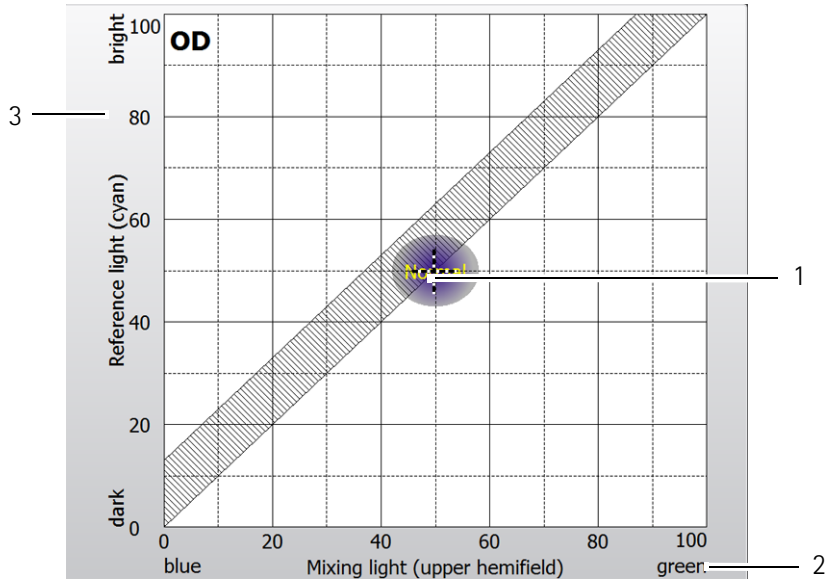
Moreland matching range

Determination of the matching range

The matching range comprises two threshold values.

To determine the threshold values, two different colour settings are used as the basis: Top test field starting with blue or cyan.

Then during the examination, you gradually approach the threshold values of the mixture. This is done with the help of the Pitt-type-diagram acc. to Moreland which is stored in the examination program.



1 Position of the mean normal equation
2 X-axis: Mixed light (top test field)
3 Y-axis: Reference light (cyan)
Fig. 6-7: Example: Pitt-type-diagram acc. to Moreland

The two extreme thresholds define the matching range.

Absolute matching range

The absolute matching range is decisive for aptitude assessments in reports and certifications. It is determined after neutral adaption of the eye, i.e. the observation of the colour test field takes place in 5 second cycles with intermittent neutral adaption of 3 seconds.

Relative matching range

The relative matching range is determined by viewing the colour test field for 15 seconds with intermittent neutral adaption of 3 seconds. It is generally higher than the absolute matching range, because the longer the test field is viewed, tuning takes place (accustoming, adaption to the colours), which affects the examination result.

The relative matching range is mainly needed for the diagnosis of acquired colour vision deficiencies, or for diagnosing "adapted" (accustoming) patients[1] with congenital colour blindness.

1. An adapted patient has become accustomed to the colours.

Tritanomaly quotient for Moreland

The tritanomaly quotient (TAQ) is not an exact equivalent of the anomaly quotient AQ. Tritanomaly quotients can, however, be calculated using the appropriate formula, or can be determined from the scale increments of the mixture by a program implemented in the device.

The tritanomaly quotient is calculated using the following formula:

$$TAQ = \frac{MT_{norm} \times (100 - MT_{prob})}{MT_{prob} \times (100 - MT_{norm})}$$

MT_{norm} is the mixture of the normal observer in scale increments on the anomaloscope that is being used (for example 50 increments on the scale; where the total scale of the mixed lights consists of 100 scale increments),

$MT_{prob.}$ is the mixture for a patient with whom a blue/green match is achieved.

Unlike the AQ, which describes a congenital cone pigment sensitivity deficiency and remains the same over the patient's lifetime, the TAQ represents a present-time observation, for example arising from an illness. The underlying cause could be illness-related loss of cyanolab, or loss of blue cones or blue ganglion cells, or a break-up of the receptive field organisation of the shortwave-sensitive system. Ageing processes of for example the lens can also play a role and manifest themselves as filter effects, if they are not compensated for by selective adaption and colour consistency.

Mean normal equation acc. to Moreland

The mean normal equation is 50/50, also refer to *fig. 6-7, page 17, item 1*.

7 Initial Operation

7.1 Before Initial Operation

Before the HMC-Anomaloskop is operated for the first time, you must c omplete 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 HMC-Anomaloskop are completed by our service personnel or by a professional authorised by OCULUS.

7.2 Setup and Connection

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

Risk of damage to the device if not handled correctly

➔ Do not expose the HMC-Anomaloskop 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" page 82*.

➔ Remove the HMC-Anomaloskop from the packaging.
Keep the packaging. You can then ship or transport the unit in the proper manner for any servicing or repairs that may arise.

➔ Place the HMC-Anomaloskop on a level surface so that the air vents on the bottom of the unit are not covered.

➔ Set up the HMC-Anomaloskop 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 laptop/computer into the jack *(fig. 7-1, page 20, item 2)*.

Attention

Electrical safety hazard

➔ Do not use the HMC-Anomaloskop immediately adjacent to other devices and do not stack it with other devices.

➔ If you use a multiple socket extension cord to connect the HMC-Anomaloskop: Use an extension cord that complies with the requirements of DIN EN ISO 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 HMC-Anomaloskop and the computer that is being used with the unit (if applicable) into the multiple socket extension cord.

➔ Use a socket with a protective earth connection which is fully operating.

➔ Connect the unit to the mains with the supplied power cable, *(fig. 7-1, page 20, item 1)*.

Make sure that the mains voltage is the same as the voltage specified on the nameplate.

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

Fig. 7-1: HMC-Anomaloskop connection

Note

Risk of equipment damage due to incorrect connection

If you do not connect the HMC-Anomaloskop properly, and the connection is live, the unit can be damaged within a short period of time.

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

➔ Please pay attention to the specifications on the nameplate.

If the plug is faulty, contact OCULUS Service or an authorised dealer to correct the problem.

7.3 Software Installation

Before first use, you must install the HMC-Anomaloskop software on your laptop or PC. Proceed as described in *Software Installation*.

For installation on a computer/laptop, we recommend:

2 GB RAM, Windows® 8, free USB port

As of April 2014, Microsoft® no longer provides support for the operating system Windows™ XP. This means that Microsoft® no longer provides any operating and security updates for Windows™ XP.

If you continue to use this operating system after support has ceased, your computer and your data are susceptible to greater security risks. We recommend that you:

- Disconnect your computer from the internet and use it as a stand-alone solution, or
- Upgrade to the latest Windows™ version

You can only conduct the examination with the computer when you use the supplied floating license key (FLK) 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.

7.4 Switching the Device On

➔ First switch on the laptop or computer and start the software, *sec. 9.2.1, page 26*.

➔ Remove the dust cover.

➔ Switch on the HMC-Anomaloskop at the On/Off switch *(fig. 7-1, page 20, item 1)*.

After a short, automatic self-test, the device is ready for operation. The On/Off switch lamp (1) lights up for control purposes.

7.5 Switching the Device Off

➔ Switch off the HMC-Anomaloskop at the On/Off switch *(fig. 7-1, page 20, item 1)*.

➔ Cover the HMC-Anomaloskop with the supplied dust cover.

Attention

Risk of electric shock if the HMC-Anomaloskop is not completely disconnected from the mains for cleaning, disinfection and maintenance.

➔ Unplug the power cord before cleaning, disinfection and maintenance.

8 Before Conducting the Examination

Before testing a patient for red/green colour vision deficiencies, we recommend that you conduct a pre-test, for example using Ishihara or Velhagen-Broschmann colour charts. If the patient incorrectly reads some or even all of the charts, a colour vision deficiency is highly probable.

An examination with the HMC-Anomaloskop will give a more accurate assessment.

8.1 Prepare the Unit for Routine Operation

To start the HMC-Anomaloskop for daily operation, you must:

- Check the connections, *fig. 7-1, page 20*
- Check whether the viewer is dirty

➔ If impurities are found: Clean the eyepiece lens; also refer to *sec. 12.2, page 71*.

➔ Disinfect the gasket at the eyepiece lens after every examination and the housing whenever necessary, *sec. 12.3, page 72*.

HMC-Anomaloskop MR: Use of the 4° add-on optics

Recommendation for Moreland examinations:

➔ Use the 4° add-on optics.
The test field is extended from 2° to 4°.

Fig. 8-1: Mounting the optical attachment lens.

➔ Disinfect the 4° add-on optics after every examination.

8.2 Prepare the Patient for the Examination

Prepare the patient for the examination, as follows:

➔ Have the patient take a seat in front of the device and make sure he is comfortable.

Attention

Risk of finger injury

➔ Make sure that neither your nor the patient's fingers, or any other object is in the tilt range of the device.

➔ Move the housing top part into position, see *page 19*.

➔ Instruct the patient how to use the controls of the HMC-Anomaloskop correctly.

- **"Mixed light" knob** (1): Adjusts the mixed light (top test field)
- **"Reference light" knob** (3): Adjustment of the brightness of the reference light (bottom test field)
- Neither of the knobs have a limit stop. If the limit of a colour scale is reached, an acoustic signal sounds.
- **"Match" button** (2): The patient presses this button if he sees the colours of the mixed and reference light in the top and bottom test fields as being the same.
- **"No Match" button** (4): The patient presses this button if he sees the mixed and reference light in the top and bottom test fields as being different.

➔ Tell the patient which eye is to be examined first and that both eyes will be examined.

➔ Advise him:

- To stay as relaxed as possible and to look into the centre of the eyepiece with that eye, so that he can centrally observe the test field. He can leave the other eye open or close it.
- That during the examination, a white test field will be displayed and that he must continue to look into the eyepiece during that phase, so that his eye adapts to neutral (neutral adaption).

➔ Let the patient focus the test field with the eyepiece so that the image is sharp.

The device has a correction range of ±6 dioptres. If the dioptre adjustment range is insufficient, or if the patient has a high cylindrical vision defect (> 1.5 dpt cyl), he can wear his glasses or contact lenses.

➔ Make sure that the patient does not wear tinted glasses or contact lenses. These can affect the examination results.

9 Using the HMC-Anomaloskop program

Here you will find:

- An overview of the available examinations, *sec. 9.1, page 25*
- Information about how to use the examination menu, *sec. 9.2, page 26*

9.1 Overview of the Examinations

Display	Meaning
Selected colour vision test	Rayleigh (red/green) Moreland (blue/green); Only possible with the HMC-Anomaloskop MR
Selected examination	For Rayleigh (red/green); options: ■ Fast Screening, *sec. 10.4.1, page 41* ■ Manual, *sec. 10.4.2, page 43* or the specific examinations ■ Normal ■ Deuteranopia ■ Deuteranomaly ■ Protanopia ■ Protanomaly For Moreland (blue/green); only possible with the HMC-Anomaloskop MR; options: ■ Manual, *sec. 10.5.1, page 48* or the specific examination ■ Normal, *sec. 10.5.2, page 51*
Matching range	Options: ■ Absolute (after 5 seconds neutral adaption) ■ Relative (after 15 seconds neutral adaption) ■ Neutral adaption off

9.2 Using the Examination Menu

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

9.2.1 Starting the HMC-Anomaloskop-program

➔ Press the [HMC-Anomaloskop] button to start the HMC-Anomaloskop program.

After the automatic calibration of the HMC-Anomaloskop, the following screen appears:

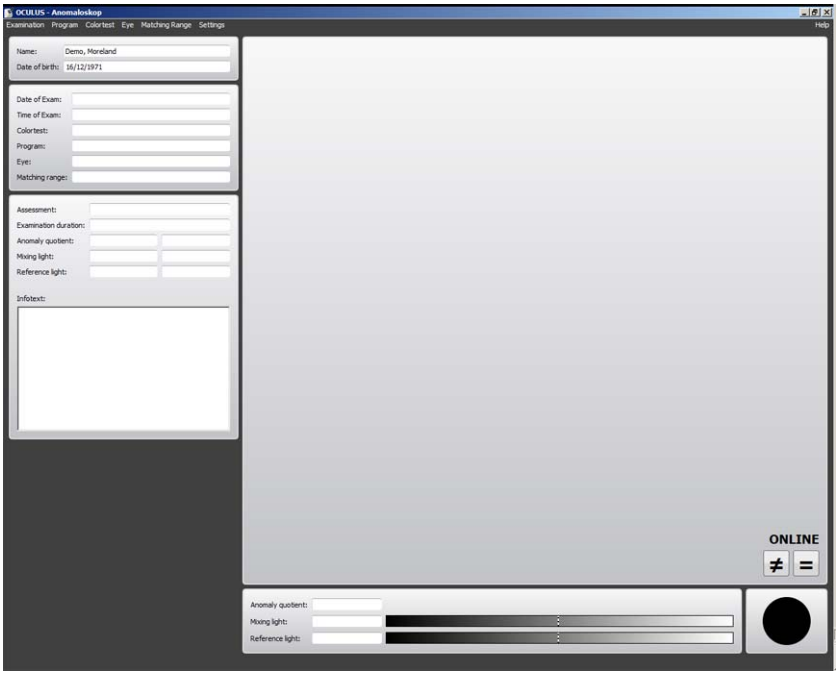
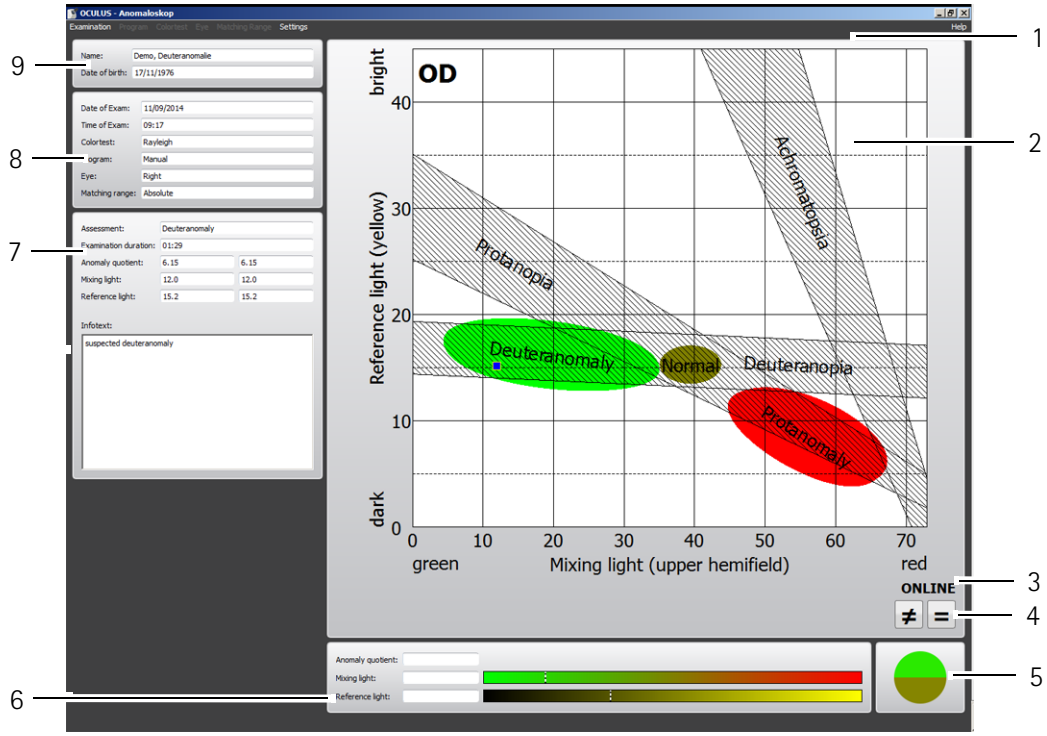


Fig. 9-1: Home screen

Example of an examination program:
Screen with Pitt diagram acc. to Rayleigh



1 *Menu bar*
2 *Pitt diagram*
3 *On or offline status indicator*
4 *Display of the "Match" and "No Match" buttons*
5 *Test field display*
6 *Display of the anomaly quotients, mixed and reference light*
7 *"Assessment" box*
8 *Information about the examination*
9 *Patient information*

Fig. 9-2: Examination menu (example)

9.2.2 Screen Elements

Patient information (9)

- Last name and first name
- Date of birth

Information about the examination (8)

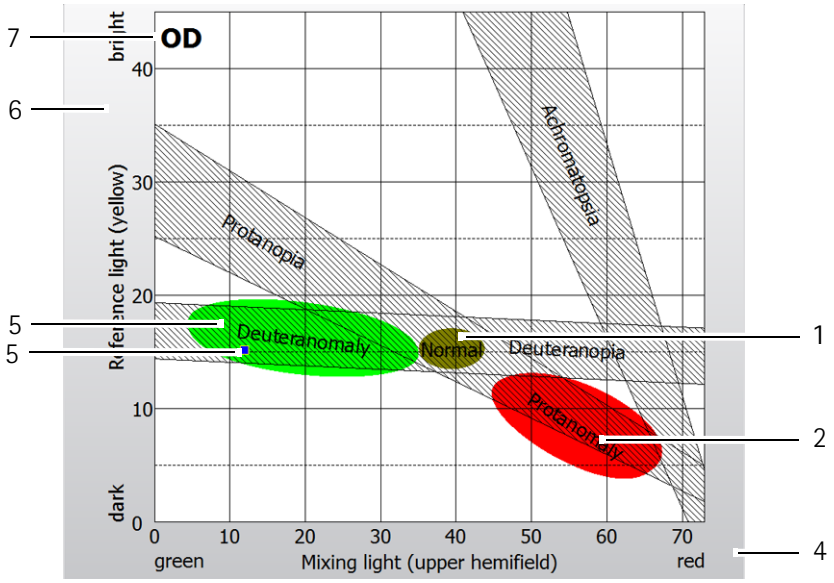
The examination parameters are shown in this field.

- Examination date
- Examination time
- Colour test used
- program used
- Eye examined
- Matching range

Diagram (2)

The presentation of the diagram *(fig. 9-2, page 27, item 2)* corresponds with the selected colour test.

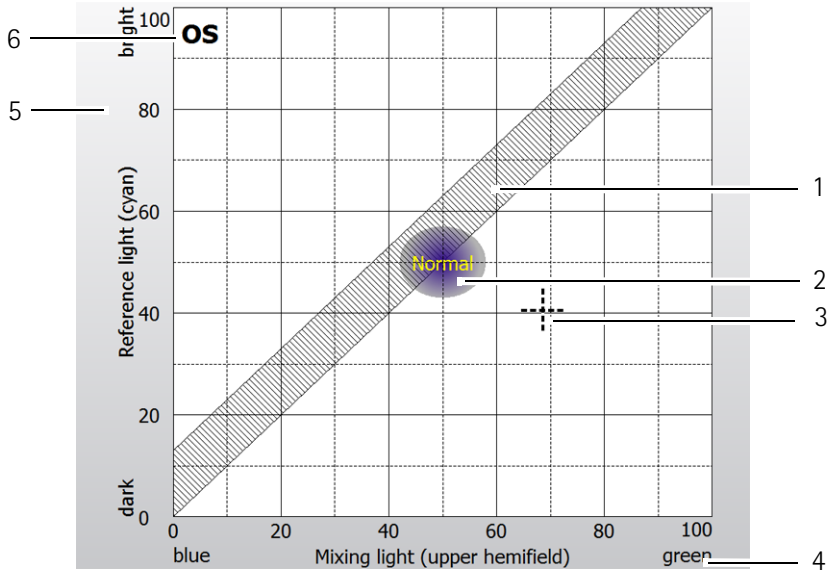
Example: Rayleigh



1 *Assessment range (here: achromatopsia)*
2 *Assessment range (here: protanomaly)*
3 *Mixed light scale from green to red (x-axis)*
4 *Position, where patient sees both test fields as matching*
5 *Assessment range (here: deuteranomaly)*
6 *Yellow reference light scale (y-axis)*
7 *Eye examined (here: right eye OD)*

Fig. 9-3: Example: Display of the Pitt diagram (Rayleigh)

Example: Moreland



1 *Assessment range*
2 *"Normal" range*
3 *Present position of the cursor*
4 *Mixed light scale from blue to green (x-axis)*
5 *Reference light scale (y-axis)*
6 *Examined eye (here: left eye OS)*

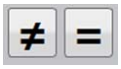
Fig. 9-4: Example: Pitt-type diagram acc. to Moreland

Depending on the program, you can move the cursor position (3) to select the display that the patient is to see, for example for the manual test.

The blue box appears at the points where the patient/examiner has pressed the „Match" button, i.e. at the examined positions that the patient perceives as being the same colour *(fig. 9-3, page 28, item 3)*.

"Match" and "No Match" buttons (4)

You can press the patient's selection here.



Test field display (5)

The approximately same colours as those seen by the patient are displayed in the top and bottom test fields.

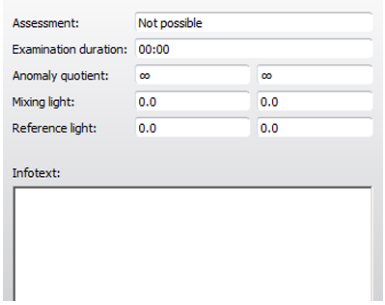
Anomaly quotients, mixed and reference light (6)

The actual anomaly quotient, mixed light and reference light values are output here in the form of numeric values and on a colour bar, *(fig. 9-2, page 27, item. 6)*.

When a Moreland examination is conducted, the tritanomaly quotient is output here.

"Assessment" box (7)

The assessment resulting from the examination and the corresponding values are shown in the "Assessment" box *(fig. 9-2, page 27, item 7)*.



Assessment:
The assessment is created automatically based on the examination results.

Mixed light and reference light:
When an examination is loaded, the two extremes of the matching range are entered.
During an examination, the last values that were saved are entered.

Infotext:
When an examination is loaded, the entered text is displayed.
You can enter an individual text here.

When an examination is active, the buttons "Start" and "End" are displayed in the "Assessment" box. To begin a new examination, press the "Start" button.

To end/stop the examination, press the "End" button.

9.2.3 Loading Previous Examinations

➔ Select the menu item [Examination] and click [Load].
The "Load examination" screen opens.

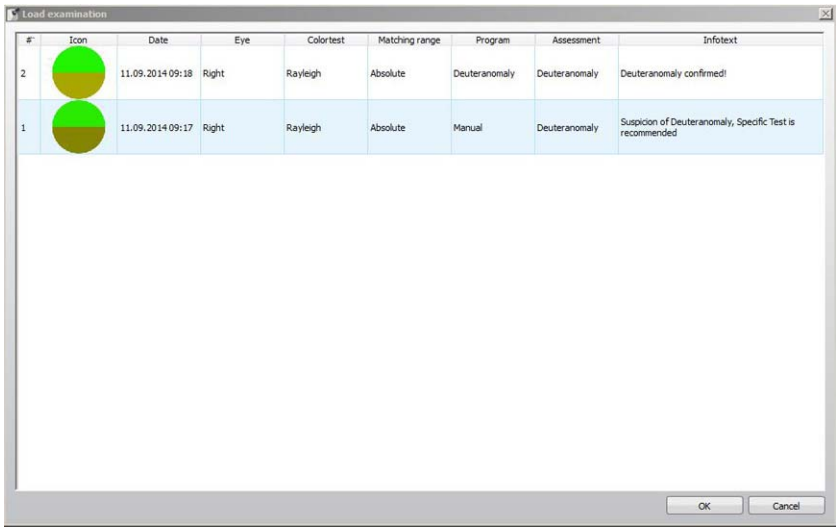


Fig. 9-5: Choose examination and load it

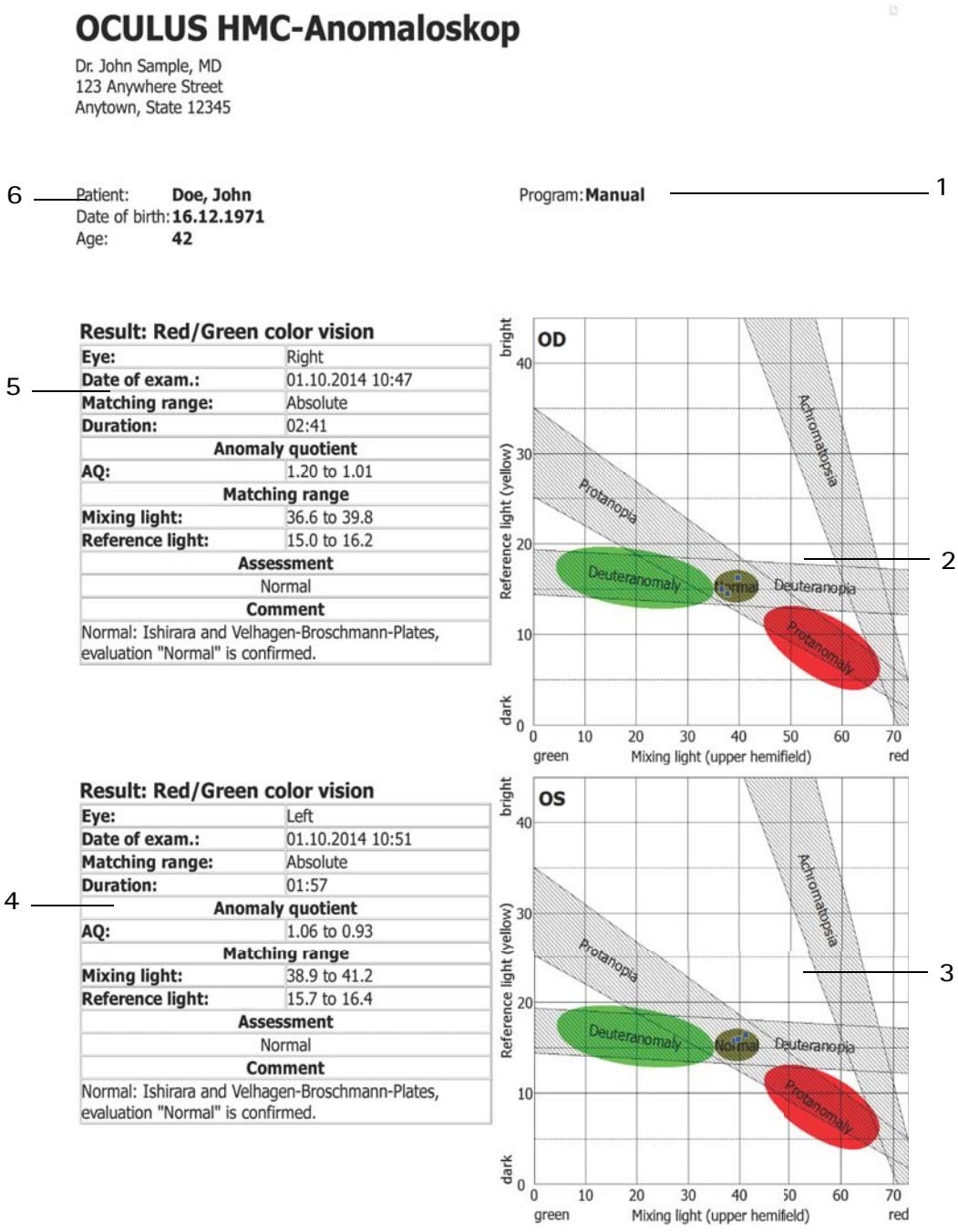
➔ Select the desired examination by clicking on it.

➔ Confirm your selection by clicking [OK], or by double clicking.
The HMC-Anomaloskop program will load the examination you have selected.

9.2.4 Print Examination Result

➔ Select the menu item Examination > Print The print preview opens.

➔ Press the printer icon button. The examination result is printed out.



OCULUS HMC-Anomaloskop

Dr. John Sample, MD
123 Anywhere Street
Anytown, State 12345

6 — Patient: **Doe, John**
Date of birth: **16.12.1971**
Age: **42**

Program: **Manual** — 1

5 — **Result: Red/Green color vision**

Eye:	Right
Date of exam.:	01.10.2014 10:47
Matching range:	Absolute
Duration:	02:41
Anomaly quotient	
AQ:	1.20 to 1.01
Matching range	
Mixing light:	36.6 to 39.8
Reference light:	15.0 to 16.2
Assessment	
Normal	
Comment	
Normal: Ishirara and Velhagen-Broschmann-Plates, evaluation "Normal" is confirmed.	

2

4 — **Result: Red/Green color vision**

Eye:	Left
Date of exam.:	01.10.2014 10:51
Matching range:	Absolute
Duration:	01:57
Anomaly quotient	
AQ:	1.06 to 0.93
Matching range	
Mixing light:	38.9 to 41.2
Reference light:	15.7 to 16.4
Assessment	
Normal	
Comment	
Normal: Ishirara and Velhagen-Broschmann-Plates, evaluation "Normal" is confirmed.	

3

1 *Selected examination program*
2 *Pitt diagram: Test result for the right eye*
3 *Pitt diagram: Test result for the left eye*
4 *Values: Test result for the left eye*
5 *Values: Test result for the right eye*
6 *Header with information about patients*

Fig. 9-6: Results printout

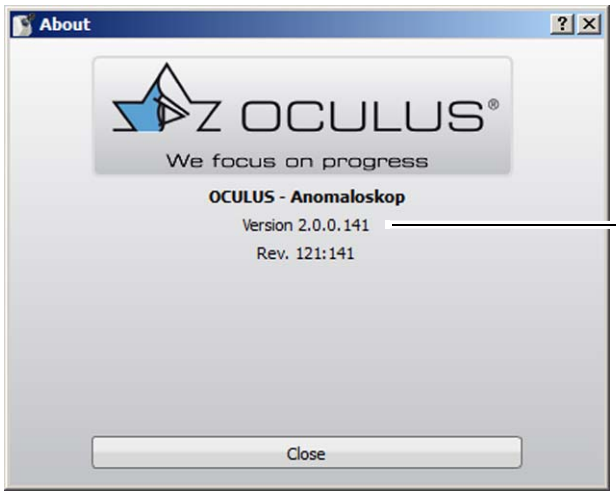
For more detailed information, for example how to display your office logo or address on the printout, refer to *sec. 9.2.6, page 33*.

➔ To return to the examination: Press the "Close" X

9.2.5 Display Help About the program

You will find information about the HMC-Anomaloskop program in the Help menu.

➔ Select the menu item [Help] and click [About...].
The following screen opens.



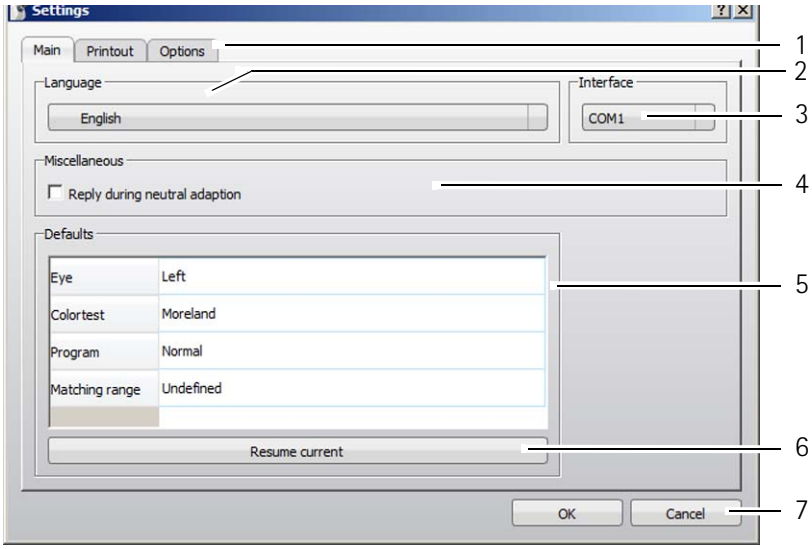
1 Version Number Example

Fig. 9-7: "OCULUS Anomaloscope" screen

9.2.6 Change Settings

You can change the default settings of the HMC-Anomaloskop program on the "Main", "Printout" or "Options" tab panels.

➔ Select the menu item [Settings] >tab panel "Main".



1 "Main", "Printout" and "Options" tab panels
2 "Language" box
3 Button for selecting the interface
4 "Miscellaneous" box
5 "Defaults" box
6 "Resume current" button
7 Buttons "OK" and "Cancel"
Fig. 9-8: "Main" tab

Change language (2)

➔ Select the language in which you want the HMC-Anomaloskop program to be displayed.

Select interface (3)

➔ Change the interface if necessary.

Allow reply during neutral adaption (4)

In the "Miscellaneous" box, you can select whether the patient is allowed to answer with "Match" or "No Match" during the neutral adaption.

➔ To allow this, activate the checkbox "Reply during neutral adaption".

Change the examination defaults (5)

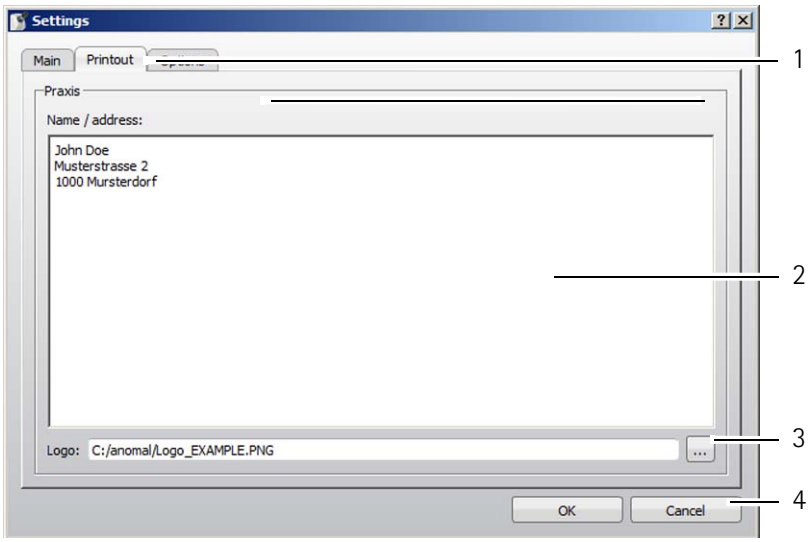
The settings for the presently active examination are shown in the list in this box. You can take over these settings for each new examination.

➔ To do so, press the button [Resume current].

Edit result printout

You can edit the result printout, for example to add your office address or your logo.

➔ Select the menu item [Settings] > "Printout" tab panel.



1 "Main", "Printout" and "Options" tab panels
2 Input field "Name/Address
3 Logo selection field
4 Buttons "OK" and "Cancel"

Fig. 9-9: "Printout" tab panel

➔ Enter the desired text in the "Name / Address" (2) input field.

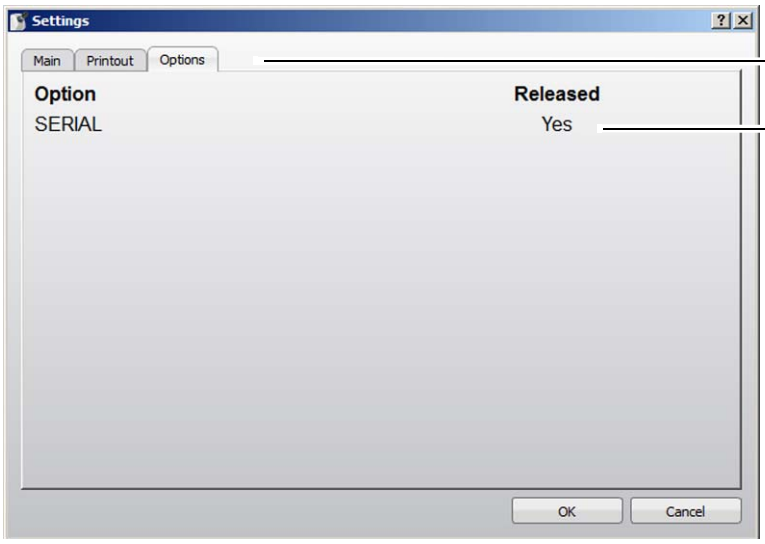
➔ Select the logo (3) that is to be shown on the printout. The following formats are possible: *.bmp, *.jpg, *.png

➔ Confirm your selections with [OK].

Display released options

You can display the released options here.

➔ Select the menu item [Settings] > "Options" tab panel.



1 "Main", "Printout" and "Options" tab panels
2 Display of the released option(s)

Fig. 9-10: "Options" tab panel

Your settings are taken over into the HMC-Anomaloskop program.

9.2.7 End program

➔ Select the menu item [Examination] and press [New patient / End]. This brings you to the Patient Data Management. Here, you can end the HMC-Anomaloskop program, or can examine a new patient.

10 Conduct the Examination

To conduct an examination:

- Start the Patient Data Management, *sec. 10.1, page 36*
- Select an examination and program, *sec. 10.3, page 40*
- Execute a selected Rayleigh program, *sec. 10.4, page 41*
- Execute a selected Moreland program, *sec. 10.5, page 48*

10.1 Start the Patient Data Management

You can enter patient data in the Patient Data Management and then use it.

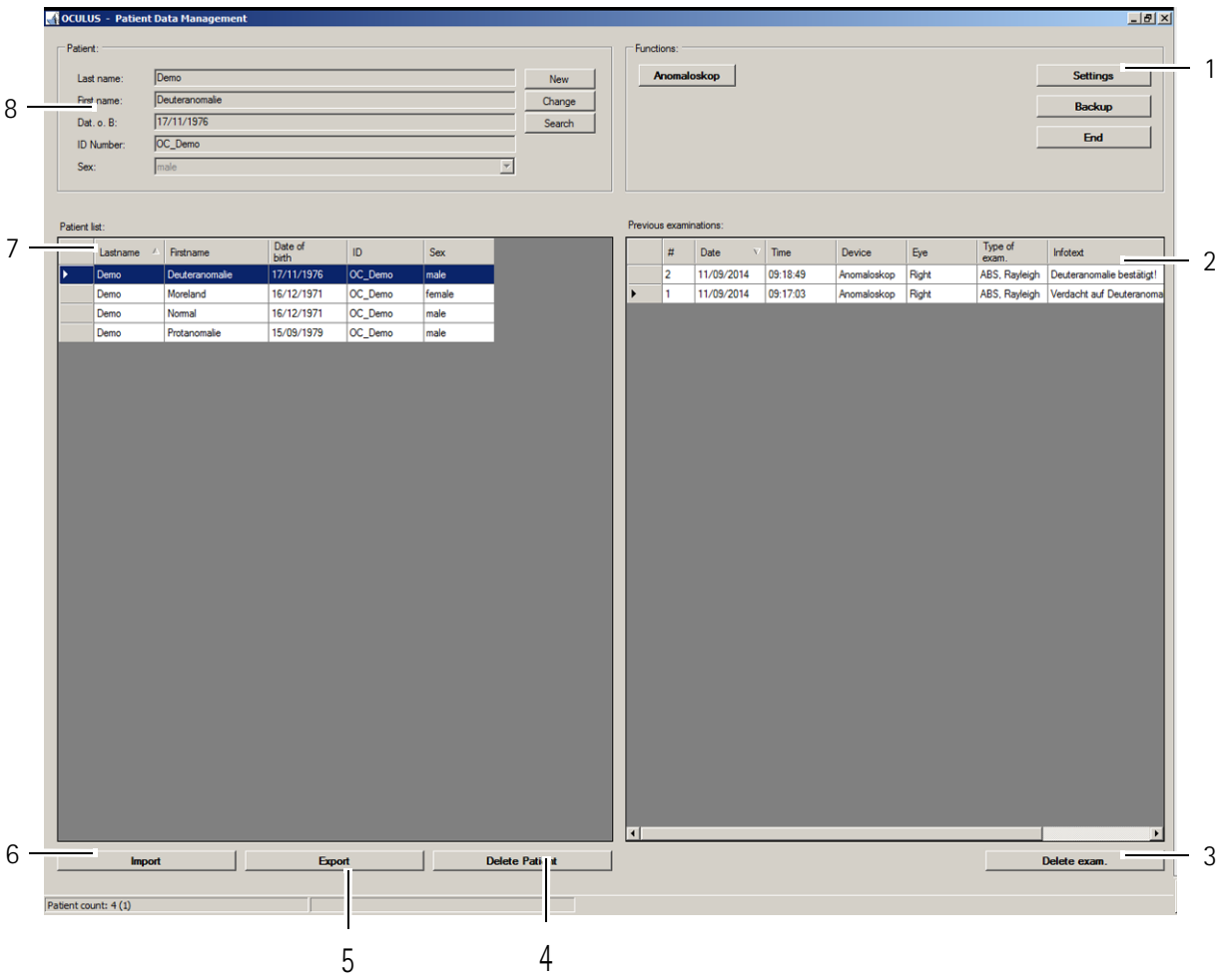
After you have switched on the computer, it first loads the operating system.

If the Windows desktop is displayed, you have to start the Patient Data Management program from there.

In the Patient Data Management, people undergoing testing are referred to as patients, as the program can also be used on other OCULUS devices.

➔ If necessary, click on the HMC-Anomaloskop icon:  .

The user interface of the Patient Data Management is displayed.



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

Fig. 10-1: User interface of the Patient Data Management

To start the HMC-Anomaloskop program, 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 *sec. 11, page 53*).

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.

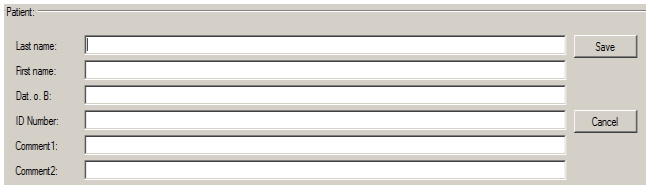


Fig. 10-2: Entering patients

Optionally you can enter an ID number for the patient.

➔ To save the data you entered, click [Save].

The patient you have just entered now appears in the patient list.

Selecting an existing patient

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

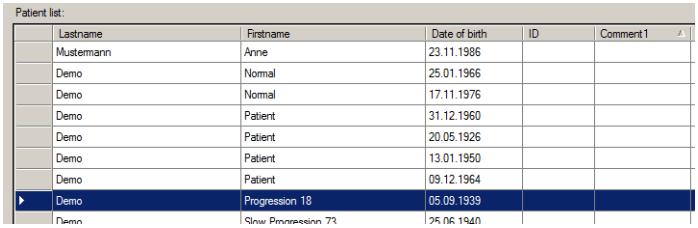


Fig. 10-3: Patient list

➔ 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.

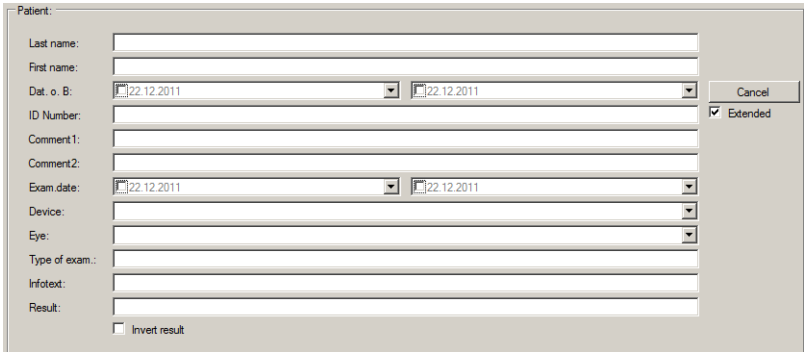


Fig. 10-4: Advanced search

➔ Enter a search parameter.
The respective patient is highlighted in the list.

➔ Press the button [End search].

➔ Proceed as for entering a patient name.

10.2 Starting the HMC-Anomaloskop program

➔ Start the HMC-Anomaloskop program, *sec. 9.2.1, page 26*.

➔ To do so, press the button [HMC-Anomaloskop].

After the automatic calibration of the HMC-Anomaloskop, the following screen appears:

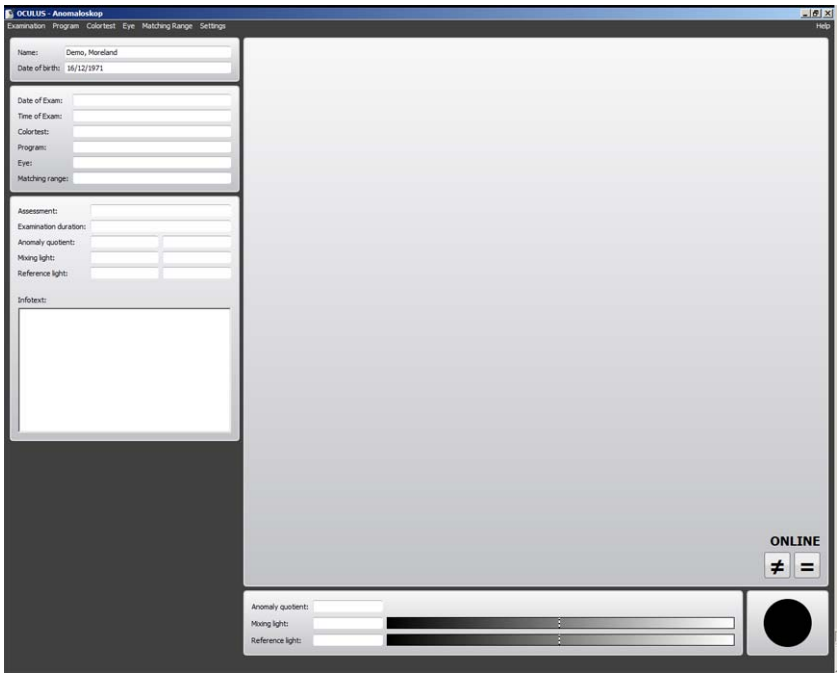


Fig. 10-5: Home screen

10.3 Select the Examination and program

Select the colour test

➔ Select the menu item [Color test] and press either [Rayleigh] or [Moreland].

You will find more information about the Rayleigh colour test in *sec. 10.4, page 41*

You will find more information about the Moreland colour test in *sec. 10.5, page 48*

Select program

➔ Select the menu item [Program] and click on the desired program:

When the colour test "Rayleigh" is selected:

- Fast Screening
- Manual
- Specific

When the colour test "Moreland" is selected:

- Manual
- Specific

Select eye

➔ Select the menu item [Eye] and press either [Right] or [Left].

Set the matching range and neutral adaption

➔ Select the menu item [Matching range] and press either [Absolute] or [Relative].

For more information, see *sec. 6.2, page 12*.

➔ Set a checkmark in front of [Neutral adaption off] if you don't want a white adaption field to be displayed between the displayed test fields.

See *sec. 6.2, page 12* for more information.

10.4 Execute the Rayleigh program

With the HMC-Anomaloskop R, you can use the following Rayleigh test programs

- Rayleigh screening test, *sec. 10.4.1, page 41*
- Rayleigh manual test, *sec. 10.4.2, page 43*
- Rayleigh specific tests, *sec. 10.4.3, page 46*

To select a program, proceed as follows:

➔ Select the menu item [Examination] and press [New].

➔ Select the menu item [Color test] and then press [Rayleigh].

10.4.1 Select and Conduct the Fast Screening Test

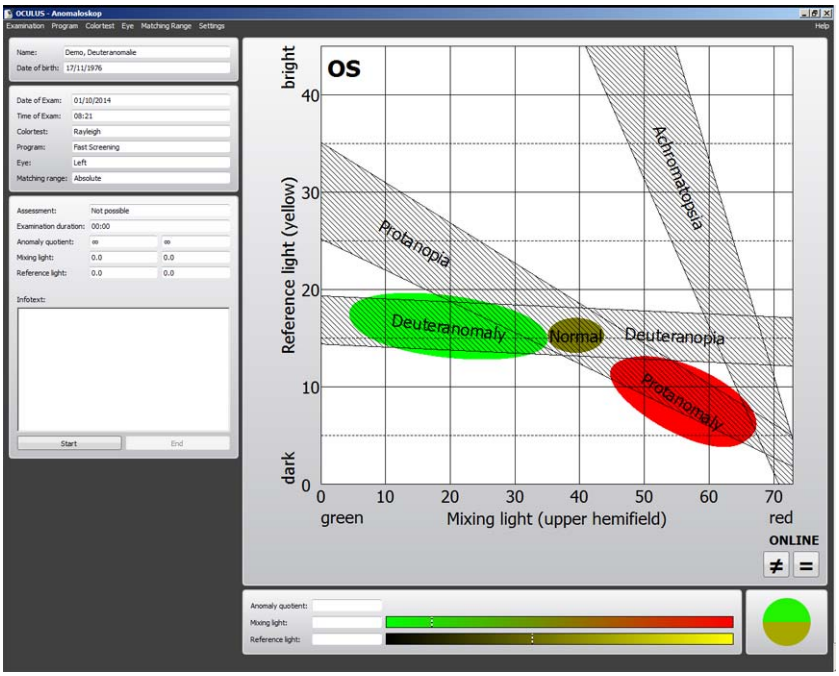


Fig. 10-6: Rayleigh screening test (protan/deuteran)

Function

You can use this examination program with the Rayleigh equation as a preliminary screening test.

Operation

➔ Colour test > Rayleigh

➔ Program > Fast Screening

➔ Matching range > Absolute

➔ Press the [Start] button.

➔ Have the patient turn the "mixed light" knob until he sees both fields as being the same.

➔ Then have the patient press the “Match“ button. A blue marking is placed at the appropriate point.

➔ Press the button [End] to end the test.

At the end of the programme, the determined assessment is displayed in the “Assessment“ box.

Information

A colour equation is presented to the patient. He must evaluate it subjectively. Depending on what has been pre-set, the coloured test field is presented for either five seconds (absolute matching range) or fifteen seconds (relative matching range) with a three-second neutral adaption between each presentation.

In the screening test, 84 different colour equations are presented to the patient, beginning with the point 0/17. The patient can select these colour equations by turning the “mixed light” knob.

When he presses the “Match“ button, a blue marking is placed at the appropriate point.

If the patient sets multiple markings, which cannot be clearly assigned to any specific colour vision deficiency, „Not possible“ appears in the [Assessment] box. If the patient sets multiple points in the "Deuteranomaly" range, then „Deuteranomaly“ appears in the [Assessment] box.

If the patient sets multiple markings, the message “Not possible“ is displayed in the [Assessment] box.

If he presses the “No match“ button during the test, it has no effect.

The screening test must be ended by pressing the button [End].

Recommendation: If more detailed information is needed, such as for example anomaly quotients and matching ranges, conduct either the manual *(sec. 10.4.2, page 43)* or a specific test.

10.4.2 Select and Conduct the Rayleigh Manual Test

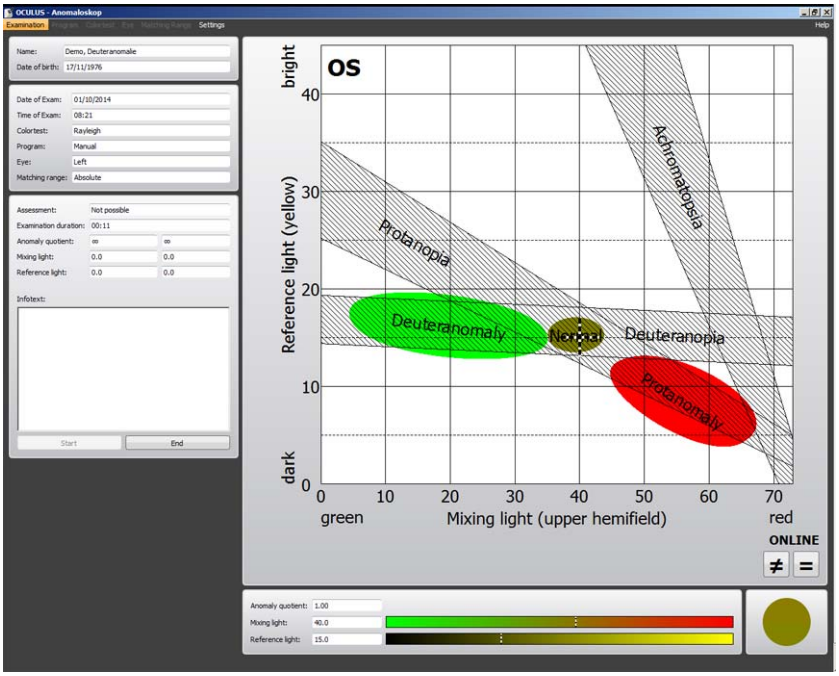


Fig. 10-7: Rayleigh manual test

Function

If the Fast Screening test, or any other preliminary test (for example Ishihara colour charts) indicates that a colour vision deficiency is present, you can determine the patient's individual matching range with this program.

Operation

More information about the strategy can be found on *page 45*.

- ➔ Colour test > Rayleigh
- ➔ Program > Manual
- ➔ Matching range > Absolute
- ➔ Press the [Start] button.

You have narrowed down the examination area with the screening test. Start the examination at the outer threshold. Present alternating colour equations from each end. Proceed from the outside to the inside to determine the patient's individual matching range.

If a screening test is not performed, the examination begins with the mean normal equation (i.e. normal mid-match) (40/15).

- ➔ Present a different colour equation.
- ➔ Move to the according position of the Pitt diagramm.

➔ Have the patient compare the top and bottom test fields. Ask the following questions:
- "What colour(s) do you see?"
- "Where is it brighter? Top? Bottom?
- "Which is redder (more orange)? Top? Bottom?" or "Where is more green? Top? Bottom?"

➔ Present a different colour equation. Proceed in increments of 10 on the scale (check scan).

➔ When the patient perceives a near colour match, switch over to the fine scan.

This switch-over point depends on the patient's colour vision deficiency.

➔ Proceed in increments of 1 on the scale (fine scan).

➔ Have the patient compare the top and bottom test fields.

When the patient sees a colour match, he must press the "Match" button. This setting is not subsequently changed by the program.

You can cancel this setting by deleting the blue marking in the Pitt diagram. To do this, move the cursor to the blue marking. Click on the right mouse button and then select "Delete".

If the patient has trouble operating the device, you can press the buttons "Match" and "No Match" for him on the screen.

You can stop the program at any time. Bear in mind that a matching range can only be determined after at least two successful matches by the patient.

➔ Repeat the examination for the other eye.

Result

At the end of the program, the determined assessment is displayed in the "Assessment" box.

Information

Aim

The aim of the test is to match both test fields so that the patient sees them as having the same colour and brightness.

Strategy

The examiner selects the colour equations by clicking with the mouse pointer in the Pitt Diagram and asks the patient for his colour perception.

Prior to conducting this test, you have already conducted a screening test to determine the patient's range (normal, deuteranomaly or protanomaly range).

The examiner then presents colour equations that lie at the thresholds of these ranges. When a colour match is determined, the matching range is narrowed down even more by means of a check scan conducted in scale increments of ten. When the patient perceives the colours as almost matching, a fine scan is then conducted in single scale increments until a colour match is reached from both ends. Either the patient or the examiner presses the "Match" button to mark this point.

Examine both eyes. Even congenital deficiencies can exhibit differences in each eye. Considerable differences, however, indicate an acquired colour vision deficiency. For information purposes: Even acquired colour vision deficiencies can affect both eyes. Further testing is therefore recommended for clarification purposes.

More information about the strategy for the examinations can be found in the *User Guide*.

10.4.3 Select and Conduct a Specific Rayleigh Test

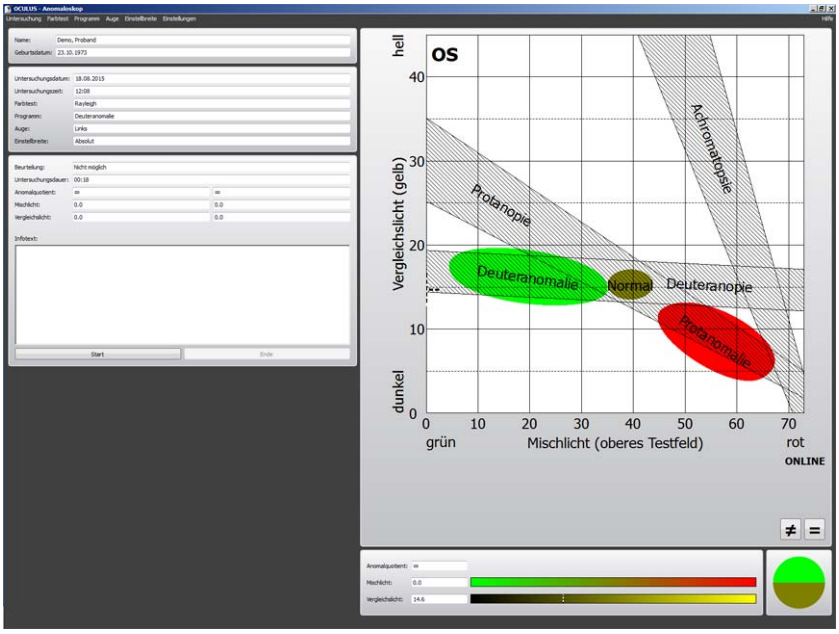


Fig. 10-8: Specific Rayleigh test (for deuteranomaly)

Function

Use this program if a colour vision deficiency is known or suspected. This program runs automatically.

Operation

- ➔ Colour test > Rayleigh
- ➔ Program > Specific
- ➔ Matching range > Absolute
- ➔ Select a specific test.

  How to conduct the test is shown using deuteranomaly as an example.
- ➔ Press the [Start] button.
- ➔ Have the patient compare the top and bottom test fields.
- ➔ Have the patient adjust the brightness with the “Reference light” knob.
- ➔ Then have the patient press either the “Match” or “No Match” button.

  The program runs automatically, you do not need to make any other entries or selections. At the end of the program, the determined assessment is displayed in the “Assessment” box.

Information

- Deuteranomaly
- Protanomaly
- Deuteranopia
- Protanopia
- Normal

For the specific tests, the program selects a matching range that lies beyond the limit of the colour vision defect in question (or of the normal range).

The patient can:

- Evaluate the brightness of the reference field
- Adjust the brightness with the bottom knob
- Determine whether the colours in the two test fields match or not. To do this, he has to press either the “Match” or the “No match” button.

The patient evaluates the brightness of the reference field. After the evaluation (match or no match), the program springs to the opposite limit of the colour vision defect in question (or of the normal range).

The program thus precisely narrows down the specific threshold equations, using large steps at the beginning. These increments become steadily smaller during the course of the examination.

As the increments at the end are so small that the colour displayed in the test field changes only minimally, the patient often does not notice this change at all and reports that the mixed light remains the same. Make sure that the patient completes the test, as the displayed colours only appear to stay the same, and it is the last settings that give the most accurate results.

10.5 Execute Moreland programs

With the HMC-Anomaloskop MR, in addition to the Rayleigh programs, you can also use the following Moreland programs:

- Manual Moreland test, *sec. 10.5.1, page 48*
- Specific Moreland test, *sec. 10.5.2, page 51*

To execute a program, proceed as follows:

➔ Check whether the 4° add-on optics has been mounted.
➔ Select the menu item [Examination] and press [New].
➔ Select the menu item [Color test] and press [Moreland].

10.5.1 Select and Execute the Manual Moreland Test

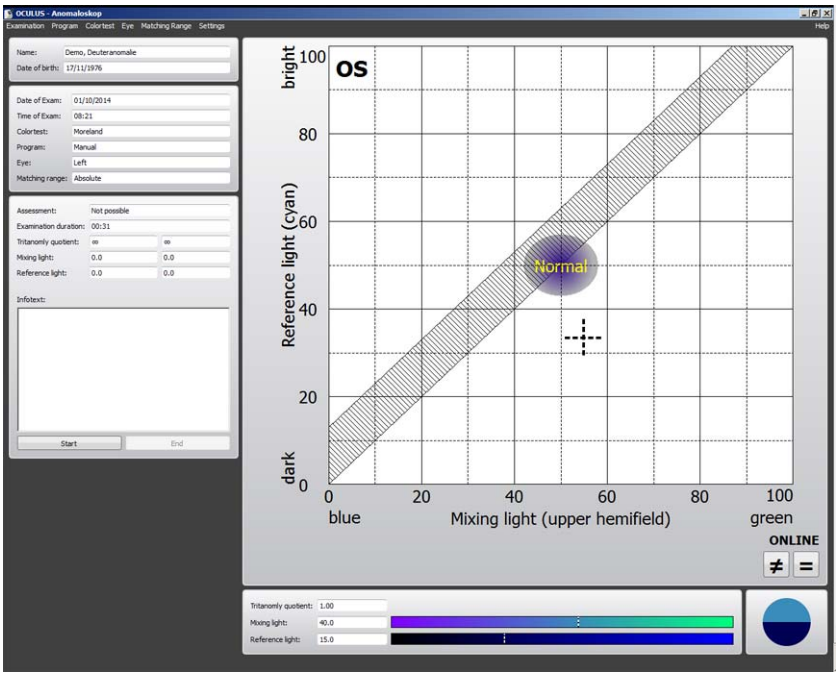


Fig. 10-9: Manual Moreland test

Function

With this program, you can determine the patient's individual matching range.

Operation

➔ Colour test > Moreland
➔ Program > Manual
➔ Matching range > Absolute
➔ Press the [Start] button.

Make sure that the patient sees the bisecting line clearly. Alternately present colour equations from each end. Start from the outside and work inwards to determine the patient's individual matching range.

- ➔ Present a colour equation by moving the cursor to the respective position in the Moreland coordinate system.
- ➔ Have the patient compare the top and bottom test fields. Ask the following questions:
  - "Where is it brighter? Top? Bottom?"
  - "Which is bluer (more green)? Top? Bottom?"
- ➔ Present a different colour equation. Proceed in increments of 20 on the scale (check scan).
- ➔ When the patient perceives a near colour match, switch over to the fine scan.

  This switch-over point depends on the patient's colour vision deficiency.
- ➔ Proceed in increments of 2 on the scale (fine scan).
- ➔ Have the patient compare the top and bottom test fields.
- ➔ When the patient sees a colour match, he must press the "Match" button. This setting is not subsequently changed by the program.

If the patient has trouble operating the device, you can press the buttons "Match" and "No Match" for him on the screen.

You can stop the program at any time. Bear in mind that a matching range can only be determined after at least two successful matches by the patient.

- ➔ Repeat the examination for the other eye.

Result

After the program has ended, the determined assessment is displayed.

Information

Check Scan:
Start at 100/90 and move in scale increments of 20 towards 50/50 and 0/15 towards 50/50 until the patient's perception changes from "greenish at the top" to "blue at the top": The equation and matching range positions are recorded in a first approximation.

Fine scan:

Conduct a fine scan of the last “greenish at the top” and adjust in steps of 2 scale increments until the first “blue at the top” is perceived.

The aim of the test is to match both test fields so that the patient sees them as having the same colour and brightness.

More information about the strategy for the examinations can be found in the *User Guide*.

10.5.2 Select and Conduct a Specific Moreland Test

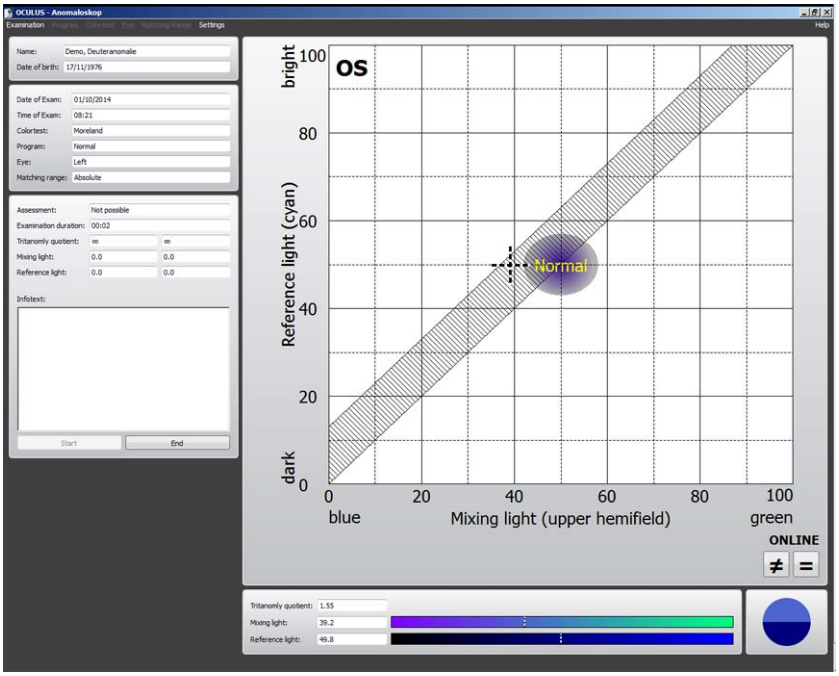


Fig. 10-10: Specific Moreland test

Function

Use this program when a precise colour vision deficiency is known. This program runs automatically.

Operation

- ➔ Matching range > Absolute
- ➔ Colour test > Moreland
- ➔ Program > Specific > Normal
- ➔ Press the [Start] button.
  This program begins with the colour equation (39/50).
- ➔ Have the patient compare the top and bottom test fields.
- ➔ Have the patient adjust the brightness with the “Reference light” knob.
- ➔ Then have the patient press either the “Match” or “No Match” button.

At the end of the program, the determined assessment is displayed in the “Assessment” box.

Information

The patient can:

- Evaluate the brightness of the reference field
- Adjust the brightness with the bottom knob
- Determine whether the colours in the two test fields match or not. To do this, he has to press either the „Match" or the „No match" button.

After the evaluation (match or no match), the program springs to the opposite limit of the colour vision defect in question (or of the normal range).

The program thus precisely narrows down the specific threshold equations, using large steps at the beginning. These increments become steadily smaller during the course of the examination.

As the increments at the end are so small that the colour displayed in the test field changes only minimally, the patient often does not notice this change at all and reports that the mixed light remains the same. Make sure that the patient completes the test, as the displayed colours only appear to stay the same, and it is the last settings that give the most accurate results.

10.6 Finishing the Exam

➔ Press the button [End] to end the examination.

Specific examination programs normally come to an end automatically.

You are then returned to the HMC-Anomaloskop main menu. You can now

- Start a new examination: Examination > New
- Change patients: Examination > New patient / End
- End the HMC-Anomaloskop program: Examination > New patient / End0

  The Patient Data Management screen is displayed. Press the button [End].

➔ Clean and disinfect the eyepiece after each exam, *sec. 12.2, page 71*.

11 Managing Patient Data

Once you have completed an examination you can do the following with the patient data:

- Rename it, *sec. 11.1, page 53*
- Export it, *sec. 11.2, page 53*
- Import it, *sec. 11.3, page 55*
- Save it, *sec. 11.4, page 56*

You can also edit the settings for the Patient Data Management, *sec. 11.5, page 59*.

In the Patient Data Management, people undergoing testing are referred to as patients, as the program can also be used on other OCULUS devices.

11.1 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.

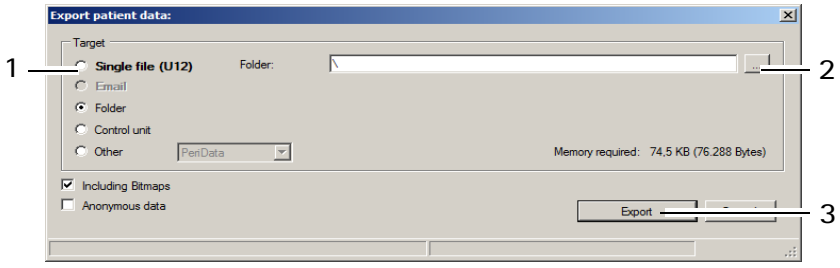
➔ Press the [Save] button.

11.2 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 as needed.

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



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

Fig. 11-1: "Export patient data" dialog

The default options for import and export of data are configured in the "Settings" field. See also *sec. 11.5, page 59*.

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 to.

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 [Open].
➔ To export the data, press the [Export] button (3).

11.3 Importing Patient Data

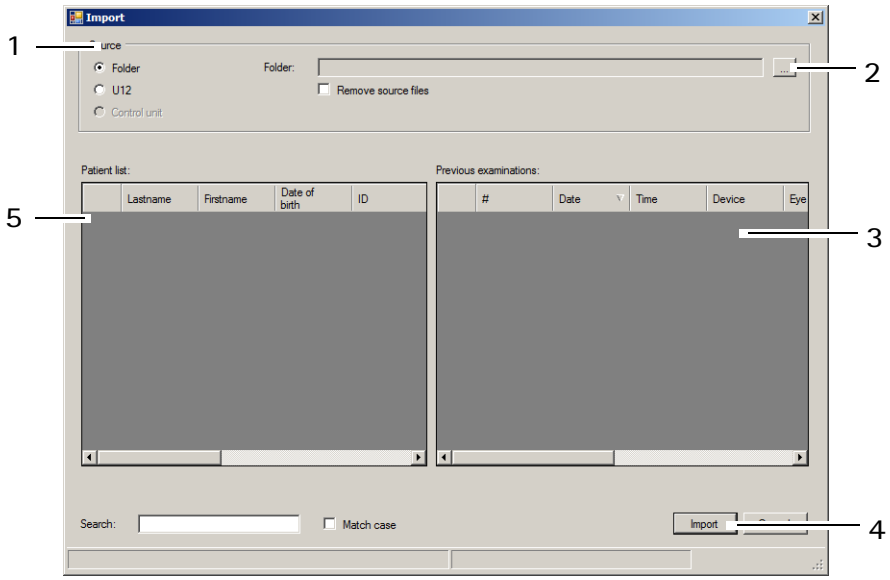
If you receive patient data, for example, on a USB stick, you can import these data.

Note

Loss of data due to computer viruses

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

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



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

Fig. 11-2: Function "Import"

The default options for import and export of data are configured in the "Settings" field. See also *sec. 11.5, page 59*.

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

➔ Select the option (1) where the source data are contained ("Folder" or "U12" (single file)").

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

➔ Press the [...] button (2).

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

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

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

➔ To import the data, press the [Import] button (4).

The data is then available in the user interface for "Patient Data Management".

11.4 Data Backup

You should make a backup copy of patient and examination data at regular intervals. In case of 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 PC and the device will not be needed.

Note

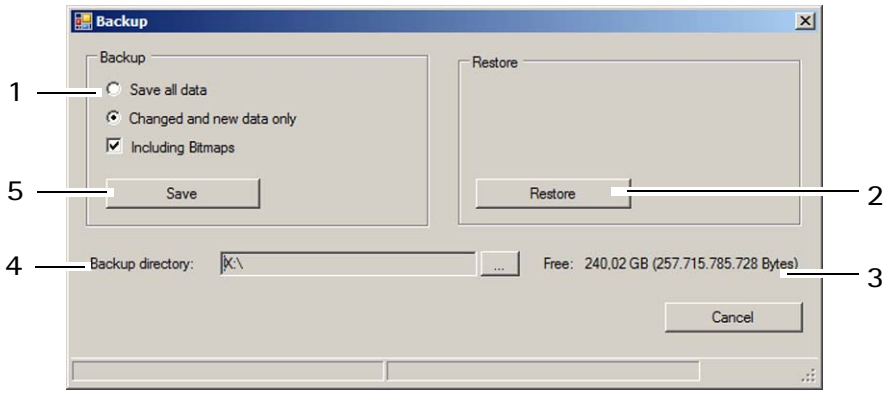
Loss of data due to computer viruses

➔ Before you start the backup, make sure that the data storage medium that you are using is free of viruses.

The general rules for the creation of backup copies apply to backing up data 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).

11.4.1 Backup Data

➔ In the upper right part of the Patient Data Management user interface, press the [Backup] button. The following dialogue appears:



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

Fig. 11-3: "Backup" dialog

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

The Patient Data Management user interface internally selects all backed up datasets.

If you select 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 (4).
➔ 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 (5). The previously selected data will then be backed up to the corresponding folder.

11.4.2 Reconstructing Data

If a loss of data occurs, the data from a previous backup can be imported again into the Patient Data Management user interface.

➔ Press the [...] button.

➔ 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 corresponding folder will be transferred to the Patient Data Management user interface.

11.4.3 Automatic Backup

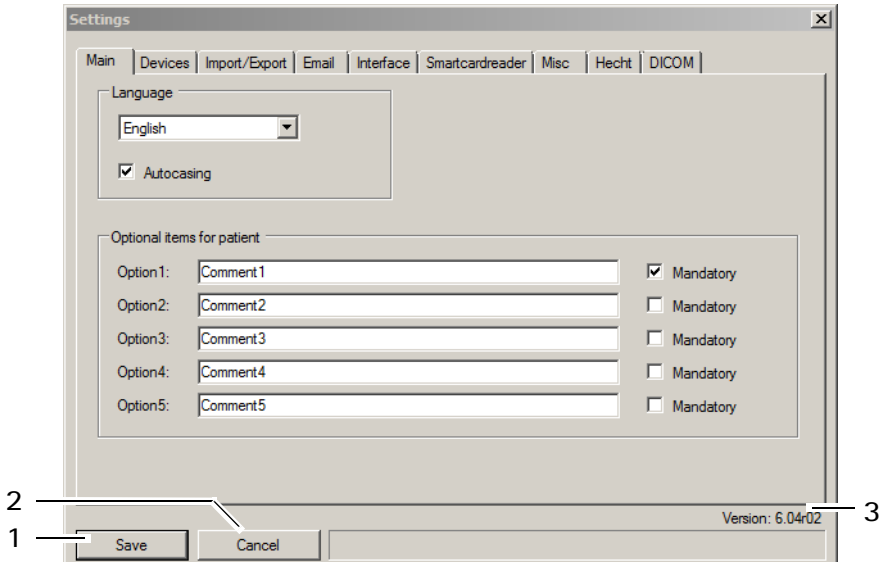
Besides the manually executed backup, there is also the option to carry out a backup when the Patient Data Management user interface is closed. The settings required for this can be made in the "Settings" field, see *sec. 11.5.3, page 64*.

11.5 Change Settings

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

➔ In the upper right part of the Patient Data Management user interface, press the [Settings] button.

The "Settings" screen is displayed. The "Main" tab panel appears in the foreground.



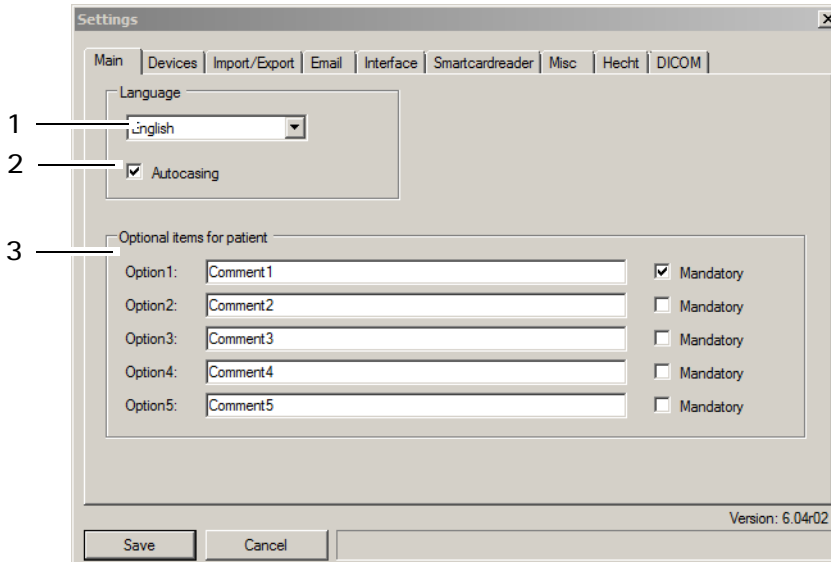
1 [Save] button
2 [Cancel] button
3 Patient Data Management program version

Fig. 11-4: "Settings" screen

The following information and buttons are available to you on the tab panels of this screen:

- The program version of the Patient Data Management user interface is shown at the bottom right (3).
- There are two buttons at the bottom left for saving (1) or discarding (2) the changes that have been made. **All** changes are saved or discarded, and then the page is closed.

11.5.1 "Main" Tab



1 "Language selection" dropdown list
2 [Autocasing] checkbox
3 Optional patient entries
Fig. 11-5: "Settings" screen, "Main" Tab

"Language" group box

➔ In the "Language" dropdown list (1), select the language that is to be displayed on the Patient Data Management user interface.

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

"Optional items for patient" group box (3)

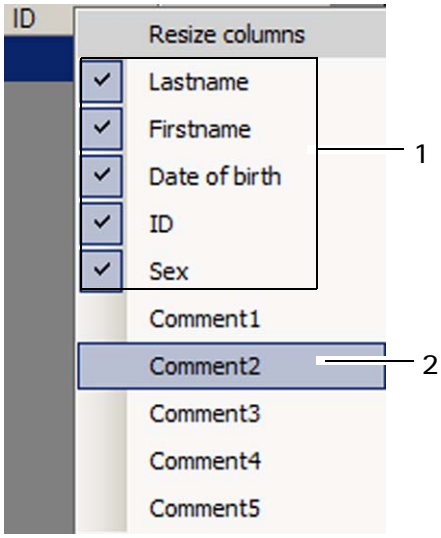
Besides the five standard attributes of first name, last name, date of birth, gender, and ID, up to five additional attributes can be freely defined.

➔ Enter the identifier for the attribute in one of the boxes option 1 to option 5, for instance "Comment".

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

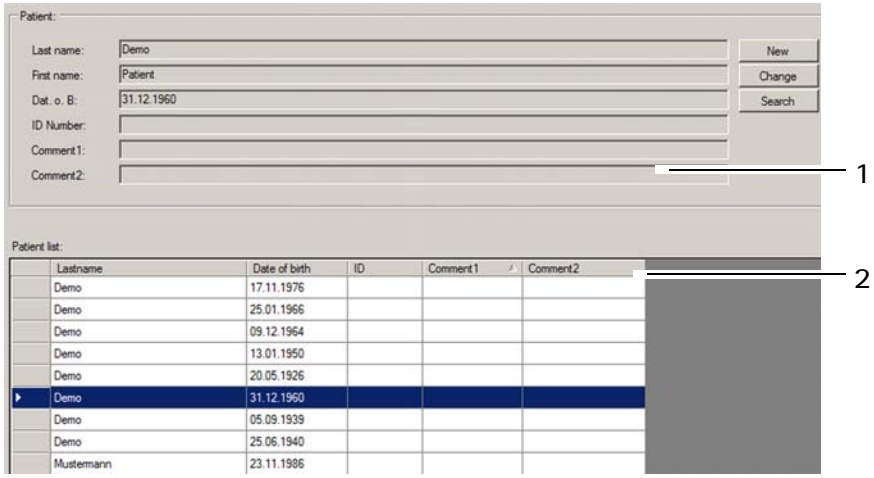
➔ Click with the right mouse button on the patient list and open the associated context menu.

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



1 Already active attributes
2 New attribute selected
Fig. 11-6: Activate new attribute

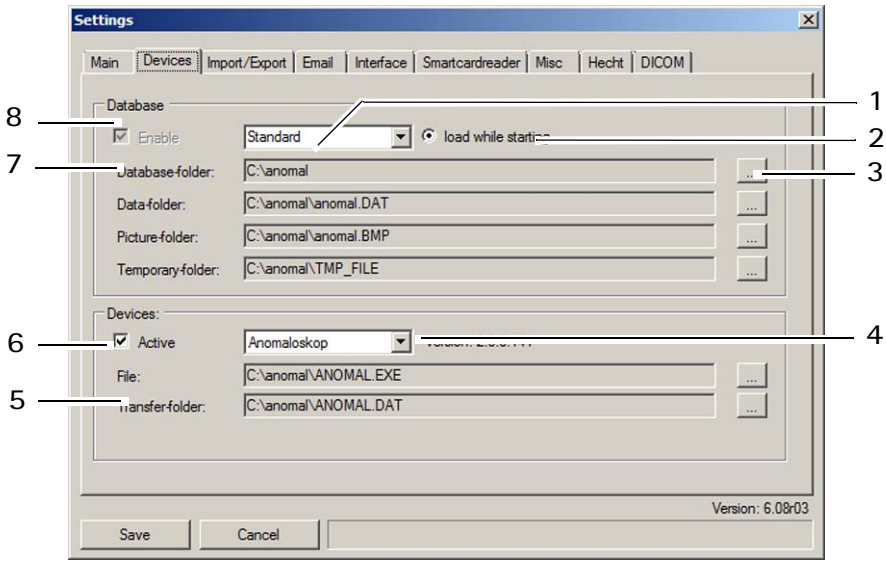
The context menu will close, and the attribute "Comment2" will also be displayed in the upper part of the input boxes for patients (1) as well as in the patient list (2).



1 Attribute "Comment2" as an input field
2 Attribute "Comment2" in the patient list
Fig. 11-7: User-defined attribute "Comment"

Selection of attributes is done in the same way in the context menu. The currently selected attributes are marked with a tick.

11.5.2 "Devices" Tab



1 *Dropdown list for selecting a database*
2 *Radio button "Load while starting"*
3 *Folder selection*
4 *Dropdown 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*

Fig. 11-8: "Devices" tab

"Database" group box

Different users can be set up for different databases.

➔ In the dropdown 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 via the individual buttons for folder selection (3).

Normally, two different folders are created and displayed for data and images during installation (8).

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

➔ For each user, activate whether the associated database should be actively switched on or not (8).

In case more than one database is active, an additional dropdown list appears on the main screen of the Patient Data Management user interface. You can activate 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 activate the option "load while starting" (2) for just one user. The associated database will then normally be loaded when the Patient Data Management user interface is started and is pre-selected.

"Devices" group box

Settings for connected devices can be carried out in the group box.

➔ In the dropdown list, select the desired device (4).

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

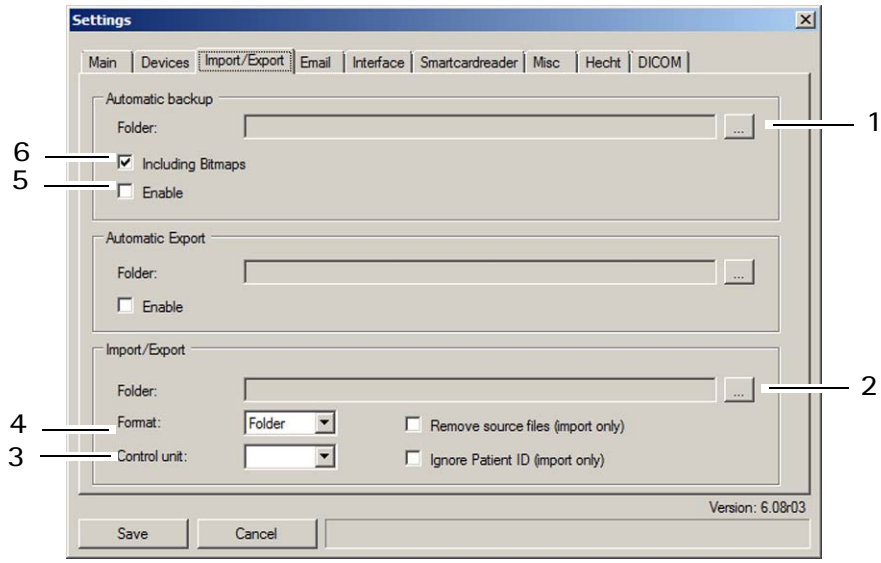
➔ Choose the path to the associated device's application file via the folder selection button.

To save patient and examination data in the database, this will initially be created in the so-called "Transfer folder". This folder is always created locally on the PC.

➔ Choose the transfer folder via the folder selection button. It should consist of the name of the device plus the file extension.DAT.

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

11.5.3 "Import/Export" Tab



1 Automatic backup folder

2 Select import/export folder

3 Interface for control unit

4 Standard format for import and export

5 [Enable] checkbox

6 [Include bitmaps] checkbox

Fig. 11-9: "Import/Export" tab

"Automatic backup" group box

Besides the manually executed backup *(sec. 11.4, page 56)*, there is also the option to carry out a backup when the Patient Data Management user interface is closed. The settings required for this can be specified in the group box.

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

➔ Selected the checkbox [Including Bitmaps] (6) if the camera images should also be backed up.

➔ Activate the checkbox [Enable] (5), if the automatic backup should be executed with the specified settings.

"Import/Export" group box

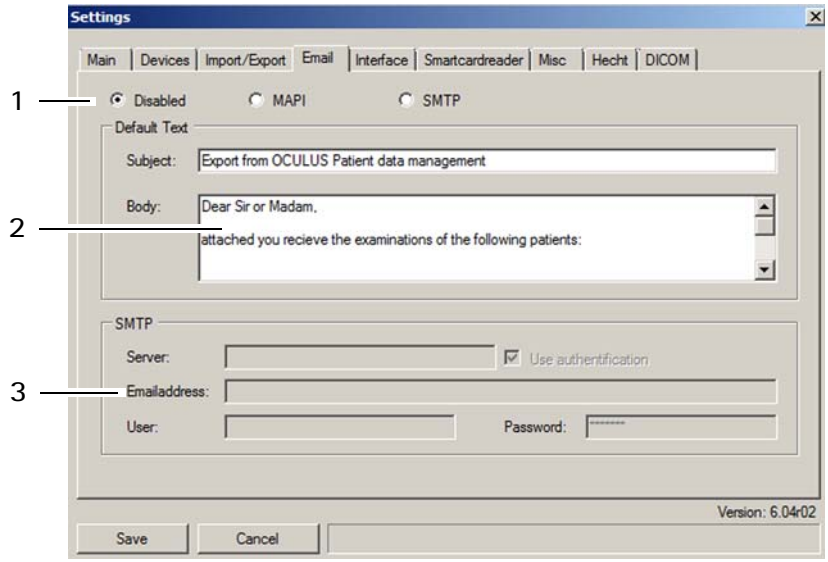
You can enter settings in this group box for import and export of Patient Data Management user interface data.

Note

The settings specified in this tab for import and export of data can be overwritten. Only typical settings are entered here.

- ➔ Select the folder via the folder selection button (1) which should be pre-selected as the standard for import or export.
- ➔ In the "Format" dropdown list (4), select whether import or export should normally occur in one folder or in a single file (U12).

11.5.4 "Email" Tab



1 Selection of the Email connection
2 Standard text for subject and body text
3 Settings for SMTP connection

Fig. 11-10: "Email" tab

With the three radio buttons in the top section of the tab panel (1), you determined whether the Email connection is activated and if so, how the data transfer is to take place.

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

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

"Default text" group box

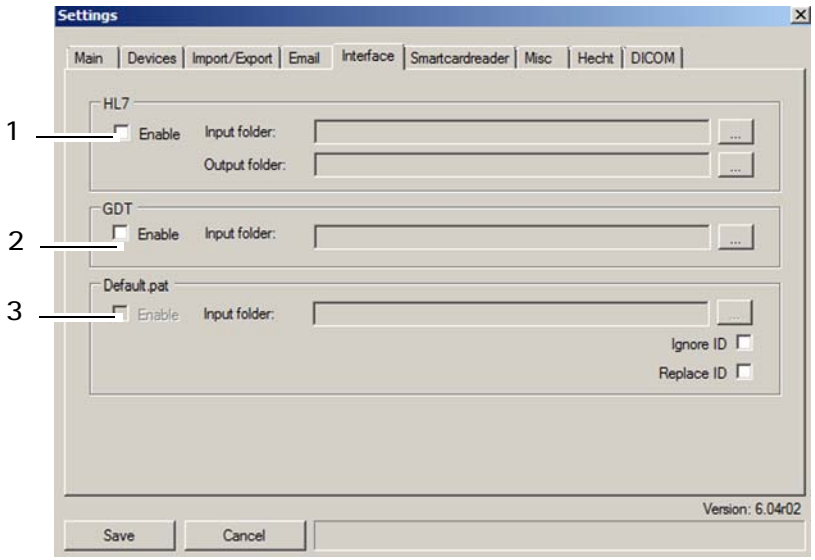
➔ Enter the text in the "Subject" and "Body" (2) boxes which should normally be pre-entered when email is sent. You can edit this text before the email is actually sent (for example specific to patients or examinations).

"SMTP" group box

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

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

11.5.5 "Interface" Tab



1 Settings for HL7
2 Settings for GDT
3 Settings for Default.pat

Fig. 11-11: "Interface" tab

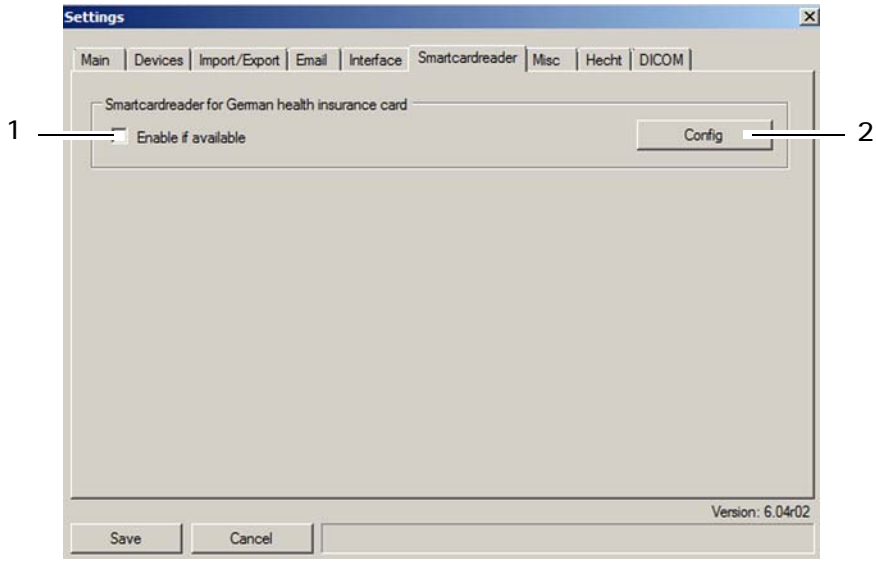
Use this tab to enter the folder for different interface types and to activate or deactivate them.

The interface "Default.pat" (3) is used if the Patient Data Management user interface is launched by a third-party program.

➔ Place the interface "Default.pat" into the third-party program's folder.

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

11.5.6 "Smartcardreader" Tab



1 [Config] button *2 [Active] checkbox*

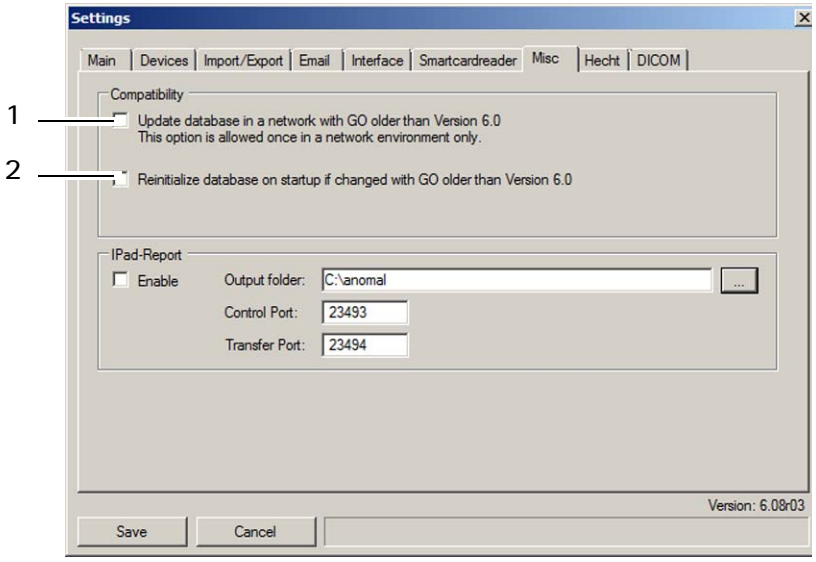
Fig. 11-12: "Smartcardreader" tab

You can configure a smartcard reader on this tab panel so that you can directly import patient data via 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 screen appears for you to select the type of smartcard reader you are using.

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

11.5.7 "Misc" Tab



1 Checkbox for managing a database *2 Checkbox for initialising a database*

Fig. 11-13: "Misc" tab

Patient data management is implemented 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 the higher technical requirements of the new version V6.x cannot be circumvented, then the corresponding settings must be specified on this tab.

- ➔ Activate the checkbox on this tab (1) on **just one PC** with an installed V6.x version.
- ➔ Make sure that this checkbox is **not** active on any other PC which has version V6.x of the Patient Data Management user interface installed.
- ➔ Activate the checkbox (2) if the data from the database are to be re-initialised during the next start-up.

This ensures that the database is automatically adjusted if another PC with the older Patient Data Management V2.x is installed.

The "IPad-Report" box presently has no function.

11.5.8 "Hecht" and "DICOM" Tab Panels

The "Hecht" and "Dicom" tab panels presently have no function.

12 Cleaning, Disinfection and Maintenance

➔ This chapter describes how to clean and disinfect the HMC-Anomaloskop, and how to replace the forehead rest and the fuses.

Note

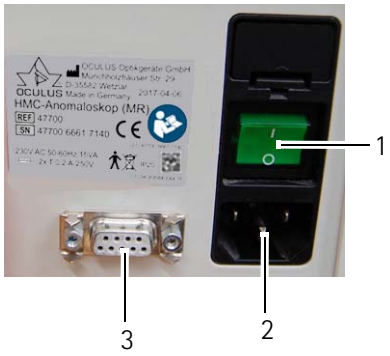
To ensure satisfactory and reliable operation, we recommend that you have the HMC-Anomaloskop checked every two years by our service department or an authorised dealer. If an error occurs which you are unable to correct, label the HMC-Anomaloskop as "out of order" and contact our service department or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

➔ 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 HMC-Anomaloskop with aggressive, chlorinated, abrasive or sharp cleaning agents.

12.1 Unplug the Equipment

➔ Turn off the unit at the On/Off (1) switch.



1 On/Off switch
2 Mains connection
3 Plug for the computer/laptop
Fig. 12-1: HMC-Anomaloskop connection

➔ Unplug the power cable from the socket (2).

➔ Disconnect the connecting cable to the computer/laptop by pulling the plug out of the socket (3).

12.2 Cleaning

Attention

Risk of electric shock if the HMC-Anomaloskop is not completely disconnected from the mains for these jobs.

➔ Turn the HMC-Anomaloskop off, *sec. 7.5, page 22*.

➔ Pull the power plug before cleaning. When disconnecting electrical

➔ connections, pull on the respective plug and not on the cable itself.

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

➔ Clean the headrest after every examination and the housing once a month, or whenever necessary.

Proceed as follows:

➔ Turn the HMC-Anomaloskop off, *sec. 7.4, page 22*.

➔ Unplug the power cord.

Cleaning the housing

➔ When cleaning, use a damp cloth and make sure that no liquid enters the HMC-Anomaloskop.

➔ Clean the plastic surfaces and painted surfaces with appropriate cleaning agents.

Clean the eyepiece lens

Dirt, dust or a fingerprint can affect the examination.

➔ Clean the eyepiece lens with a soft cloth or lens brush, or with alcohol or a lens cleaner, if necessary.

Clean the eyecup

➔ Clean the eyecup with a mild soap solution.

12.3 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; Softpack 48x, Art. No. 165711

➔ Disinfect the eyepiece after every examination and the housing whenever necessary.

➔ If you use a 4° add-on optics: Disinfect the 4° add-on optics after every examination.

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

12.4 Maintenance

Attention

Risk of electric shock if the HMC-Anomaloskop is not completely disconnected from the mains for these jobs.

➔ Turn the HMC-Anomaloskop off, *sec. 7.5, page 22*.

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

Note

Faulty examinations due to damaged equipment

If an error occurs that you cannot resolve

➔ Label the damaged HMC-Anomaloskop as “out of order”.

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

➔ Use only undamaged HMC-Anomaloskop devices.

12.4.1 Replacing the Fuse

The HMC-Anomaloskop has two fuses. These are located in a small fuse box integrated in the mains power plug.

You can replace a blown fuse.

Attention

Risk of electric shock if the HMC-Anomaloskop is not completely disconnected from the mains for these jobs.

➔ Turn the HMC-Anomaloskop off, *sec. 7.5, page 22*.

➔ Unplug the power cord before maintenance, *sec. 12.1, page 70*.

Note

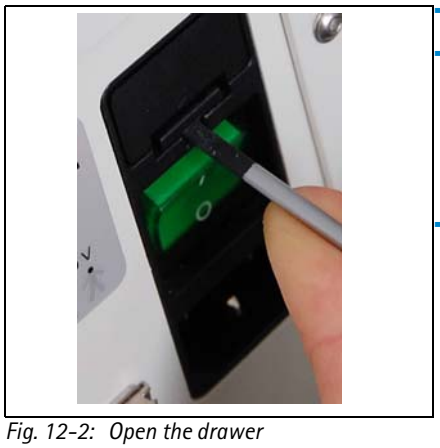
Function loss due to incorrect fuse

➔ Use only the fuse type that is specified on the nameplate, *sec. 2, page 2*.

Materials needed:

- Small screwdriver

➔ Turn the HMC-Anomaloskop off, *sec. 7.4, page 22*.



➔ Unplug the power cord.

➔ Open the drawer with a small screwdriver.

Insert the screwdriver into the bottom, narrow slit.

Lever the screwdriver upwards, in the direction of the arrow.

This unlocks the drawer and it protrudes slightly out of the holder.

➔ Pull out the drawer.

Fig. 12-2: Open 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 HMC-Anomaloskop to the mains.

You can now turn on the HMC-Anomaloskop and start doing exams.

Fig. 12-3: Replacing the fuse

13 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 authorised dealer.

Error	Possible source	Remedy
Nothing happens when the power switch is turned on	The HMC-Anomaloskop is not connected to the power supply	Plug the power cable into the socket or into the low heat device socket at the HMC-Anomaloskop
	Power failure or power socket is not active	Inform the in-house electrician
No function when the power switch is pressed, but the pilot lamp on the power switch is lit	The computer/laptop is not connected properly	Check that the connector is plugged in properly
	The unit has been switched off and back on again too quickly	Wait approx. 5 seconds before turning the unit back on again
	program crash	Switch off and re-start the HMC-Anomaloskop (and the computer/laptop if applicable), whereby the computer/laptop must be re-started (re-booted) first
	The device fuses have blown	Change the fuses (see *sec. 12.4.1, page 73*)

Error	Possible source	Remedy
Patient claims he cannot see anything	Examination has not been started	Begin the examination
	The unit is in stand-by mode	Press any key on the computer/laptop
	program crash	Switch off and re-start the HMC-Anomaloskop (and the computer/ laptop if applicable), whereby the computer/laptop must be re-started (re-booted) first
Message from the computer/ laptop "No communication"	The serial cable of the computer/ laptop is not connected properly.	Make sure that the plug is inserted correctly, then begin again
	Wrong interface (port) has been used at the computer/laptop or has been set in the program.	Select the correct interface (port) at the computer/laptop or set it in the program (in the Settings menu, under [System->] in the data transfer box)

14 Transport and Storage

The HMC-Anomaloskop, must be properly dismantled and packed before being transported or stored.

14.1 Transport and Storage Information

Storage

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

➔ Do not store the HMC-Anomaloskop in conditions in which temperatures above 50°C and below -10° C could occur.

In accordance with DIN EN 60601-1, the storage conditions are:

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

Transport

The transport and storage conditions according to DIN EN ISO 60601-1 are:

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

After storage and transport

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

14.2 Disassembly and Packing

➔ End the current session.

➔ Unplug the power cord.

Attention

Risk of equipment damage due to incorrect shipment and improper storage

➔ Avoid shocks, vibration and contamination.

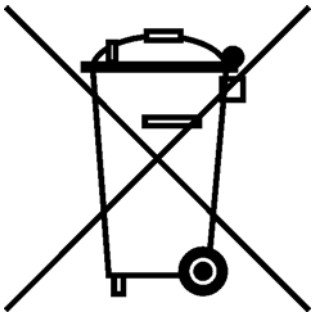
➔ Avoid high temperatures and humidity.

➔ Transport the HMC-Anomaloskop carefully.

➔ Store the HMC-Anomaloskop in accordance with the storage conditions.

➔ Keep away from heating elements and moisture.

15 Disposal



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

➔ Dispose of the HMC-Anomaloskop in a compliant manner.

16 Terms of Warranty and Service

16.1 Terms of Warranty

Please note the following warranty provisions:

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

16.2 Assumption of Liability for Functions and Damage

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

- Only use the equipment in conformance with this instruction manual.
- There are no parts either on or inside the HMC-Anomaloskop that require maintenance or repair by the user. If assembly work, modifications, adjustments, repairs, changes or service is performed by unauthorised personnel, or if the HMC-Anomaloskop is improperly maintained or handled, then any liability by OCULUS is voided.
- If the above-referenced work is performed by authorised persons, then a certification of the work shall be requested from this service t echnician which shall state any changes to factory defaults or to operating ranges. This certification must contain the date of performance and statement of the performing firm, with signature.
- On request, and for this purpose, OCULUS will supply authorised persons with spare parts lists and additional descriptions.
- Make certain that only original OCULUS parts are used.

16.3 Manufacturer and Service Address

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

Germany:

OCULUS Optikgeräte GmbH

Münchholzhäuser Straße 29

D 35582 Wetzlar

Tel.: + 49 (0) 641/2005-0

Fax: + 49 (0) 641/2005-255

Email: sales@oculus.de

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WA 98223-1337
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Fax +1 425-670-0742
e-mail: sales@oculususa.com
http://www.oculususa.com

17 Declaration of Conformity

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D-35582 Wetzlar
Germany

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Konformitätserklärung
Declaration of Conformity

Wir, OCULUS Optikgeräte GmbH, erklären in alleiniger Verantwortung, dass die unten beschriebenen Medizinprodukte allen Anforderungen der nachstehenden Richtlinie und den damit verbundenen harmonisierten Normen entsprechen: 93/42/EWG

We, OCULUS Optikgeräte GmbH, declare on our own responsibility that the medical devices described below are in compliance with requirements of the following directive and their related harmonized standards: 93/42/EEC

Produktbezeichnung/ **Product name**	Anomaloskop/ Anomaloscope
Artikelnummer und Typ/ **Article number and type**	47700 HMC-Anomaloskop (MR) 47720 HMC-Anomaloskop (R) 47710 HMC-Anomaloskop (MR) 47715 HMC-Anomaloskop (R)
Konformitätsbewertungsverfahren/ **Conformity assessment procedure**	Richtlinie 93/42/EWG: Anhang VII Conformity according: 93/42/EEC, Annex VII
Ort, Datum/ Place, date	**Name und Funktion/** Name and function
Wetzlar, 24.01.2015	Qualitätsmanagement / Quality Manager OCULUS Optikgeräte GmbH

Eckhard Loh

18 Technical Data

Technical Specifications

Dimensions (W x D x H) With 4 ° optical attachment lens	245 x 356 x 325 mm (9.6 x 14.0 x12.8 in) 245 x 415 x 435 mm (9.6 x 14.0 x17.2 in)
Weight	5.4 kg (11.9 lbs)
HMC-Anomaloskop R, 230 V HMC-Anomaloskop, MR, 230 V	
■ Max. power consumption	15 VA
■ Voltage	230 V AC
■ Frequency	50 – 60 Hz
HMC-Anomaloskop MR, 115 V	
■ Max. power consumption	15 VA
■ Voltage	115 V AC
■ Frequency	50 – 60 Hz
Shelf life	Up to 10 years

Ambient Conditions

Temperature	+10°C to +35°C
Humidity	30% to 75%
Air pressure	700 hPa to 1060 hPa

Storage conditions according to DIN EN 60601-1

Ambient temperature range	-10°C to +55°C
Relative humidity, including condensation	10% to 95%
Air pressure range	700 hPa bis 1060 hPa

Transport conditions according to DIN EN 60601-1

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

Classification according to DIN EN 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

Other Data

Pupil intensity	175 Troland ±50%
Light source neutral adaption	White light, comparable to standard illuminant C (6750 K)
Wavelengths of the testfield colours	
■ Moreland (nur HMC-MR)	
Blue	436 ±2 nm (10 ±2 nm)
Cyan	480 ±2 nm (10 ±2 nm)
Blue-green	490 ±2 nm (10 ±2 nm)
■ Rayleight	
Green	549 ±2 nm (10 ±2 nm)
Yellow	589 ±2 nm (10 ±2 nm)
Red	666 ±4 nm (10 ±2 nm)
	(halfwidths in brackets)

Viewing angle of test field

Rayleigh	2° ±10%
Moreland	With 4 ° optical attachment lens

Computer

Use a computer which is in conformity with the DIN EN 60950 standard.

Recommended computer specifications	Intel Pentium N3710, 500 GB HDD, 4 GB RAM, Windows® 7, 64bit

19 Appendix

19.1 Electromagnetic Compatibility

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

No particular measures are required for OCULUS equipment and systems.

Portable and mobile HF communications appliances can affect medical, electric equipment.

Definition of the minimum operational quality or essential performance characteristics

- Brief flickering of the device's illumination during the examination is permissible, as it does not affect the diagnosis, treatment and monitoring.
- A brief interruption of the USB connection during the examination is permissible, as it does not affect the diagnosis, treatment and monitoring.

Attention

The use of accessories, converters, and cables that do not meet OCULUS specifications can result in increased emissions or a reduced interference immunity of the HMC-Anomaloskop.

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

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

➔ Do not use the OCULUS-specified accessories, converters and cables for any device other than the HMC-Anomaloskop.

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	
47700	HMC-Anomaloskop MR (Moreland and Rayleigh), 230 V	
47720	HMC-Anomaloskop R	
47715	HMC-Anomaloskop MR (Rayleigh), 115 V	
05200320	Kabel with plug, EU standard	2.5 m (8.2021 feet)
05200210 (110 Volt)	Kabel with plug, US standard	2.5 m (8.2021 feet)

19.2 Guidance and Manufacturer's Declaration - Electromagnetic Emmisssions for the HMC-Anomaloskop

Guidance and manufacturer´s declaration electromagentic emmissions IEC 60601-1-2, 5.2.2.1, table 1		
The OCULUS HMC-Anomaloskop is intended for operation in the electromagnetic environment specified below. The user of the HMC-Anomaloskop should ensure that it is being used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The HMC-Anomaloskop uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
HF-emissions CISPR 11	Class B	
Harmonics emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	complies	

Guidance and manufacturer´s declaration electromagentic immunity, IEC 60601-1-2, 5.2.2.1, table 2

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	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%.
Electrical Fast transient/bursts IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 6100-4-5	± 1 kV kine(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_τ (> 95% dip in U_τ) for 0,5 cycle 40 % U_τ (60% dip in U_τ) for 5 cycles 70% U_τ (30% dip in U_τ) for 25 cycles <5% U_τ (> 95% dip in U_τ) for 5 s	< 5% U_τ (> 95% dip in U_τ) for 0,5 cycle 40 % U_τ (60% dip in U_τ) for 5 cycles 70% U_τ (30% dip in U_τ) for 25 cycles <5% U_τ (> 95% dip in U_τ) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the HMC-Anomaloskop requires continued operation during power mains interruptions, it is recommended that the HMC-Anomaloskop be powered from an uninterruptible power supply or battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_τ is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer´s declaration electromagentic immunity,
IEC 60601-1-2, 5.2.2.2, table 4

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – Guidelines
			Portable and mobile RF communications equipment should be used no closer to any part of HMC-Anomaloskop, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 Mhz	V_{rms}= 3 V	$d = \left[\frac{3,5}{(V_1)}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	E = 3 V/m	$d = \left[\frac{3,5}{(E_1)}\right]\sqrt{P}$ 80MHz to 800 MHz $d = \left[\frac{7}{(E_1)}\right]\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range (b). 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 HMC-Anomaloskop is used exceeds the applicable RF compliance level above, the HMC-Anomaloskop should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HMC-Anomaloskop.

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

Recommended separation distances between portable and mobile RF communications equipment and the HMC-Anomaloskop, IEC 60601-1-2, 5.2.2.2, table 6

The HMC-Anomaloskop in intended for us e in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the HMC-Anomaloskop can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 3

as recommended below, according to the maximum output power of the communications equipment.

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

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

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

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

Manufacturer and Service Address

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E-mail: sales@oculususa.com
http://www.oculususa.com