MANUAL.

binophor.

BLOCK OPTIC

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Version 0.72 E | 05.04.2019

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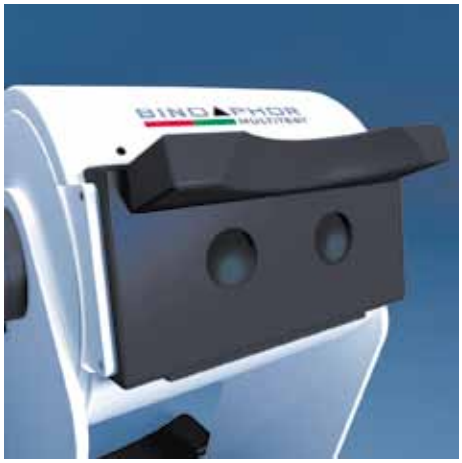
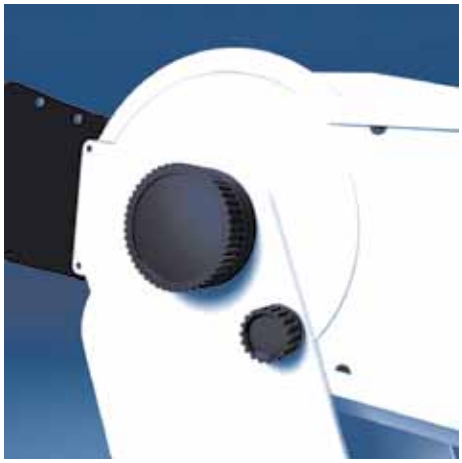




Introduction

Thank you very much for your confidence which you expressed by purchasing this visual acuity system. With the Binophor you have chosen a modern fully developed product which has been produced and tested according to strict quality criteria. Continuous research and development might lead to changes in version and scope of supply. Therefore in the instruction manual details could be slightly different in some cases. If you have any questions or need further information regarding the unit, please don‘t hesitate to call us or send a fax. Our service team will be glad to help you.

Device Specifications

Device Type	Binophor
Manufacturer	Block Optic Design GmbH Semerteichstr. 60 D-44141 Dortmund
Phone	+49 231/1087785-0
Fax	+49 231/1763065
E-mail	info@block-optic.com

Intended Application

The Binophor is a compact device for testing the visual acuity and mesopic vision with and without glare. It is used in ophthalmology and occupational medicine.

Unintended Application

Other applications as those described above are prohibited. During wrong practice unpredictable hazard can occur.

Scope of supply

The Binophor can be delivered with various equipment. The actual scope of supply is listed in the detailed delivery note

Safety Remarks

a) Please read the instruction manual carefully and make yourself acquainted with all functions before you start to operate the device.

b) Don‘t change anything at the system by yourself as this might impact the safety and leads to the expiry of the warranty.

c) This system is not intended for use in areas with risk of explosions.

d) Do not operate the Binophor if you observe visible damages. Breakdowns which have impact on the safety need to be repaired immediately. In this case, please contact an authorized service technician at Block Optic.

e) Please let all repairs of the Binophor be done by a service technician authorized by Block Optic.

f) Only use original accessory parts for the Binophor.

g) If the system will not be used for a longer period, please turn off the main switch and turn out the power plug.

h) Accessories which will be connected with the electric supply of the Binophor need to be proven to comply with the appropriate DIN EN or IEC specifications. Furthermore all configurations have to comply with the requirements of the system standard DIN EN 60601-1-1 (IEC 601-1-1) and its modifications. Coupling of non-medical devices (e.g. dataprocessing devices) to a medical electronical system such as the examination unit must not lead to a safety degree for patient, user, and the environment which is beyond DIN EN 60601-1-1 (IEC 601-1-1) and its modifications. If the admissible leakage current is exceeded by the coupling, protective measures according to the system standard DIN EN 60601-1-1 (IEC 601-1-1) and its modifications need to be provided. After installation or later modifications the system must not put any risk to the patient, the user or the environment.

Text Accentuation

Important parts of the text in the instruction manual are marked by accentuations and key words. The following accentuations are used in the actual instruction manual:

Important!
Indicates important information. Please read this information to maintain the high safety and function level of the device.

Special note!
Indicates information for proper usage.

Please read this information to avoid any misuse.

Liability of Manufacturer

The device has been manufactured according to the latest technical development and acknowledged technical safety directives. Block Optic considers itself responsible for any impact on safety, reliability and performance of the device only if:

- Mounting, extensions, readjustments, modifications or repairs are carried out by authorized persons,
- the electric installation of the concerned room complies with the requirements of VDE 0107 and
- the device is used according to the instruction manual.

Responsibility of User

The user is responsible for:
- compliance with standards for prevention of accidents and the directives for establishment, operation and application of medical devices (Medical Device Operating Directive)
- MPBetriebV,
- operation,
- maintenance,
- duly and safe condition of the product and
- storage of the instruction manual at the usage site.

Warranty

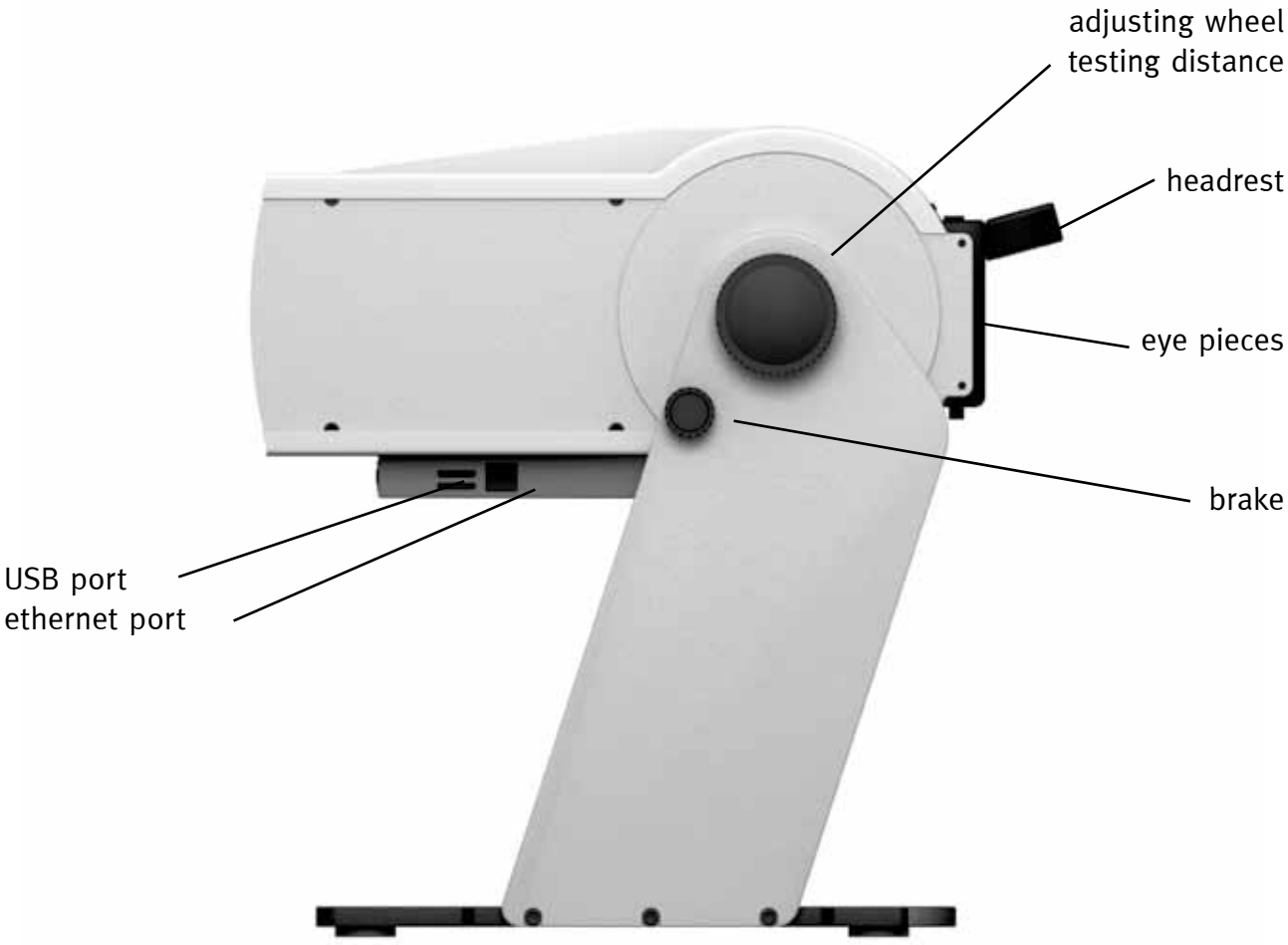
The „Allgemeinen Verkaufs- und Lieferbedingungen“ of Block Optic are effective as the basic principle.

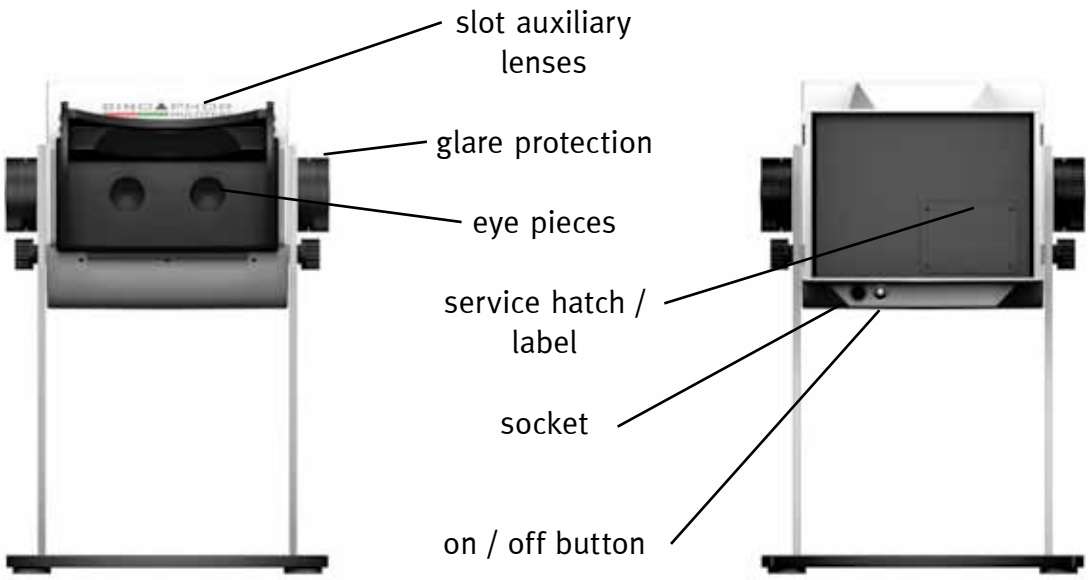
General Information

The Binophor is a compact device for testing the

- mesopic vision with and without glare (DIN 58220-7)
- visual acuity for far and near vision (DIN 58220-5)
- visual acuity for driving related tests (DIN 58220-6)
- visual acuity for german occupational medicine test G25
- visual acuity for german occupational medicine test G37
- visual acuity according to JAR-FCL 3 (german interpretation)

Control Elements





Commissioning

After transportation or a long storage period wait with the initial commissioning for about 4-5 hours. Prevent high temperature variation e.g. from cold areas into warm rooms to avoid fogging of the optical components.

The installation place of the device should be chosen in a way that the eye pieces are not pointing to light sources, whether natural or artificial ones.

Connect the plug of the power supply into the socket at the rear of the Binophor and the power cord into a socket. The device can be switched on and off with the main switch.

Power on the remote tablet and wait until the remote application is started.

The Binophor is now ready for operation.

If the power supply, power supply cable or power cord is damaged, the usage of the device is prohibited.

Before each examination make shure that the lenses of the eye pieces are clean to avoid incorrect results.

General Information

The application BinoControl drives the various tests, takes care of multiple patients and sends the results to a computer or printer.

BinoControl Installation

Normally the Binophor will be delivered with a remote tablet. In this case the application is already installed and both devices are paired to each other.

It is also possible to use an own tablet or smartphone for the control of the Binophor.

Minimum requirements for BinoControl are an Android OS version 4.0 or above and Bluetooth.

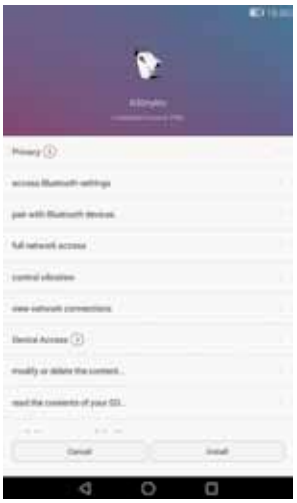
Depending on the device and Android version the following pictures can vary.

The application can be downloaded from:

www.downloads.block-optik.de/BinoControl/BinoControl.apk

To install the application the point Settings -› Security -› Unknown sources must be checked.

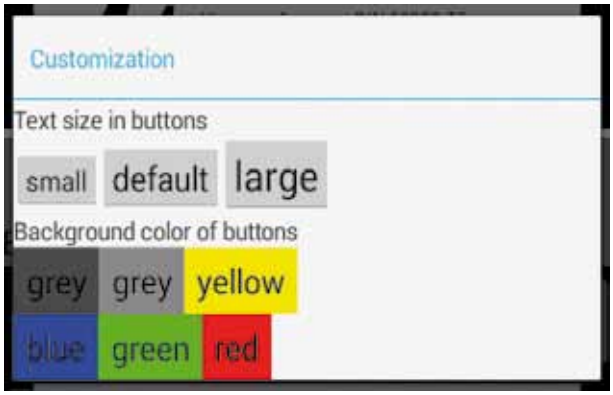
The application needs a some rights to function properly. Accept the following message to continue installation.



Check regulary if updates of the application are available. These can contain bug fixes or additional new features. The remote tablet must be connected to the internet for this. The update function can be found BinoControl -> Info -> Update.

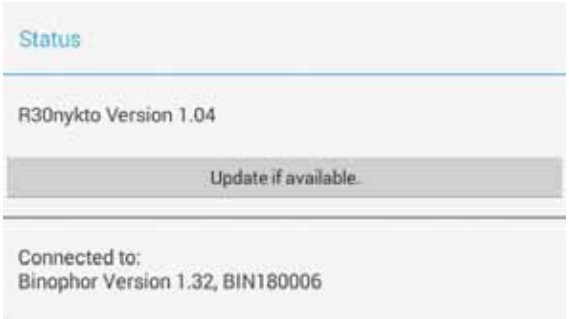
Personalize BinoControl

The menu item „Surface“ (?), which can be found at the end of the examination list, contains controls to alter the text size and colour schemes.



Software Version

The menu item „Status“ (?) shows the serial number of the connected Binophor as well as its software version.



Start an examination

The Binophor contains different types of examinations, which are shown in a list. Each examination contains a test sequence where the individual steps are listed. Those steps, e.g. far vision acuity, also contain a fixed sequence, which has to be tested successively. In our far vision example the right eye is checked first, then the left eye and finally binocular vision in the acuity steps 0.2 - 1.0. There is no need to test all acuity steps if not desired. Different colours and text information show the state of the individual steps.

A touch on an examination immediately starts the test sequence.

Process of an examination

Make shure the head rest is sterilized and the ocular lenses are clean. Place the patient in front of the Binophor in a way that the forehead reaches the head rest comfortably. Adjust the inclination of the device if necessary. Lose the brake wheels on both sides and tilt the Binophor. Tighten the wheel brakes after the correction. Choose the desired testing distance with the adjusting wheel.

Make sure the patient always looks into the eye pieces binocular.

If the patient has an ametropia, the correction glasses for the respective testing distance must be worn.

End an examination

After finishing an examination a detailed summary of each step is shown. The lower part of the summary will show three buttons with the meaning from left to right:

- switch back to the testing sequence (🡐)
- delete the examination (⃠)
- save the examination

Depending on the pre-settings the results can be

- saved as PDF-file, or transmitted to a suitable patient software (🖬).
- passed to the android printer service (🖳).

On saving the file will be stored in the tablets „Download“ folder with an auto generated filename (patients information and time stamp).

If the examination was started through a request of the patients software, (🖬) does not save the PDF, but transmittes the examination results to the back to the patients softare.

For printing the PDF-file will be saved temporarely and passed to the android printer service. The printer has to be accessible via WLAN and its drivers have to be installed on the tablet.

Connection to a patient software

The main requirement for a connection to a patient software is that the software supports the GDT protocol and a network without domains.

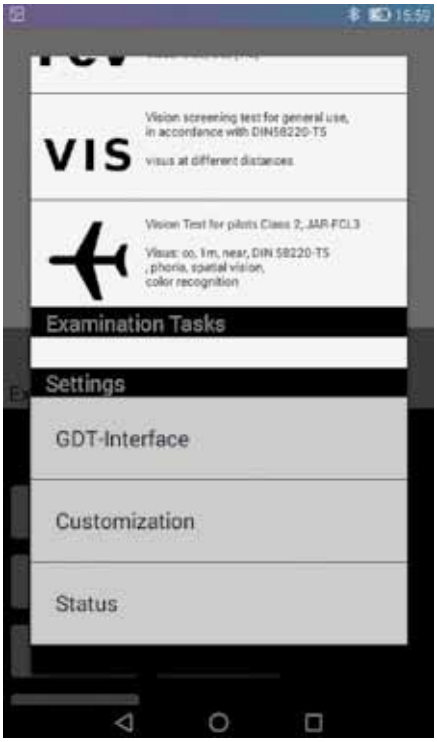
The patient software must send a legal examination request and interpret the received results so the operator is able to evaluate the examination.

A detailled description of the protocol can be provided by Block Optic if necessary.

A requirement for the GDT interface is a shared network folder with read/write permission for either the Binphor and the patient software.

Before setting up the folder connect the Binophor to the network with an ethernet cable.

The menu item „GDT-Interface“ is for setting up the interface.



The menu itself is password protected against accidential changes.

Before accessing the shared folder, a user name and a password in the fields „User“ and „Pass“ must be entered.

Additionally two files, which contain sent and received data, are necessary for a correct GDT transfer. The names of these files must not be longer than 8 characters and must not contain alphanumerical characters. Umlauts and special characters are not supported.

The filenames must eventually be changed following the specification of the patient software developer. The names must be filled in the fields „Send File“ and „Receive File“.

If the entries are complete and correct different working groups are available.

Choose the working group first, the the computer. If nothing is available, please check the password, user name, cable and network.

At last the path to the shared folder must be entered.

Mesopic contrast vision with and without glare

Flowchart
Distance: infinity
Testing: mesopic contrast vision without glare
Timer to ensure dark adaptation
5x1 Landolt ring Vis 0.1, binokular, contrast 23:1
5x1 Landolt ring Vis 0.1, binokular, contrast 5:1
5x1 Landolt ring Vis 0.1, binokular, contrast 2.7:1
5x1 Landolt ring Vis 0.1, binokular, contrast 2:1

Testing: mesopic contrast vision with glare
Fixation object
5x1 Landolt ring Vis 0.1, binokular, contrast 23:1
5x1 Landolt ring Vis 0.1, binokular, contrast 5:1
5x1 Landolt ring Vis 0.1, binokular, contrast 2.7:1
5x1 Landolt ring Vis 0.1, binokular, contrast 2:1

This test sequence is in accordance with DIN 58220 Part 7.

Before testing the mesopic vision, the patient has to adapt to darkness. A period of 10-15 minutes should be maintained. Clip the glare protection to the head rest to reduce incident light from the sides. The adjusting wheel for the testing distance must be turned to infinity.

The patient has to name the direction of the opening for each Landolt ring. The so called termination criterion notes that at least 60% of the optotypes must be correct. The contrast level is passed when 3 of 5 orientations are named right. As soon as the contrast level 2:1 is passed the first time, a fixation object in form of a red circle appears. Explain the patient that a glare light will appear next, but he still has to look onto the fixation object NOT into the glare light.

Summary

- **dark adaptation: at least 5, better 10 minutes**
- **adjusting wheel switched to infinity**
- **3 of 5 orientations must be recognized per contrast level**
- **patient should not look into glare light**

Vision screening test for general use

Flowchart
Distance: variable
Testing: visual acuity
5 Landolt rings Vis 0.2 - Vis 1.0, right eye
5 Landolt rings Vis 0.2 - Vis 1.0, left eye
5 Landolt rings Vis 0.2 - Vis 1.0, binocular

2 different layouts available

This test sequence is in accordance with DIN 58220 Part 5.

Before starting the test the adjusting wheel must be switched to the desired testing distance. The sequence for this test is right eye, left eye and binocular. The following acuity steps are shown: 0.2, 0.32, 0.4, 0.5, 0.63, 0.7, 0.8, 1.0. The patient has to name the direction of the opening for each Landolt ring. At least 60% of the openings per acuity step must be named correctly. As soon as the terminal criterion is fulfilled, the next acuity step will be shown. A long touch on the buttons „Visus far / near“ will swap the layout.

Summary
- **adjusting wheel switched to desired distance**
- **3 of 5 orientations must be recognized per acuity step**
- **long touch on button „Distance“ will swap the layout**

Vision screening tests (option)

In the variants

(1) with alternative optotypes
(2) single optotypes

Flowchart
Distance: variable
Testing: visual acuity
Optotypes: for children, numbers, letters, snellen and landolts rings.
Acuity steps: 0.2-1.0

2 different layouts per opotype and distance available

This generalized test sequence is NOT in accordance with DIN 58220 Part 5.

Before starting the test the adjusting wheel must be switched to the desired testing distance. The sequence for this test is right eye, left eye and binocular. The following acuity steps are shown: 0.2, 0.32, 0.4, 0.5, 0.63, 0.7, 0.8, 1.0. Variant (1) presents 5 optotypes at once, whereas variant (2) shows only one optotype per screen but with 5 screens per acuity step. The patient has to identify the optotype or its orientation. At least 60% has to identified correctly, before the terminal criterion ist fulfilled and the next acuity step will be shown automatically. A long click on the menu button „Distance“ toggles between near and far, a long click on the menu button of the specific optotype toggles the set.

Summary

- **adjusting wheel switched to desired distance**
- **3 of 5 optotypes/orientations must be recognized per acuity step**
- **long click on button of the optotype of distance will toggle the set or the distance.**
- **test sequence is not in accordance with DIN 58220 Part 5**

Road traffic related vision screening test

FeV appendix 6.1
classes A, A1, A2, B, BE, AM, L and T

Flowchart
Distance: infinity
Testing: visual acuity
4 Landolt rings, Vis 0.32, right eye
10 Landolt rings, Vis 0.7, right eye
10 Landolt rings, Vis 1.0, right eye (option)
4 Landolt rings, Vis 0.32, left eye
10 Landolt rings, Vis 0.7, left eye
10 Landolt rings, Vis 1.0, left eye (option)
4 Landolt rings, Vis 0.32, binocular (option)
10 Landolt rings, Vis 0.7, binocular (option)
10 Landolt rings, Vis 1.0, binocular (option)

2 different layouts available

This test sequence is in accordance with DIN 58220 Part 6.

The placement of the Binophor should be chosen in a way that the patient is not dazzled by bright areas of light falling into the eye pieces. The examination room should be moderate illuminated. Before starting the test the adjusting wheel has to be switched to infinity. The test starts with a training row in the acuity size of 0.32 for each eye. The test sequence is explained

to the patient. At least 60% of the openings per acuity step must be named correctly, 6 out of 10. As soon as the terminal criterion is fulfilled, the next acuity step will be shown. A long touch on the button „FeV 6.1“ will swap the layout.

Summary

- **adjusting wheel switched to infinity**
- **6 of 10 orientations must be recognized per acuity step**
- **minimum acuity R/L Vis 0.7/0.7**
- **long touch on button „FeV 6.1“ will swap the layout**

FeV appendix 6.2
Classes C, C1, CE, C1E, D, D1, DE, D1E and driving license for passenger transportation

Flowchart
Distance: infinity
Testing: visual acuity
4 Landolt rings, Vis 0.32, right eye
10 Landolt rings, Vis 0.8, right eye
10 Landolt rings, Vis 1.0, right eye (option)
4 Landolt rings, Vis 0.32, left eye
10 Landolt rings, Vis 0.8, left eye
10 Landolt rings, Vis 1.0, left eye (option)
4 Landolt rings, Vis 0.32, binocular
10 Landolt rings, Vis 0.8, binocular
10 Landolt rings, Vis 1.0, binocular

2 different layouts available

Distance: infinity
Testing: colour vision
Ishihara 5, 7, 16, 29, 15, 45

Distance: infinity
Testing: phoria
Phoria horizontal
Phoria vertical

Distance: infinity
Testing: stereopsis
Stereo test 800“, 600“, 400“, 200“, 100“, 50“
Stereo test 100“

This test sequence is in accordance with DIN 58220 Part 6.

The placement of the Binophor equals the demands from Fev 6.1. Before starting the test the adjusting wheel has to be switched to infinity. The test starts with a training row in the acuity size of 0.32 for each eye. The test sequence is explained to the patient. At least 60% of the openings per acuity step must be named correctly, 6 out of 10. As soon as the terminal criterion is fulfilled, the next acuity step will be shown. A long touch on the button „FeV 6.1“ will swap the layout. The colour vision tests are passed when all plates are named correctly.

Two tests are available to detect a horizontal or vertical phoria. The left eye looks at coloured circles with numbers next to them and the right eye sees a vertical arrow. An orthophor patient will see the arrow above the middle circle with the number 4. Each circle distance is one prism dioptre (1cm/m). If the patient doesn‘t see an arrow above the circles he has a significant phoria. The vertical phoria test works analogue. A significant phoria is present when the patient sees the arrow above the circles 1 or 7 or no arrow is seen. The phoria tests don‘t work with monocular looking patients.

The result of the stereo test with variable values is the smallest value achieved. The stereo test with constant 100“ offset is passed when 3 out of 5 circles were recognized.

Summary

- **adjusting wheel switched to infinity**
- **6 of 10 orientations must be recognized per acuity step**
- **minimum acuity R/L Vis 0.8/0.8, binocular 1.0**
- **long touch on button „FeV 6.2“ will swap the layout**
- **colour vision test: all plates must be recognized**
- **phoria test: arrow above number or outside the screen**
- **stereo test: variable: smallest angle recognized, constant: 3 out of 5 must be recognized**

G25

Flowchart
Distance: infinity
Testing: visual acuity
5 Landolt rings Vis 0.2 - 1.0, right eye
5 Landolt rings Vis 0.2 - 1.0, left eye
5 Landolt rings Vis 0.2 - 1.0, binocular

Distance: near (33cm or 40cm)
Testing: visual acuity
5 Landolt rings Vis 0.2 - 1.0, right eye
5 Landolt rings Vis 0.2 - 1.0, left eye
5 Landolt rings Vis 0.2 - 1.0, binocular

Distance: work-related
Testing: colour vision
Ishihara 5, 7, 16, 29, 15, 45

Distance: work-related
Testing: phoria
Phoria horizontal
Phoria vertical

Distance: work-related
Testing: stereopsis
Stereo test 800“, 600“, 400“, 200“, 100“, 50“
Stereo test 100“

Distance: infinity
Testing: mesopic contrast vision without glare
Timer to ensure dark adaptation
5x1 Landolt ring Vis 0.1, binokular, contrast 5:1
5x1 Landolt ring Vis 0.1, binokular, contrast 2.7:1

Testing: mesopic contrast vision with glare
Fixation object
5x1 Landolt ring Vis 0.1, binokular, contrast 5:1
5x1 Landolt ring Vis 0.1, binokular, contrast 2.7:1

G25 consists of a series of visual tests. It starts with a visual acuity test for far and near vision like the „Vision screening test for general use“ on page 17. Binocular vision testing is an option. The following tests have a testing distance that is work related. The adjusting wheel has to be switched to this distance.

The colour vision tests are passed when all plates are named correctly.

Two tests are available to detect a horizontal or vertical phoria. The left eye looks at coloured circles with numbers next to them and the right eye sees a vertical arrow. An orthophor patient will see the arrow above the middle circle with the number 4. Each circle distance is one prism dioptre (1cm/m). If the patient doesn‘t see an arrow above the circles he has a significant phoria. The vertical phoria test works analogue. A significant phoria is present when the patient sees the arrow above the circles 1 or 7 or no arrow is seen. The phoria tests don‘t work with monocular looking patients.

The result of the stereo test with variable values is the smallest value achieved. The stereo test with constant 100“ offset is passed when 3 out of 5 circles were recognized.

The mesopic contrast vision test is like the „Mesopic contrast vision with and without glare“ on page 16, except there are just two contrast levels.

Summary

- **far vision acuity**
  - **adjusting wheel switched to infinity**
  - **3 of 5 orientations must be recognized per acuity step**
- **near vision acuity**
  - **adjusting wheel switched to 33cm or 40cm**
  - **3 of 5 orientations must be recognized per acuity step**
- **adjusting wheel switched to work related distance**
- **colour vision test**
  - **all plates must be recognized**
- **phoria test**
  - **arrow above number or outside the screen**
- **stereo test**
  - **variable: smallest angle recognized, constant: 3 out of 5 must be recognized**
- **mesopic contrast vision**
  - **dark adaptation: at least 5, better 10 minutes**
  - **adjusting wheel switched to infinity**
  - **3 of 5 orientations must be recognized per contrast level**
  - **patient should not look into glare light**

G37

Flowchart
Distance: infinity
Testing: visual acuity
5 Landolt rings Vis 0.2 - 1.0, right eye
5 Landolt rings Vis 0.2 - 1.0, left eye
5 Landolt rings Vis 0.2 - 1.0, binocular

Distance: near (33cm or 40cm)
Testing: visual acuity
5 Landolt rings Vis 0.2 - 1.0, right eye
5 Landolt rings Vis 0.2 - 1.0, left eye
5 Landolt rings Vis 0.2 - 1.0, binocular

Distance: near work related
Testing: visual acuity
5 Landolt rings Vis 0.2 - 1.0, right eye
5 Landolt rings Vis 0.2 - 1.0, left eye
5 Landolt rings Vis 0.2 - 1.0, binocular

Distance: infinity
Testing: colour vision
Ishihara 5, 7, 16, 29, 15, 45

Testing: phoria
Phoria horizontal
Phoria vertical

Testing: stereopsis
Stereo test 800“, 600“, 400“, 200“, 100“, 50“
Stereo test 100“

G37 consists of a series of visual tests. The focus is on acuity test with different distances. The visual acuity test is like the „Vision screening test for general use“ on page 17.

The colour vision tests are passed when all plates are named correctly.

Two tests are available to detect a horizontal or vertical phoria. The left eye looks at coloured circles with numbers next to them and the right eye sees a vertical arrow. An orthophor patient will see the arrow above the middle circle with the number 4. Each circle distance is one prism dioptre (1cm/m). If the patient doesn‘t see an arrow above the circles he has a significant phoria. The vertical phoria test works analogue. A significant phoria is present when the patient sees the arrow above the circles 1 or 7 or no arrow is seen. The phoria tests don‘t work with monocular looking patients.

The result of the stereo test with variable values is the smallest value achieved. The stereo test with constant 100“ offset is passed when 3 out of 5 circles were recognized.

Summary

- **far vision acuity**
  - **adjusting wheel switched to infinity**
  - **3 of 5 orientations must be recognized per acuity step**
- **near vision acuity**
  - **adjusting wheel switched to 33cm or 40cm**
  - **3 of 5 orientations must be recognized per acuity step**
- **work related vision acuity**
  - **adjusting wheel switched to work related distance**
  - **3 of 5 orientations must be recognized per acuity step**
- **adjusting wheel switched to work related distance**
- **colour vision test**
  - **all plates must be recognized**
- **phoria test**
  - **arrow above number or outside the screen**
- **stereo test**
  - **variable: smallest angle recognized, constant: 3 out of 5 must be recognized**

JAR-FCL3 Class 2 (german interpretation)

Flowchart
Distance: infinity
Testing: visual acuity
5 Landolt rings Vis 0.2 - 1.0, right eye
5 Landolt rings Vis 0.2 - 1.0, left eye
5 Landolt rings Vis 0.2 - 1.0, binocular

Distance: 1 meter
Testing: visual acuity
5 Landolt rings Vis 0.2 - 1.0, right eye
5 Landolt rings Vis 0.2 - 1.0, left eye
5 Landolt rings Vis 0.2 - 1.0, binocular

Distance: near (33cm or 40cm)
Testing: visual acuity
5 Landolt rings Vis 0.2 - 1.0, right eye
5 Landolt rings Vis 0.2 - 1.0, left eye
5 Landolt rings Vis 0.2 - 1.0, binocular

Distance: infinity
Testing: colour vision
Ishihara first 15 plates of 24 edition

Testing: phoria
Phoria horizontal
Phoria vertical

Testing: stereopsis
Stereo test 800“, 600“, 400“, 200“, 100“, 50“
Stereo test 100“

The JAR-FCL3 for pilots class 2 demands to test the visual acuity for 3 distances. The process is like the „Vision screening test for general use“ on page 17.

Two tests are available to detect a horizontal or vertical phoria. The left eye looks at coloured circles with numbers next to them and the right eye sees a vertical arrow. An orthophor patient will see the arrow above the middle circle with the number 4. Each circle distance is one prism dioptre (1cm/m). If the patient doesn‘t see an arrow above the circles he has a significant phoria. The vertical phoria test works analogue. A significant phoria is present when the patient sees the arrow above the circles 1 or 7 or no arrow is seen. The phoria tests don‘t

work with monocular looking patients.

The result of the stereo test with variable values is the smallest value achieved. The stereo test with constant 100“ offset is passed when 3 out of 5 circles were recognized.

The mesopic contrast vision test is like the „Mesopic contrast vision with and without glare“ on page 16, except there are just two contrast levels.

The 15 colour vision tests are for screening purposes only, they are not a replacement for the originals.

Summary

- **far vision acuity**
  - **adjusting wheel switched to infinity**
  - **3 of 5 orientations must be recognized per acuity step**
- **near vision acuity**
  - **adjusting wheel switched to 1 meter**
  - **3 of 5 orientations must be recognized per acuity step**
- **near vision acuity**
  - **adjusting wheel switched to 33cm or 40cm**
  - **3 of 5 orientations must be recognized per acuity step**
- **adjusting wheel switched to infinity**
- **phoria test**
  - **arrow above number or outside the screen**
- **stereo test**
  - **variable: smallest angle recognized, constant: 3 out of 5 must be recognized**
- **colour vision test**
  - **all plates should be recognized, screening only**

Using the tests

The usage of all tests is optimized for a touchscreen. This allows an intuitive operation of all the tests, because with touching or swiping gestures the navigation is quite easy.

The upper area of the remote tablet shows the actual test or optotype in the Binophor. Depending on the test, the operation of the tests is slightly different.

Visual acuity tests

The displayed optotypes in the Binophor are shown in the upper part of the remote control. This part of the screen also shows which eye is examined and the amount of seen and unseen optotypes. The actual optotype that has to be recognized by the patient is shown in solid black. Touching the ☑ symbol marks the optotype as recognized, touching the ☒ symbol means the patient didn‘t recognized the orientation of the Landolt ring.

The lower part of the remote screen is divided into columns. The left column shows the distance, the middle column the examined eye and the right column the actual acuity. Each column can be scrolled with swiping gestures up and down.

The numbers in brackets below the acuity in the right column shows how many optotypes were named correct, e.g. 3/4 means, that 3 out of 4 optotypes were named right.

A second different set of optotype orientations can be loaded by touching long on the „Visus far / near“ buttons in the left column.

All optotypes, whether recognized or not, will be documented in a protocol at the end of the examination. This protocol can be used in different ways (see „End an examination“ on page 13)

The terminal criterion as stated in the ISO 8596 is in use, which means as soon as 60% of the optotypes were recognized, the next acuity step will be shown automatically or the test will be ended if the optotypes were named wrong.

Mesopic contrast vision with and without glare

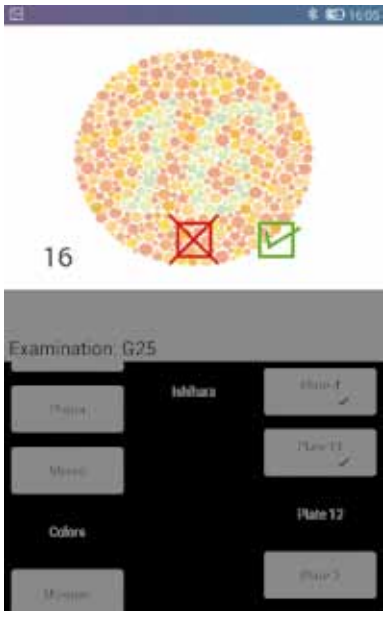
The control of the mesopic test is nearly identical to the visual acuity test. The only difference is that the patient sees one Landolt ring at a time, while all are shown on the remote tablet.

The columns in the lower part inform the operator about the glare staus and the contrast level of the optotype.

Colour vision test

The colour vision tests are Ishihara like and allow the operator to mark if the patient has seen(☑) or not seen(☒) the number in the field.

The test sequences G25 and G37 allow digital colour vision tests. Although the plates were recreated with maximum care, they are perhaps not a complete replacement to the original physical plates.



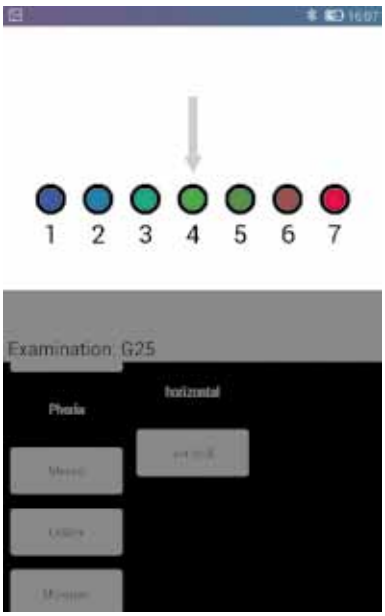
Stereotest

Two variants of the stereo test exist in the Binophor: a version with a constant stereo angle and a version with a variable one. The control of both test is equal: the symbol, which is shown stereoscopic in the Binophor is shown brighter on the remote tablet. The answer of the patient can be directly marked on the displayed test.

The columns in the lower part show additional information, e.g. the actual stereo angle or the amount of seen/unseen symbols. As with all tests, each result will be documented.

Phoria test

A horizontal and vertical component of a phoria can be tested. Both tests are similar. The patient has to name the number below or next to the arrow. A touch on the named number stores the result for the documentation. If the patient doesn‘t see an arrow the abort symbol (☒) must be pressed.



Care and Maintenance

Cleaning the housing

The housing has to be cleaned wit a dry, lint-free cloth. Take care that no liquid pours into the device. Don‘t use detergents, since they can damage the finish or plastic parts.

cleaning the head rest

The headrest has to be cleaned with a common antiseptic before each examination.

Cleaning the oculars

The oculars should be cleaned before each examination with a microfibre cloth.

Maintenance interval

To ensure the illumination and glare values that ar demanded in the standard DIN 58220-T7, the Binophor has to be calibrated every two years.

Key figures

Test sequences	german occupational medicine test G25
	german occupational medicine test G37
	Vision screening test for general use (DIN 58220-5)
	Road traffic related vision screening test (DIN 58220-6)
	Mesopic contrast vision with and without glare (DIN 58220-7)
	JAR-FCL 3 class 2 (german interpretation)

Specifications

testing distances	33 cm, 40 cm, 57 cm, 1 m, infinite
display size	5°
colour coordinates	x 0,32 / y 0,34
brightness photopic	120 cd/m²
brightness mesopic without glare	0,032 cd/m²
brightness mesopic with glare	0,1 cd/m²
glare illumination	0,35 lx
dimensions	ca. 330x265x460 mm
weight	ca. 5,8 kg
main voltage	230 V / 50 Hz
power consumption	25 W
maintenance and calibration interval	2 years
operation conditions temperature of the environment relative humidity air pressure	 between +10°C and +40°C between 30% and 75% between 800hPa and 1060hPa

Software options and accessories

33 12 0050	Binophor additional optotypes
additional optotypes for acuity tests with single or row presentation: • Snellen E‘s • letters • numbers • Landolt‘s rings • children symbols	
33 12 0000.1	Binophor slide-in profile for testing of night myopia
slide-in profile with power of -0.5, -1.0, und -1.5 dpt	
33 12 0000.2	Binophor slide-in profile for testing of hyperopia
slide-in profile with power of +0.5, +1.0, und +1.5 dpt	
33 12 0004	Binophor transport case
transport case with dual wheels and pull-out handle colour black	

EG-Konformitätserklärung
Declaration of Conformity

Block Optic Design GmbH
Semerteichstr. 60
44141 Dortmund

erklärt hiermit, dass das nachstehende Produkt
declares that the following device

Bezeichnung — Binophor
Name

Geräteart — Sehtest nach DIN 58220 Teil 5, Teil 6, Teil 7
Type

den Anforderungen der Richtlinie 93/42/EWG
meets the requirements of the directive 93/42/EC

entspricht und unter Einhaltung folgender Normen
in compliance with the following directives

DIN EN 60601-1
DIN EN 60601-1-2
DIN 58220

als Medizinprodukt der nachstehenden Klasse zugeordnet wurde
as a medical device of

Klasse 1
Class 1

CE

Ort, Datum
Place, Date

Dortmund, den 04.04.2019

Name, Funktion
Name, Function

Jörg Grawunder, Geschäftsleitung

MANUAL.

binophor.

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