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#### Introduction

Thank you very much for your confidence which you expressed by purchasing this visual acuity system. With the Polaphor HD 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 Polaphor HD Visual acuity system

Manufacturer Block Optic Ltd.

Semerteichstr. 60 D-44141 Dortmund

### **Intended Applications**

The Polaphor HD is used to examine the monocular and binocular acuity of the eyes. It is used for optometry and ophthalmology.

## **Unintended Application**

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

### Scope of supply

The Polaphor HD 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 Polaphor HD 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 Ltd.
- e) Please let all repairs of the Polaphor HD be done by a service technician authorized by Block Optic Ltd.
  - f) Only use original accessory parts for the Polaphor HD.
- 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 Polaphor HD 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:

#### Caution!

Indicates a potentially hazardous situation. Please note such precaution measures to prevent any damage from patients or objects.

#### 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 Ltd. 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 Ltd. are effective as the basic principle.

#### General information

The Polaphor HD is a visual acuity system of the next generation. A high-resolution flat panel monitor combined with a powerful computer form the basis for unlimited test possibilities.

You can switch easily through different visual acuity steps and even groups of optotypes by the clearly designed infrared remote control.

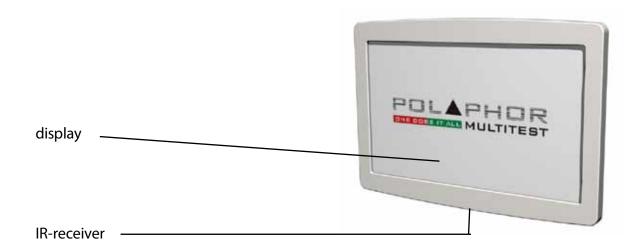
It is even possible to do refractions for official purposes with the Polaphor HD, because the display of the Landolt rings complies with the ISO 8596.

Many charts for monocular and binocular correction and for recognizing phorias come with the standard version of the Polaphor HD.

Because of the use of a computer new tests can be implemented into the Polaphor HD if desired.

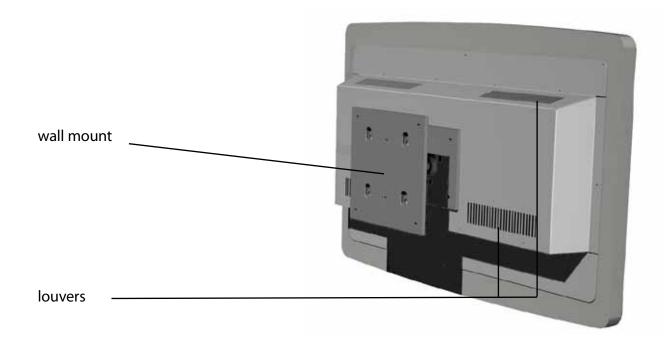
The Polaphor HD box contains the visual acuity system Polaphor HD, the IR remote control, and the manual. A special designed wall mount for the adaption of the Polaphor HD is enclosed.

### Polaphor HD - front view





#### Polaphor HD – rear view

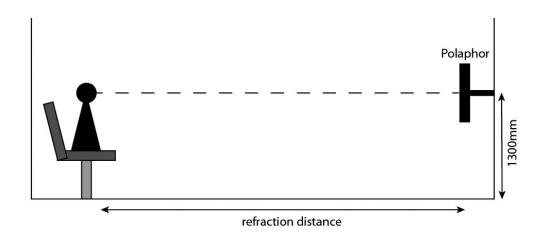


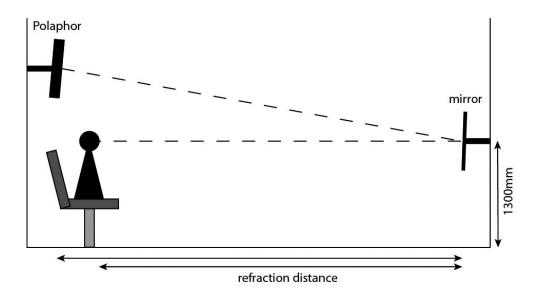
### Mounting

Important for the correct mounting of the Polaphor HD is on the one hand the refraction distance and on the other hand the height to achieve the best separation of the eyes.

The Polaphor HD allows a refraction distance between 3,0 and 7,0 meters and must be adjusted individually for each refraction room. The size of the optotypes is calculated automatically for the entered distance. When choosing the height of the Polaphor HD, have in mind the middle eye height of the patients (about 130 cm). The Polaphor HD has to be adjusted in that way that an optimal separation of both eyes is achieved.

Normally one visual acuity system or Polaphor HD is used in an examination room. If more than one Polaphor HD should be used in the same examination room an adjustment of the software inside the remote control is necessary. In this case please contact your local distributor.





# Putting into operation

Connect the appliance plug with the appropriate female connector at the bottom of the Polaphor HD. The equipment is ready to use and can be turned on and off with the main switch.



#### Before the first use

Before the first use personal settings must be made in the menu of the Polaphor HD to achieve the correct results.

Pressing the "menu"-key on the remote control opens the menu so personal adjustments can be made. At first it is necessary to enter the refraction distance with the left and right arrow keys. The optotypes, polarized tests and Schober test are automatically calculated dependend on the entered distance. For reliable and reproducible results the distance from the entrance pupil to the optotype must be measured.

The visual acuity system Polaphor HD is designed without any mechanic or movable parts. This results in a compact, wearing free and fail-safe instrument. Nevertheless, if a defect occurs please contact your local distributor with a detailed description of the malfunction.

#### Safety note

Only skilled service technicians are allowed to open the visual acuity system for maintenance or repairs.

Caution! Do not pour any liquids over the device especially the louvers! Do not

cover the louvers!

Important! Keep in mind to turn off the Polaphor HD with the main switch every

day.

#### Care and maintenance

The surface has to be cleaned with a dry cloth. Never use aggressive detergents; the sensitive surface could be damaged!

### The menu

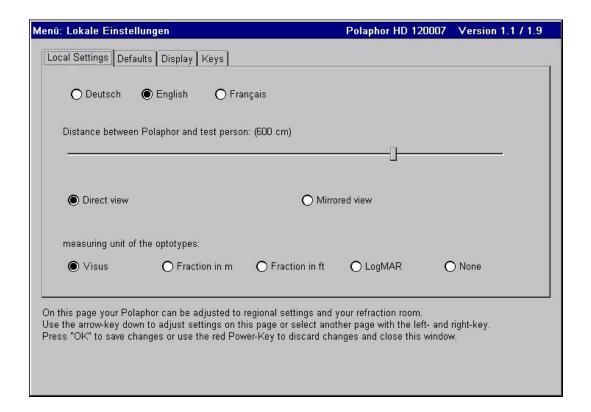
By pressing the "menu"-key on the remote control opens the menu of the Polaphor HD:

With the and weekeys the checkmark (bright area) can be moved to the characteristic that should be changed. The settings are changed with the keys.

By pressing the "OK" key the changed settings will be saved. By pressing the "stand-by" key the menu is left without any changes.

Special note!

It is advisable to change the desired settings in one turn and press the "OK" key.



#### Language

The possible settings are german, english and french.

#### **Distance**

The refraction distances can be adjusted from 300 to 700 centimeters in steps of 10 cm. The



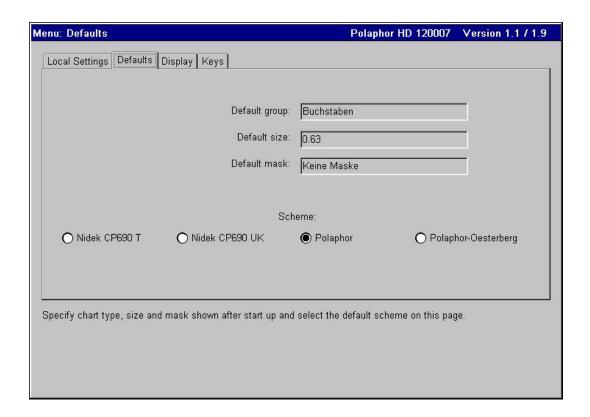
size of the optotypes, polarized tests and Schober Test is calculated automatically depending on the distance.

#### Do not mirror screen / Mirror screen

If you work with a path-folding mirror you have to mark it here.

## Naming of chart size

The naming can be set as logarithmic acuity step, fraction in meters or feet or as a logMAR step. The size can also be turned off completely.



### Chart group after power on

Determines the standard optotype after power on. The settings are children symbols, E's, Landolt's rings, letters and numbers.

### Chart size after power on

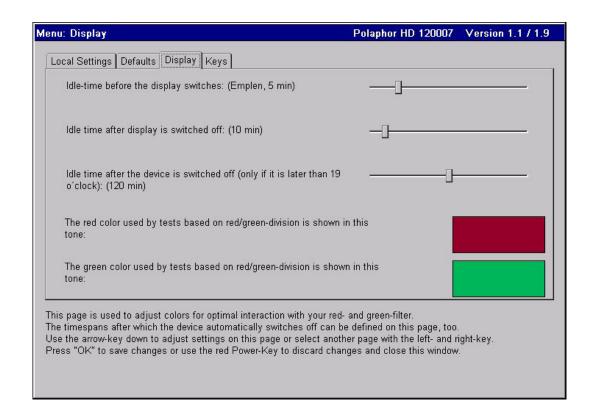
Determines the size of the optotypes after power on. The naming depends on the settings "Naming of chart size".

## Mask after power on

You can start with the group display (max. 2x5 optotypes), a single line (max. 1x5 optotypes) or a single optotype.

## **Displayed Scheme**

If different children symbols are available, the desired set can be chosen. The children symbols can be directly displayed with a push on the remote control's key for children symbols.





#### Change display

After the entered time the display changes. A keystroke on the remote control will end this function.



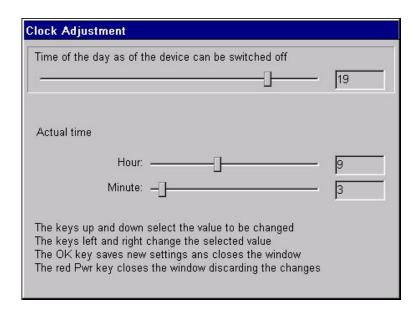
Pushing the "menu" key will open a window where the type of picture (emblem, photo or slideshow) can be selected that will be shown.

### Switch screen off

After the entered time the screen will turn off, the device will enter the stand-by mode. A short push of any key on the remote control will turn on the screen again.

### Switch device off

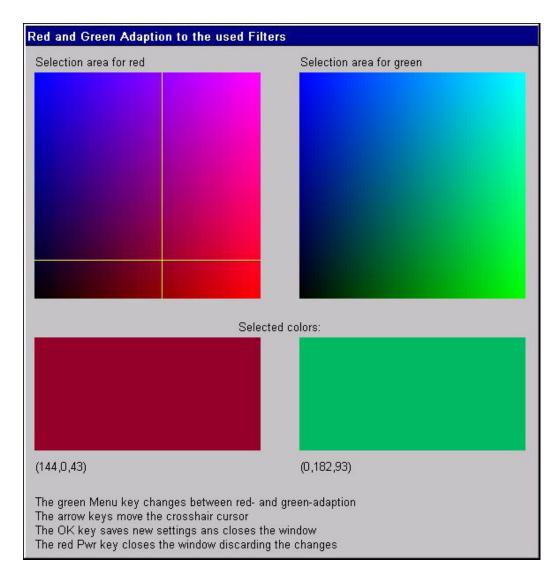
After the entered time the device will turn off. A long push of any key on the remote control will start the computer again.



Pushing the "menu" key will open a window where the local time can bet set.

### Colour adjustment for red

The lenses used for red/green tests in phoropters or trial lenses are different. To achieve optimal results with the Schober and Worth test it is necessary to adjust the colours red and green of the Polaphor HD.

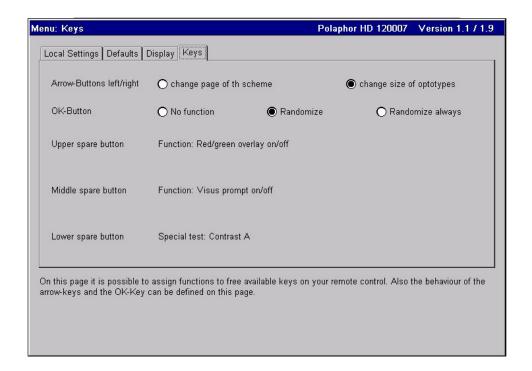


Pushing the "menu" key will open a window where for red/green adjustment. Look through the green filter and move the cross bar with the arrow keys to that area where the colour red is extinguished. Press the "OK" button to keep this value and go back to the menu. Pushing the "menu" key again will directly start the procedure for green colour.



### Colour adjustment for green

The green adjustment is equal to the adjustment of red with the difference that the red filter must be used.



### Arrow keys show next page

The minimum amount of optotypes as noted in the ISO 8596 is shown. Depending on the refraction distance and acuity step the arrow keys \*\* must be pushed more than once to change the acuity step.

### Arrow keys change acuity

The ISO 8596 demands a minimum amount of optotypes per acuity step. The Polaphor HD complies to this standard. When the function is active the acuity step will be increased or decreased with the arrow keys with no care about the standard.

### Random presentation

Three different settings are available:

- always the same optotypes are shown
- always the same optotypes are shown, the randomized optotypes are shown after pressing

the "OK" key

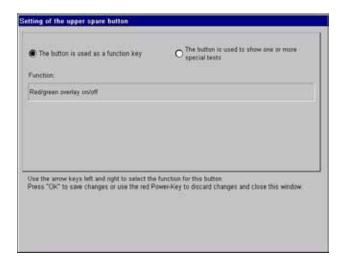
every time the display changes randomized optotypes are shown

### Function of the upper, middle and lower free key

A variety of useful tests can be assigned to the three free keys: These tests can be selected using the "Menu" key.

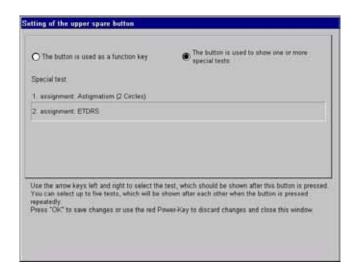
Free key used for a function

Functions like r/g filter or vertical mask are shown by pressing the keys. Pushing the "OK" key will save the actual selection.



Free Key used for special test

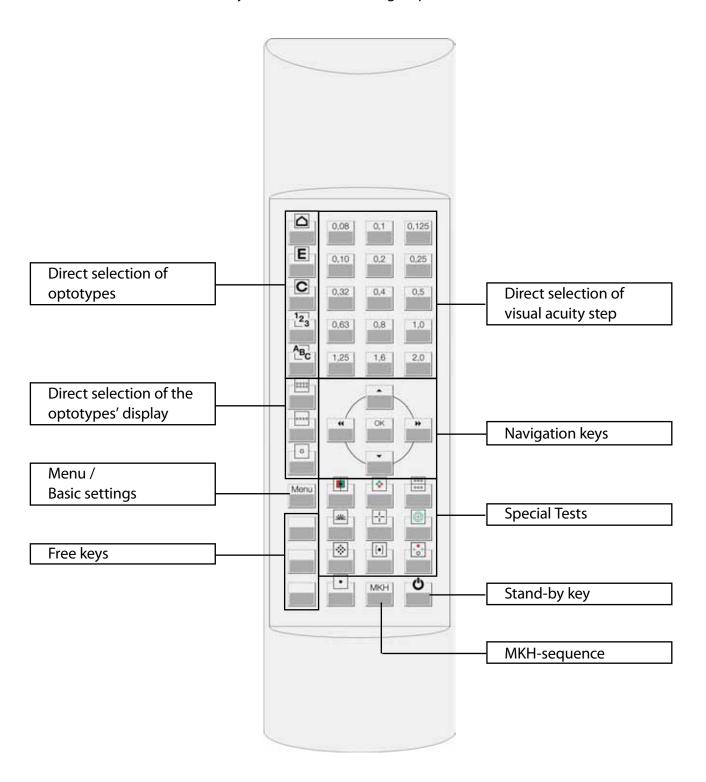
Up to five special tests can be programmed on a free key. Pressing the **★** keys will scroll through the available tests like contrast or ETDRS. For an additional assignment of the same key press the **★** ★ keys. "OK" will save the selection and return to the menu.





## Working with the Polaphor HD

The remote control has 44 keys, which are sorted in groups:



### Direct selection of optotypes

With the following keys the sort of optotypes can be chosen directly:

Children symbols

Tumbling E's

Landolt's rings

Numbers

Letters

## Direct selection of the visual acuity step

The visual acuity step that belongs to the corresponding key is shown with the actual sort and display of optotypes. The acuity steps 0,05 and 0,063 can be reached with the keys **\*** if the acuity step 0,08 is chosen.

## Direct selection of the optotypes' display

The three keys that belong to that function control the display of the optotypes. The following features are available:

Display of one optotype

Display of a row of optotypes

Display of a group of optotypes

#### **Navigation**

The navigation of the Polaphor HD is realized with the four arrow keys and the "OK"-button of the remote control. Depending on the refraction step different functions are possible:

#### a) Menu mode:

When the menu is called with the corresponding "menu"-key, the basic settings of the Polaphor HD can be changed. For a detailed description please read the chapter "menu".



#### b) Refraction mode:

In the refraction mode the arrow keys offer different functions:

With the left and right arrow keys you can switch through the visual acuity steps.
When

the maximum amount of optotypes is shown, as said in the International Standard 8596, the next higher or lower acuity step is displayed.

▲ With the arrow up and down keys the group of optotypes can be changed, the acuity step will stay the same.

With the "OK"-key the randomize function is called if the proper function is enabled in the menu.

#### c) Special tests:

Some keys for the special tests contain more than one test.

With the arrow buttons you can switch through the available tests. You can achieve the same result by pressing the special test key again.

When polarized tests are shown the impression for each eye can be changed by pressing the "OK"-key. If the function is activated an arrow is shown in the lower right corner of the display.

## Menu / basic settings

The menu is shown when the proper key is pressed. To save the changed settings just press the "OK"-key. The changes are active immediately and no restart of the Polaphor HD is necessary. Pressing the "Stand-by"-key will leave the menu and the changes will have no effect.

#### Special tests

The Polaphor HD comes with more special tests than there are keys available on the remote control. That means some keys contain more tests. To show these tests you can press the arrow keys  $\P \ ($  or  $\triangle \ \ )$  or the proper key on the remote control again. The following tests come with the Polaphor HD.

	monocular red/green test
	bichrome balance test, Cowen test
000	binocular test, binocular test with fusion object
<u> </u>	astigmatism wheel, cross pattern
	cross test, cross test with fusion object
( <del>+</del> )	Schober test
<b>*</b>	astigmatism dots
[•]	coincidence test vertical, horizontal
++++	Worth test
•	fixation point
MKH	cross test, pointer test, double pointer test, coincidence test, stereo test (basis 20 mm and 11 mm), stereo test (D5), random-dot hand test, random dot step test, Cowen test

## Stand-by key

By this key the Polaphor HD is switched into the stand-by mode. The stand-by mode is also activated after 5 minutes when no keystroke was made on the remote control.

## Free keys

The linking of the functions/tests with the free keys is set up in the menu. A keystroke on the according key starts the function/test.



#### C-test (Haase/Hohmann)

#### Features:

The C-test is adjustable from a distance of 3.0 - 5.6 meters. If a greater distance is adjusted, the size of 5.6 meters will be kept. This will result in small inaccuracies.

The C-test includes three charts: 30′, 17.2′ and 2.6′ in the acuity steps from 0.16 – 1.25. Each test is divided in three screens with 4 acuity steps. The test can also be shown with children symbols, E's, numbers and letters. The randomizer can be used with the "OK" key.

#### Navigation:

To use the C-test, it must be linked to a free key. Two versions of the C-test are available:

#### C-test /\:

The normal arrangement of the Landolt rings. Small acuity steps are at the bottom of the screen and high acuity steps at the top.

#### C-test \/:

The inverse arrangement of the optotypes: Small acuity steps are at the top of the screen high acuity steps at the bottom.

Pushing the free key starts the C-test with an intersymbol distance of 17.2'. Four acuity steps are shown starting with 0.16. Depending on the chosen test the acuity step can be increased with the  $\blacktriangle$   $\blacktriangledown$  buttons. So you you can switch through the 4 screens of each test.

Press the (4) key to advance to the next test with an optotype distance of 2.6′ (30′). The distance of the actual test is shown in the lower right corner of the screen, the acuity steps are on the left side next to the optotypes.

The C-test can be used with Landolt rings, and also with other optotypes like children symbols, E's, numbers and letters. Just press the appropriate button on the remote control (see page 14) to show children symbols instead of Landolt rings.

During the C-test the display can be varied. It is possible to show just one row or one single optotype. In this case you can navigate with the arrow buttons as normal.

The randomizer can be used by pressing the "OK" button.

To leave the C-test just press a special test key or one key of the direct acuity selection.

#### Special note!

- if the C-test is shown with a distance of 30′, push the **4** key to go directly to the 2.6′ test.
- the function "show/do not show chart size" can be linked to another

#### free key and be used in combination with the C-test

#### **ETDRS** test

#### Features:

The ETDRS-test is adjustable for a distance of 3.0 – 6.0 meters. The standard charts and the revised ones with each 3 tests are integrated. The randomizer can be used during the ETDRS test by pushing the "OK" button.

#### Navigation:

To use the ETDRS-test, it must be linked to a free key. Two versions of the ETDRS-test are available:

ETDRS: The standard sequence from 1982 (chart R, 1, 2) Revised ETDRS: The new sequence of the letters (chart 1, 2, 3)

Press the free key to start with the (revised) ETDRS test chart R(1). Outgoing from the highest acuity step as many rows as possible are shown. Lower acuity charts can be shown by pressing the button. There the width of the screen is to small to show all 5 letters, the keys can be used to scroll to this letters.

Press the free key again to advance to the next chart 1(2). Another press leads to the chart 2(3). The name of the actual test is shown in the lower right corner of the screen, the acuity steps are on the left side next to the letters.

During the ETDRS test the display can be varied. It is possible to show just one row or one single optotype. In this case you can navigate with the arrow buttons  $extbf{ iny}$  as normal.

The randomizer can be used by pressing the "OK" button.

To leave the ETDRS test press any key, except the navigation buttons.

Special note! The function "show/do not show chart size" can be linked to another

free key and be used in combination with the ETDRS test

#### **Contrast Type A**

#### Features:

During the refraction it is possible to change the contrast of the optotypes. The following contrast levels are available:



75%, 50%, 40%, 30%, 20%, 10%, 7.5%, 5%, 3%, 1.5%, 1%, 0.5%

When the contrast test is active, the group of optotypes, the acuity step and the display of the optotypes can be changed as well as the randomize function can be used with the direct selection buttons on the remote control. A small picture of the displayed optotypes can be seen in the lower left area of the display. Just one contrast level is diplayed per screen.

Navigation:

To use the Contrast Test A, it must be linked to a free key.

Pressing the free key changes the contrast to 75%. Each press of the key lowers the contrast at the mentioned values, pressing the key increases the contrast.

#### Snellen bars

The Snellen bars, a special astigmatism figure, is integrated in the sequence of the other astigmatism tests like astigmatism wheel and cross pattern.

The figure can also be linked to a free key.

#### Astigmatism test

The astigmatism test is chosen in the menu and linked to a free key. By pushing this key an astigmatism circle is shown two acuity steps less than the actual acuity step. The size of the circle can be changed either with the arrow keys or with the direct acuity selection key. To leave the test the free key must be pressed again.

Special note!

The function "show/do not show chart size" can be linked to another free key and be used in combination with the astigmatism test

#### **Pictures**

The Polaphor HD can show different pictures like an emblem, photo or a slideshow.

The pictures must be a JPG file and should have a size of 1920x1080. Copy them to a memory stick and plug it into the USB port. A message window appears and the pictures are copied to the internal memory. If a memory stick with pictures on it is connected to the Polaphor HD once more the existing images are replaced by the new ones.

#### **Emblem**

The name of the file must be "Logo.jpg".

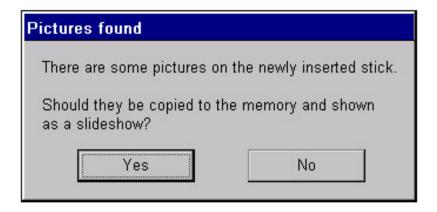
#### **Foto**

The picture can have any name, but there must be only one picture on the memory stick.

#### Slideshow

The pictures can have any name, but there must be more than one picture on the memory stick. Should the pictures be displayed in a desired sequence, the must be sorted on the memory stick before copying them to the Polaphor. It is advisable to name them picture1, picture2 etc.

An existing slideshow will be deleted when the new one is copied to the Polaphor.





#### Optional tests and modules

### Contrast and acuity B

#### Features:

The contrast and acuity test B simulates the Freiburg Acuity and Contrast Test, developed by Professor Bach. It is a test subject steered test, at which the shown contrast values or acuity steps are calculated with the Best PEST method and Maximum Likelihood algorithm.

#### Navigation:

To use the contrast or acuity test B, it must be linked to a free key. Another push on the remote control opens a new window as shown below, where different settings must be made to guarantee correct results.





Optotype: determines the kind of optotype, that is used during the test

Distance: the distance can be entered with the arrow keys. The distance ranges from 0,2 - 8,0 meter and is <u>independent</u> from the refraction distance in the main menu.

Display: if you work with a path-folding mirror you have to mark it here

Size of the optotype: determines the size of the chosen optotypeduring the test

Contrast of the optotype: determines the contrast of the chosen optotype during the test

Number of trials: determines how often the patient has to recognize the alignment of the optotype

Every 6th trial easy: motivates the patient with an easy to recognize optotype

Number of directions: choose between 4 or 8 directions when using the Landolt ring

TimeOut: a value of "0" means the patient has infinite time for his response, otherwise after the entered time the response is treated as not recognized

ISO-correction: the result is adapted to the demands of the ISO 8596

Pressing the appropriate key starts the test. The patient has to enter on the separate remote control where he sees the opening of the Landolt ring. Depending on the responses the next contrast level or acuity step will be calculated. If the patient doesn't see an opening he has to guess (forced choice). At the end of the test sequence the contrast threshold or acuity will be shown.

The test can be quit at any time pressing any key on the remote control. A press on the free key will start a new test sequence.

#### Ishihara

#### Features:

The "Ishihara" Test consists of 24 plates. The plates are distance dependent from 0,4 - 1,6 meter. The size of the plates will not change at a distance larger than 1,6 meter.

#### Navigation:

To use the Ishihara Test, it must be linked to a free key. Another push on the remote control opens a new window as shown below, where different settings can be customized.

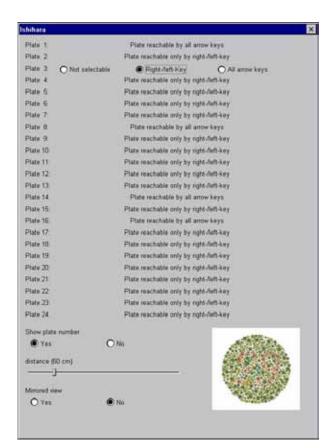


Plate 1 - 24: for each plate can be defined if it should be shown or which of the arrow keys must be pressed to get to the plate.

Show number of the plate: shows the number of the plate in the lower right corner of the display or hides it.

Start Ishihara Test with: detemines the plate which starts the sequence

Distance: the distance can be entered with the arrow keys. The distance ranges from 0,4 - 1,6 meter and is <u>independent</u> from the refraction distance in the main menu. The size of the plates will not change at a distance larger than 1,6 meter.

Display: if you work with a path-folding mirror you have to mark it here



The test can be quit at any time pressing any key on the remote control. A press on the free key will start a new test sequence.

# **Errors**

description The display is dark	possible causes  Connector plug missing	correctives  Connect the appliance plug with the socket and turn on the system
	Fuse defect	Check the two fuses in the drawer of the main switch
	The Polaphor HD is in the stand-by mode	Press any key on the remote control for about 1 second.
The remote control doesn't work	Batteries are empty.	Change the batteries.
	The IR receiver is covered.	Make sure a free line of sight to the receiver is existing
The separation is not optimal	The Polaphor HD is not aligned.	Loose the screws on the ball joint and align the Polaphor HD
The wrong optotypes are shown or change autonomous.	Other instruments control the Polaphor HD.	A new coding of the remote control is required. Please contact the service hotline.



## Software update

A software update can consist of up to two files with the typical suffix \*.upd. These files must be copied into the main directory of a memory stick. If the stick is plugged into the Polaphor HD it will be recognized automatically.

A window appears asking to install the update. Select the desired option with the  $\blacksquare$   $\blacksquare$  key and confirm with the "OK" key.

After installing the update the Polaphor HD must be restarted.

# Description

examination distance:	3,0 – 7,0 meters, in steps of 10cm
visible area:	about 530x297mm
frame color	similar RAL 9016
color coordinates white (CIE):	x 0,31 / y 0,33
control:	IR remote control, 44 keys
axis of polarization:	45°/135°
acuity steps:	0,05-2,0 (logarithmic)
charts:	Landolt's rings*
	tumbling E's
	letters
	numbers
	children symbols
	Schober test
	Worth test
	cross test
	pointer test
	double pointer test
	coincidence test
	stereo test (base 20mm and 11mm)
	stereo test (base 20mm and 11mm)
	stereo test (5" to 30")
	random dot hand test
	random dot stufen test
	binocular test
	Cowen test
	bichrome balance test
	monocular red/green test
	astigmatism wheel
	cross pattern
	astigmatism dots
	fixation point



masking:	single, row and group display
naming of charts:	visual acuity steps, logMAR, fraction in meter or feet
misc:	random display of optotypes
	use with path folding mirror possible
	own tests can be implemented
	stand-by mode

<sup>\*</sup> The display of the Landolt's rings is conform with the ISO 8596.

# Technical data

dimensions (incl. wall mount):	W 642 mm / H 440 mm / D 235 mm		
weight:	13,5 kg		
main voltage:	230 V/50 Hz		
power consumption:	60 watts active		
	10 watt stand-by		
panel quality:	complies ISO 13406-2 / Class II		
fuses:	primary: 2 x 3,15A T		
maintenance and			
calibration intervals:	every 5 years		
operation conditions:			
temperature of the environment	between +10°C and +40°C		
relative humidity	between 30% and 75%		
air pressure	between 800hPa and 1060hPa		



### **Declaration of conformity**

For the following named product

Visual acuity system by Block Optic Ltd.

Polaphor HD

It is confirmed that the product meets the requirements as determined by the European Community:

89/336/EWG

electromagnetic compatibility

93/42/EWG

medical products

Evaluation of the products complies with the standards listed below:

EN 60601-1

Medical electrical equipment. General requirements for basic

safety and essential performance

EN 55011

emission of electromagnetic interference

IEC 801

immunity from electromagnetic interference

This declaration in responsibility for the manufacturer:

Block Optic Ltd., Rosenowstr. 18, 44141 Dortmund, Germany

is submitted by:

H. C. Block, Geschäftsführer

rechtsgültige Unterschrift

Dortmund, Germany

March 2011

(place)

(date)



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