VISUPHOR 500
Digital phoropter

Documentation set

ZEISS

Contents

User manual
VISUPHOR 500
Digital Phoropter
[000000-2075-933-GA-en-GB-230822]

VISUPHOR 500
Digital phoropter

User manual

Notice

FCC Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

FCC Caution:

Any changes or modifications not expressly approved by the party responsible

for compliance could void the user's authority to operate this equipment.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.

IMPORTANT NOTE:
FCC Radiation Exposure Statement:
This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

This equipment should be installed and operated with minimum distance 20 cm between the radiator and your body.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

IC Statement

This Class B digital apparatus complies with Canadian ICES-003.

Cet appareil numérique de la classe B est conforme á la norme NMB-003 du Canada.

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

This radio transmitter (identify the device by certification number or model number if Category II) has been approved by Industry Canada to operate with the antenna types listed below with the maximum permissible gain indicated. Antenna types not included in this list, having a gain greater than the maximum gain indicated for that type, are strictly prohibited for use with this device.

This device and its antenna(s) must not be co-located or operation in conjunction with any other antenna or transmitter.

The device could automatically discontinue transmission in case of absence of information to transmit, or operational failure. Note that this is not intended to prohibit transmission of control or signaling information or the use of repetitive codes where required by the technology.

IMPORTANT NOTE:

IC Radiation Exposure Statement:

This equipment complies with IC RSS-102 radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator & your body.

Cet équipement est conforme aux IC RSS-102 des limites d'exposition aux rayonnements définies pour un environnement non contrôlé.

Contents

Notes on the user manual

Purpose and availability of the documentation

This user manual describes the safety precautions, functions, usage, performance parameters and care and maintenance measures of the VISUPHOR 500 Digital Phoropter.

Correct operation of the system is imperative for its safe and successful function. You should therefore ensure that you are thoroughly familiar with this user manual before setting up and using the VISUPHOR 500 the first time.

The user manuals and other documentation enclosed with the VISUPHOR 500 should be kept accessible to users at all times to ensure that the information required for use of the VISUPHOR 500 is readily available.

Questions and comments

If you have any questions or comments concerning this user manual or the VISUPHOR 500, please contact ZEISS service or your local dealer. (Contact details see reverse).

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Explanation of symbols used

The symbols used in this user manual refer to important safety information which may warn against possible health risks or fatal injuries and contain useful notes. Whenever you see these symbols, read the accompanying information carefully and observe all safety notes and information in this user manual and on device labels.

WARNING

Indicates a hazardous situation which could result in death or serious bodily injury if the appropriate safety precautions are not heeded.

CAUTION

Indicates a hazardous situation which could result in minor or moderate injury if the appropriate safety precautions are not heeded.

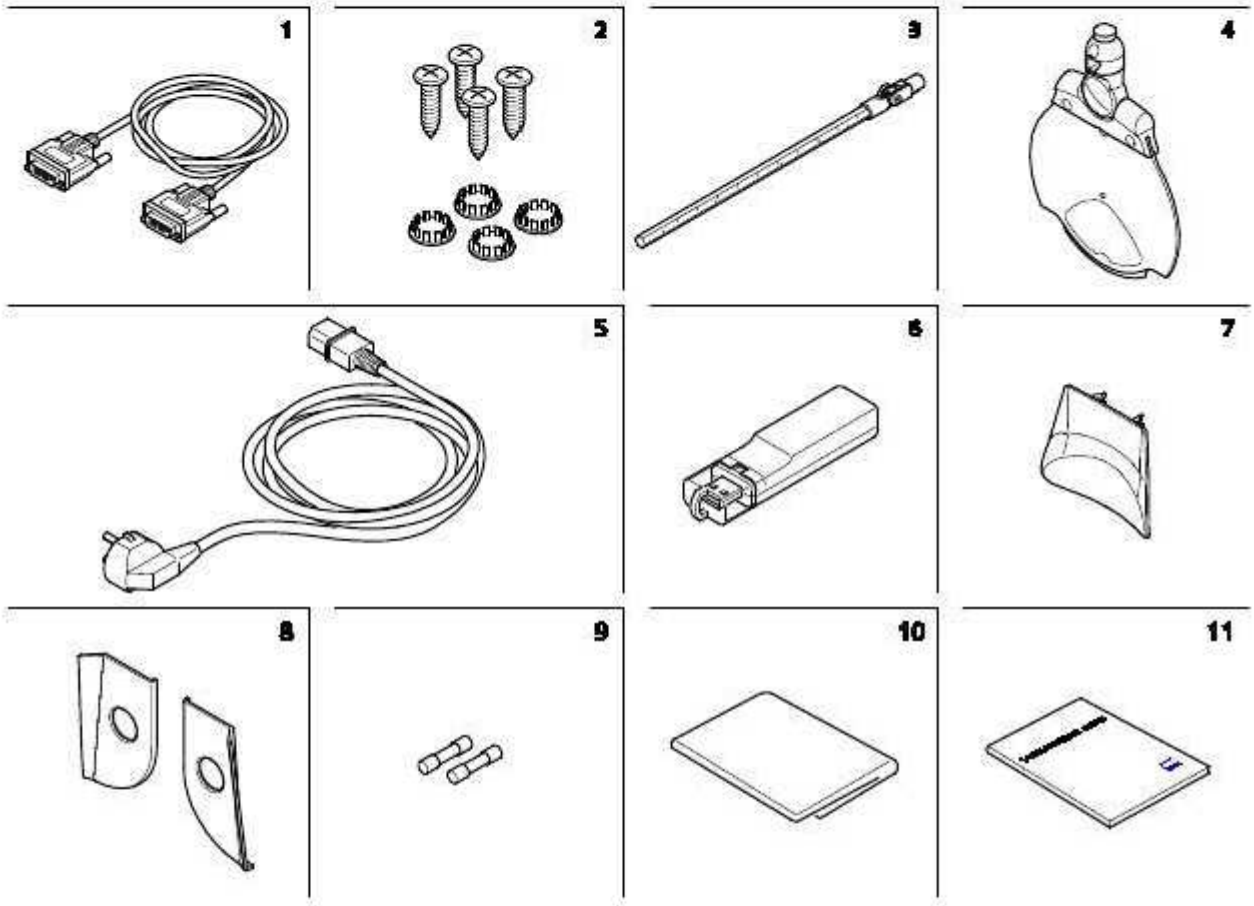
CAUTION - PROPERTY DAMAGE

Indicates possible device damage if the appropriate safety precautions are not heeded.

Information, hints and advice for better understanding of the instructions to be observed in the operation of the device.

Package check list

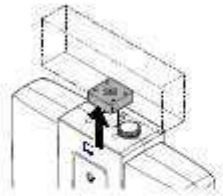
The package includes the basic device comprising the phoropter head and junction box and also the parts shown below.



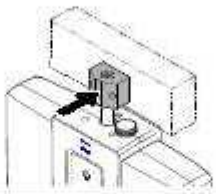
1 Phoropter head connecting cable
2 Fastening screws with screw covers for covering the connector compartment (Fig. 27)
3 Fixing rod for near-point chart (length 70 cm)
4 Near-point chart
5 Power cable for junction box
6 Bluetooth®/USB adapter
7 Forehead rest (replacement part)
8 Face rests (replacement part)
9 Fuses (replacement part)
10 Dust cover
11 Documentation set

Fig. 1 Package check list (without assembly adapter)

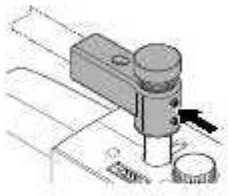
Adapter for mounting the device to the bottom part of a support arm



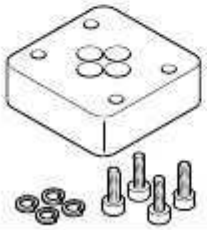
Adapter for mounting the device to the front part of a support arm



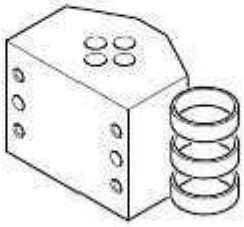
Adapter for mounting in axial direction of a support arm



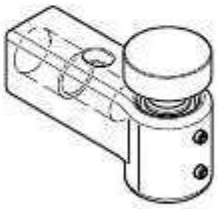
ZDR10 including mounting set (4 Allen screws M4x12mm and 4x corresponding E-rings D 7.4 mm)



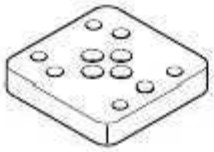
ZDR18 with 3 spacers



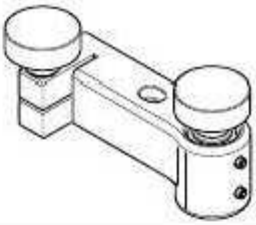
ZDR19



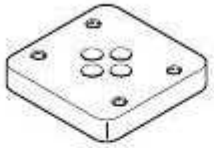
ZDR14



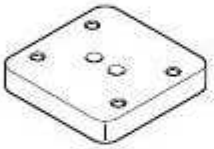
ZDR20 (optional)



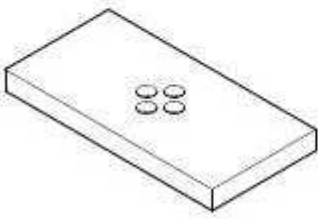
ZDR15



ZDR16

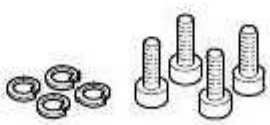


ZDR17



Mounting set 1:
4 Allen screws M3x10 mm,
4 corresponding E-rings D 5.4 mm

Mounting set 2:
4 Allen screws M4x10 mm,
4 corresponding E-rings D 7.4 mm



Mounting set 3:
Allen screw M5x15 including washer D 9.8 mm (fixed to ZDR 19)
Phillips screw 0.25″x16 mm

Fig. 2 Package check list of assembly adapters and corresponding mounting sets

Country-specific information and labels

Classification/Manufacturer's declaration

WARNING - GENERAL HAZARD

This device may be set up, operated and used only for the intended use and in accordance with local country-specific regulations, generally accepted engineering standards and occupational safety and accident prevention regulations. Further notes on classification are to be found in Section *Technical data*, page 56 and following.

EMC:	See Section *Electromagnetic compatibility*, page 58 and following.
HF transmitter:	See Section *Technical data/HF transmitter specifications*, page 57.
UMDNS No.:	13-313

This declaration shall be rendered invalid if changes are made to the product without the manufacturer's authorization.

The junction box for VISUPHOR 500 corresponds to the relevant requirements in the EU Directive on radio installations and telecommunication equipment. The corresponding declaration of conformity can be obtained in English from Carl Zeiss Meditec AG (contact details on reverse).

Intended use

VISUPHOR 500 Digital Phoropter is used to identify refractive values based on feedback from the patient being examined (subjective refraction). The device is used to support eye care/ophthalmology specialists (ophthalmologists, optometrists and opticians) when prescribing corrective eyeglasses and contact lenses.
VISUPHOR 500 Digital Phoropter is a computer-controlled unit for the subjective refraction of patients. In addition to identifying the refractive values, the unit is also used to detect anomalies in the patient's binocular vision, such as muscle balance, binocular balance, anisoconia, fusion, stereopsis etc.

Patient population

The device was developed for a wide patient population.
In principle, people of all age groups can be examined in accordance with the side effects and contraindications.

Side effects/contraindications

VISUPHOR 500 Digital Phoropter should not be used for:

- Patients who cannot provide any usable feedback (infants, mentally retarded persons, ...).
- Patients who are not able to bring themselves into position in front of the device as a result of their physical condition (e.g., due to their physical size, postural defects, ...) or to keep still (e.g., due to Parkinson's disease).
- Patients who could be injured by using the device (e.g., injuries to their forehead or face).
- Patients with infectious eye diseases.
- Patients who wore contact lenses directly prior to examination.

Intended user profile

CAUTION - RISK ARISING FROM OPERATING ERRORS

This device may only be installed, operated, used and maintained by persons who have been properly trained or who have the required knowledge and experience to do so. Please also adhere to the national qualification guidelines applicable in your country.

Notification to manufacturers and authorities

In member states of the European Union, the responsible organization or person must report serious incidents to his competent authority. In all other countries, comparable rules apply where national legislation so requires.

Disposal of the product

The packing material should be kept to be used for a future move or for repairs.

If you want to dispose of the packing material, please use a recognized collection system for recycling.

The system contains electronic components. At the end of the service life, the device and the batteries installed in it have to be disposed of properly according to the national laws.

Disposal of the device within the EU

In accordance with applicable EU guidelines and national regulations at the time at which the product was brought onto the market, the product specified on the consignment note is not to be disposed of via the domestic waste disposal system or communal waste disposal facilities.

For detailed information on the disposal of the product, please contact your local dealer or the device manufacturer or its legal successor company. Please read latest Internet information provided by the manufacturer.

Where the product or its components are resold, the seller must inform the buyer that the product must be disposed of in accordance with the currently applicable national regulations.

External labels

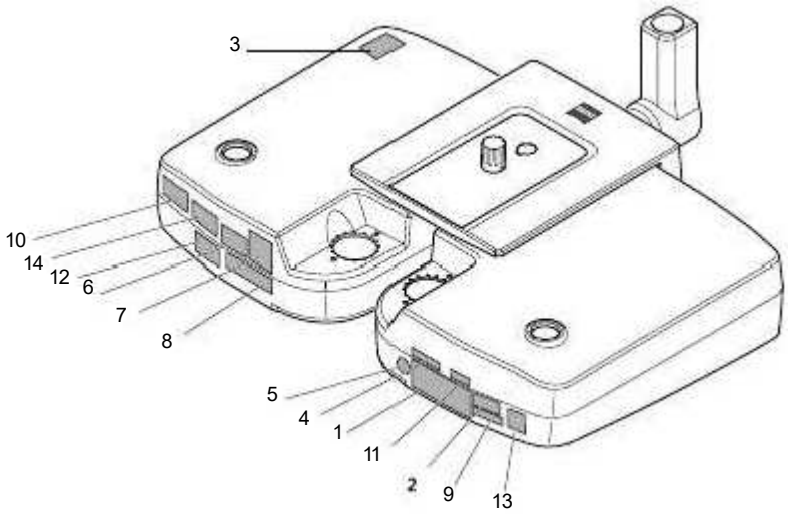
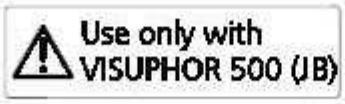


Fig. 3 Warning and information labels on the VISUPHOR 500

Item	Label	Explanation
1		Type label Manufacturer Date of manufacture Applied part type B DC voltage
2		Identification label **REF** Catalogue number/part number **SN** Serial number Bottom: Serial number as barcode
3		Device identification code (data matrix, serial number, and device name)
4	Not applicable	Not applicable
5		"Observe user manual" information label
6		CE approval label and disposal advice for EU EU conformity symbol with identification number of notified body Disposal advice for EU
7		UL approval for USA and Canada
8		Warning label Use of the approved junction box

Item	Label	Explanation
9	lade Korea	Country of origin label
10	Not applicable	Not applicable
11	Not applicable	Not applicable
12	MD	Label for marking the device as a medical device
13	Not applicable	Not applicable
14	Not applicable	Not applicable

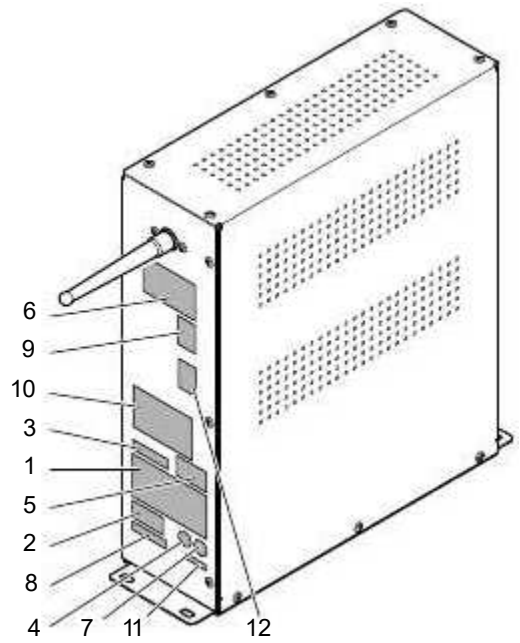


Fig. 4 Warning and information labels on the junction box

Item	Label	Explanation
1		Type label Manufacturer Date of manufacture Applied part type B AC voltage DC voltage
2		Identification label **REF** Catalogue number/part number **SN** Serial number Bottom: Serial number as barcode
3	Not applicable	Not applicable
4		"Observe user manual" information label
5		CE marking label and disposal advice for EU EU conformity symbol with identification number of notified body Disposal advice for EU
6		Label with the MAC address of the Bluetooth module and the registration numbers for the USA, Canada and Japan
7		"Disconnect device from the power supply before opening" information label
8		Country of origin label
9		HF transmitter (see Section *Electromagnetic compatibility*/page 58)

Item	Label	Explanation
10		Approval label for Brazil
11	Not applicable	Not applicable
12	Not applicable	Not applicable

Performance specifications

Functional description

The VISUPHOR 500 digital phoropter allows the subjective refraction for a patient to be determined easily within a very brief period. Objective refraction data, as provided by an automated refractometer/keratometer (ARK) can be transferred directly to the phoropter control unit via a digital interface. It then can be used as the starting point for the interactive optimization phase controlled by patient feedback. In order to navigate the individual stages in the subjective refraction process, VISUPHOR 500 is included in a fully-integrated digital refraction system, which provides an intuitive user interface and which controls the digital phoropter as well as the visual acuity chart projector VISUSCREEN (see *"VISUSCREEN 100/500 user manual - Subjective refraction with VISUPHOR 500"*).

VISUPHOR 500 itself comprises the two components of the phoropter head and the junction box.

To simplify matters, the phoropter head itself is referred to as VISUPHOR 500. It includes more than one hundred precision lenses which are swiveled into the two examination windows that the patient looks through. These movements are controlled by the computer. In addition the distance between the examination windows can be set up according to the pupil distance of the patient, and the angle of inclination between them can be varied.

The VISUPHOR 500 junction box (JB) supplies the digital phoropter with electricity. Furthermore, it also offers two RS232 interfaces to connect an autorefractor and a digital lensmeter for transferring the objective refraction data. Communication with the VISUSCREEN control unit is via the Bluetooth interface.

Characteristics

VISUPHOR 500 offers the following functions:

- Set-up for sphere, cylinder, prism
- Various special lenses: cross-cylinder, Maddox rod, red/green filter, polarizing filter, ...
- Automated occlusion of the examination window to minimize the adaptation of the patient's eye during the change of lens
- Setting up pupil distance
- Variation of working distance for close range

Detailed information on value ranges, tolerances, etc. can be found in Section *Technical data*, page 56 and following.

Service life

WARNING - GENERAL HAZARD

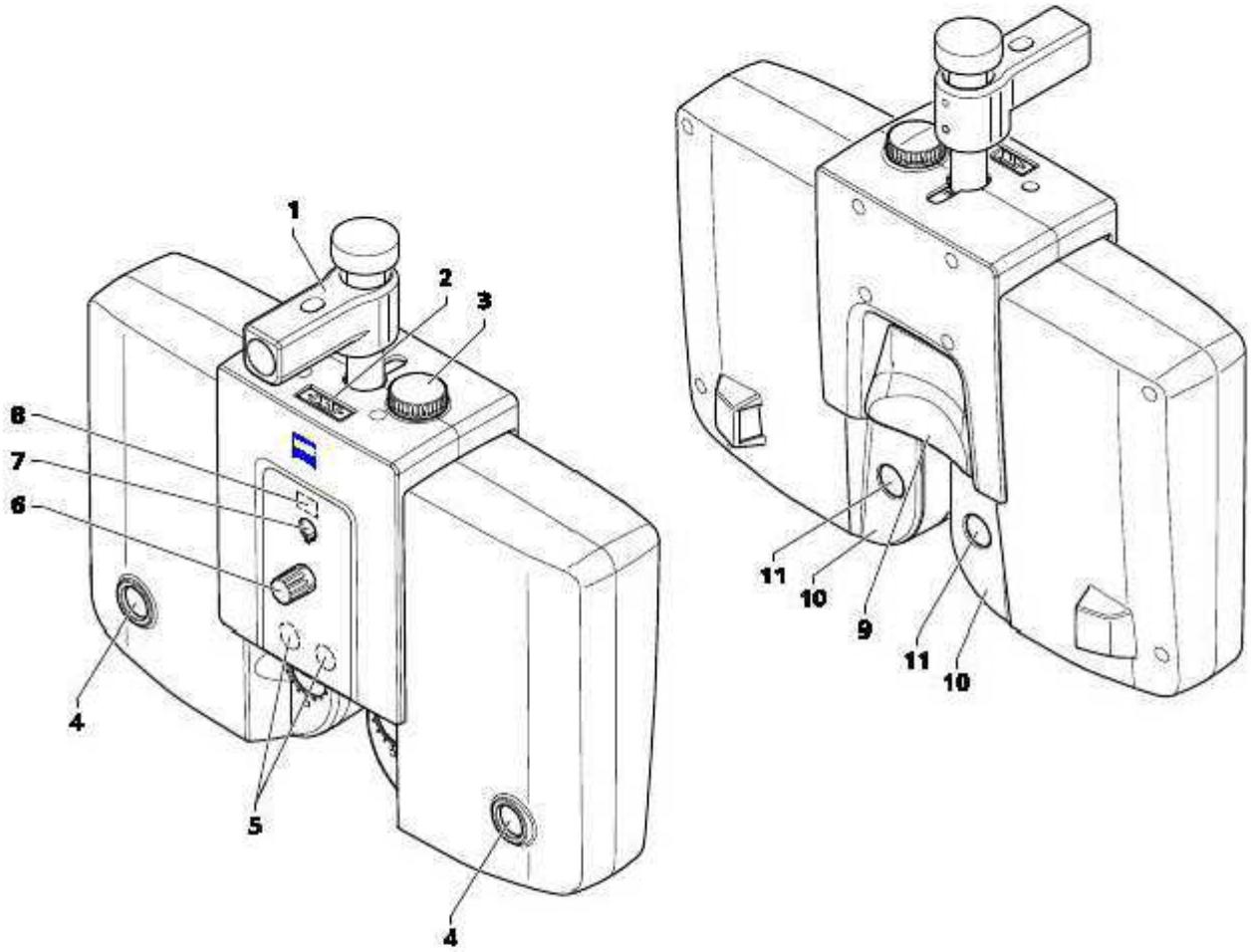
The development, production and maintenance of this device, together with associated risks, are based on an expected service life of seven years, assuming that the device is serviced at the specified intervals.

Modifications to the product or failure to follow the manufacturer's instructions may substantially reduce the expected service life and significantly increase the risks associated with the use of this device.

It is the responsibility of the institution operating this product to follow the manufacturer's instructions and to decide on the risk/benefit ratio upon expiration of the expected service life or maintenance and inspection intervals specified by the manufacturer.

Description of the device

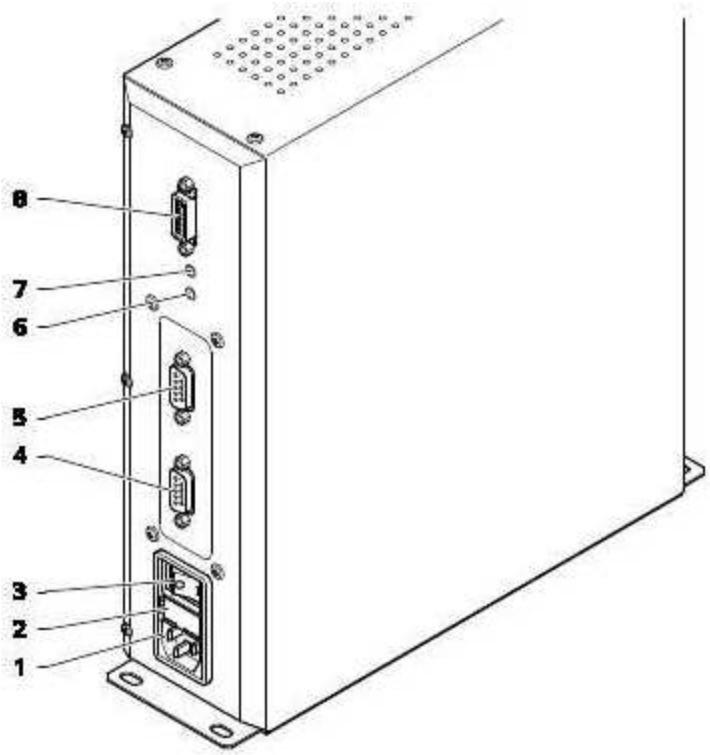
Phoropter head



1 ZDR19 assembly adapter
2 Spirit level
3 Leveling screw to orient the phoropter head on the horizontal plane using the spirit level
4 Control window for the patient's corneal vertex distance
5 Illumination for near-point chart
6 Adjustment screw for forehead rest to set up the corneal vertex distance
7 Mount for the fixing rod of the near-point chart
8 Control lamp forehead rest
9 Forehead rest
10 Face rest
11 Examination window

Fig. 5 VISUPHOR 500 - Control and functional elements on operator and patient side

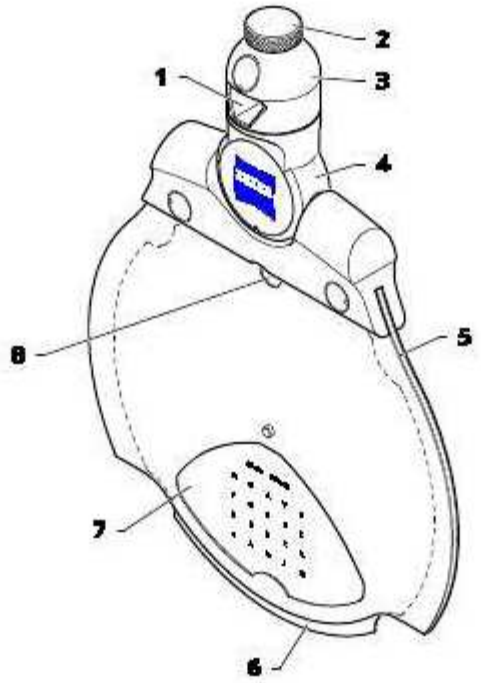
Junction box



1 Power connection - appliance socket for connection to the power cable
2 Fuse compartment - slot for device fuses
3 Power switch (on/off) - toggle switch for switching the device on (I) and off (O)
4 Interface Com2 for connecting an autorefractor or digital lensmeter
5 Interface Com1 for connecting an autorefractor or digital lensmeter
6 Two-color status LED (green/blue)
green: device is ready for use
blue: Bluetooth connection with VISUSCREEN control unit is available
7 Service button - may only be used by trained service technicians
8 Interface for connecting the phoropter head

Fig. 6 Junction box - Control and functional elements

Near-point chart



1 Mounting for fixing rod
2 Screw to fix the near-point chart to the fixing rod
3 Head section of near-point chart
4 Intermediate piece
5 Body of near-point chart
6 Turntable with 8 optotype cards (four each on front or rear of turntable)
7 Viewing window for selected optotype card
8 Field for showing card number

Fig. 7 Near-point chart - functional elements

Installation

Notes on installation and use

WARNING - GENERAL HAZARD

Do not store or operate the device in ambient conditions other than those prescribed (see Section *Technical data*, page 56).

The device should be set up so that the power cable can be disconnected from the power supply quickly and easily without any tools.

WARNING - RISK OF ELECTRIC SHOCK

When connecting external devices to the interfaces of the device, you are configuring a medical system. The operator is responsible for operating of the device and for meeting the safety and EMC requirements defined in IEC 60601-1-1 or IEC 60601-1:2005, chapter 16 (medical electrical systems) and IEC 60601-1-2.

Do not use additional extension cables or portable multiple sockets.

The electrical installation must conform to IEC 60364-7-710 or the applicable national regulations. This includes the integration of a ground fault circuit interrupter (GFCI).

To avoid the risk of electrical shock, this device may only be connected to a power supply network which is provided with a protective ground conductor.

Ensure that the power supply connector is suitable and certified for the local connection. If the supplied power cable must be replaced, the following specifications must be adhered to as a minimum:

- Protective ground conductor resistance maximum 0.1 Ω
- Local certification of the power cable for connection to medical devices
- Device plug C13 conforming to IEC 60320
- Cross-section at least 0.75 mm^2/AWG 18
  Hospital Grade design for specific countries (e.g. USA, Canada)
  (For cables > 2.5 m the cross-section must be increased to 1.5 mm^2)

This device generates, uses and emits high-frequency radiation and can cause disruptions to other devices in the vicinity. This type of disruption could indicate improper or manipulated installation. Please contact ZEISS Service or your dealer if this device causes damage or disruption to other devices (contact information see reverse).

WARNING - FIRE HAZARD

The device is not suitable for operation in explosion risk areas (e.g. combustible mixture of anesthetic, cleaning or disinfecting agents with air, oxygen or nitrous oxide).

The electrical installation must conform to IEC 60364-7-710.

CAUTION - PROPERTY DAMAGE

Do not store or use this device in damp rooms. Do not expose the device to water splashes, dripping water or sprayed water.

Please also observe the following information when selecting a suitable location to install the device:

- Do not expose the device to direct sunlight. Sunlight and strong light can impact the results of the examinations.
- Avoid locations where temperatures can be expected to fluctuate strongly (e.g. close to heating units or windows). This leads to steam condensing on the protective glass in the examination window and on the optical components inside the device.

Do not expose the device to mechanical shock or vibration.

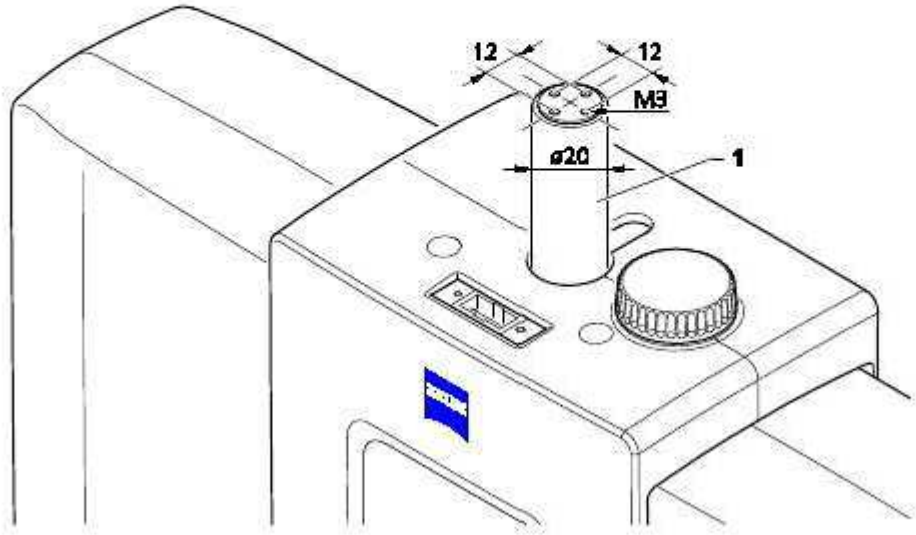
Unpacking and installing the device

The device will be unpacked and installed by one of your dealer's specially trained technicians.

Please ensure that the structure handed over to you is not changed.

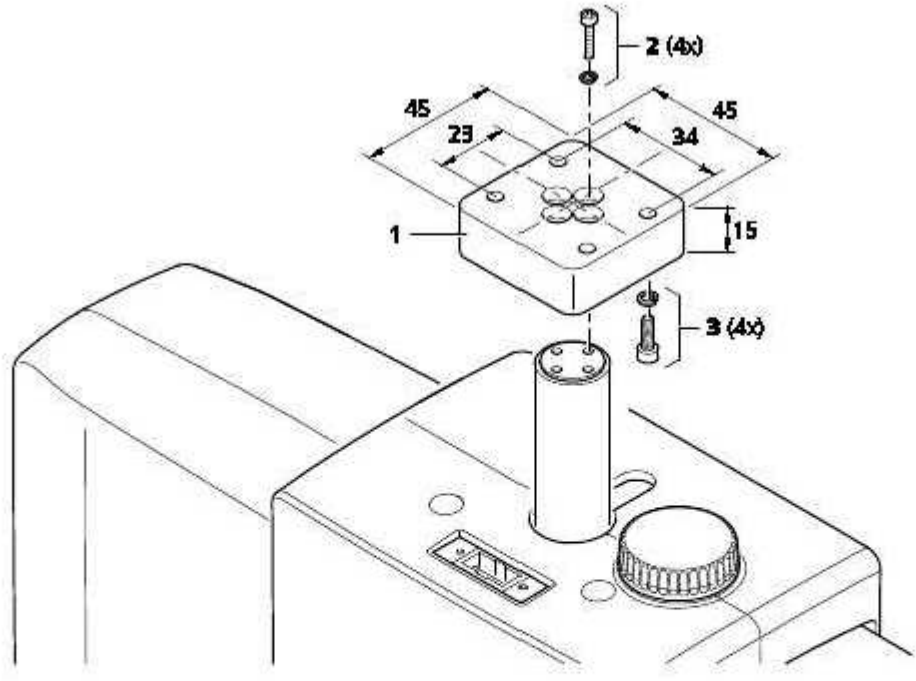
Please pay attention to ensure that the area directly surrounding the junction box, in particular the side with the ventilation slits, is kept free of other items.

Interfaces to mount the phoropter head



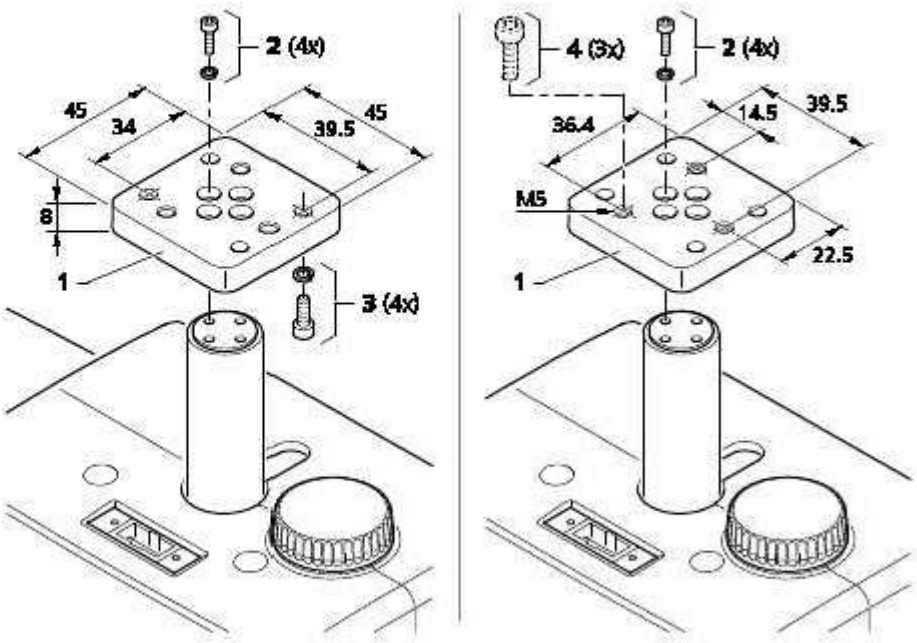
1 Fixing bolts

Fig. 8 Interface dimensions for vertical mounting of the phoropter head



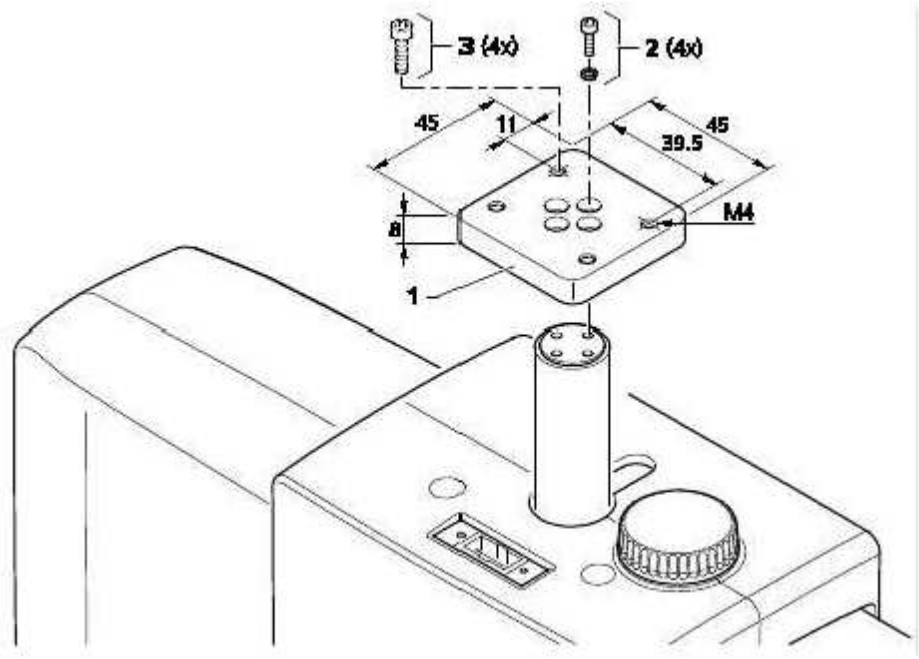
1 Assembly adapter ZDR10
2 Screws (M3x14 mm) and corresponding E-rings belonging to ZDR19 (see **3**, Fig. 15)
3 Screws and corresponding E-rings for mounting set belonging to ZDR10

Fig. 9 Interface dimensions for mounting the phoropter head with the assembly adapter ZDR10



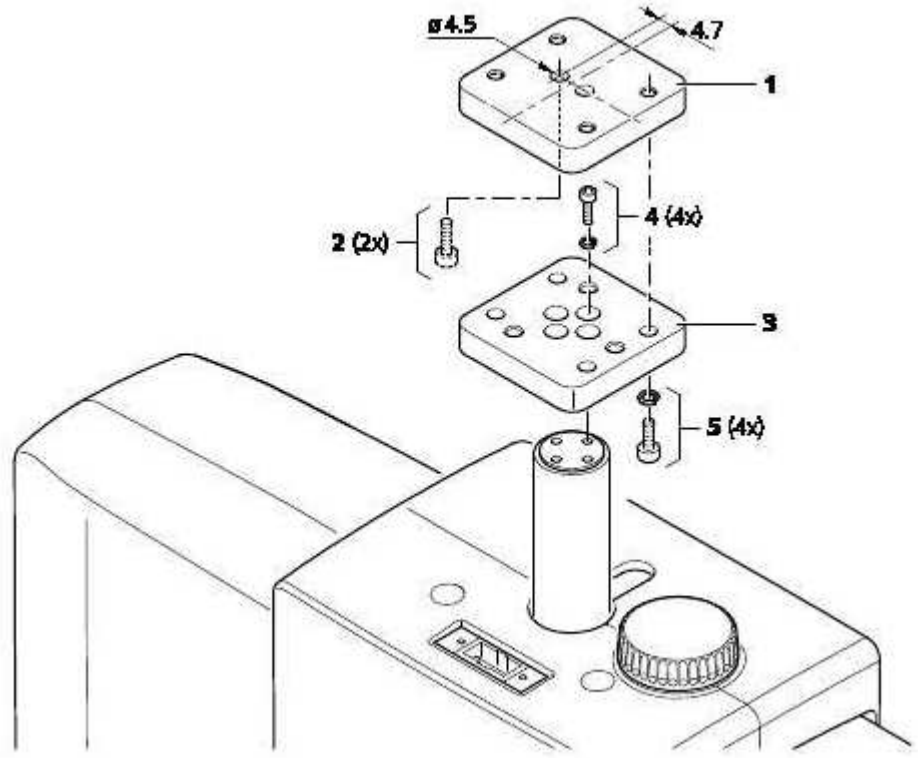
1 Assembly adapter ZDR14
2 Screws and E-rings from mounting set 1
3 Screws and E-rings from mounting set 2
4 Screws not included in the package (use screws (M5) fitting to supporting arm)

Fig. 10 Interface dimensions for mounting the phoropter head with the assembly adapter ZDR14



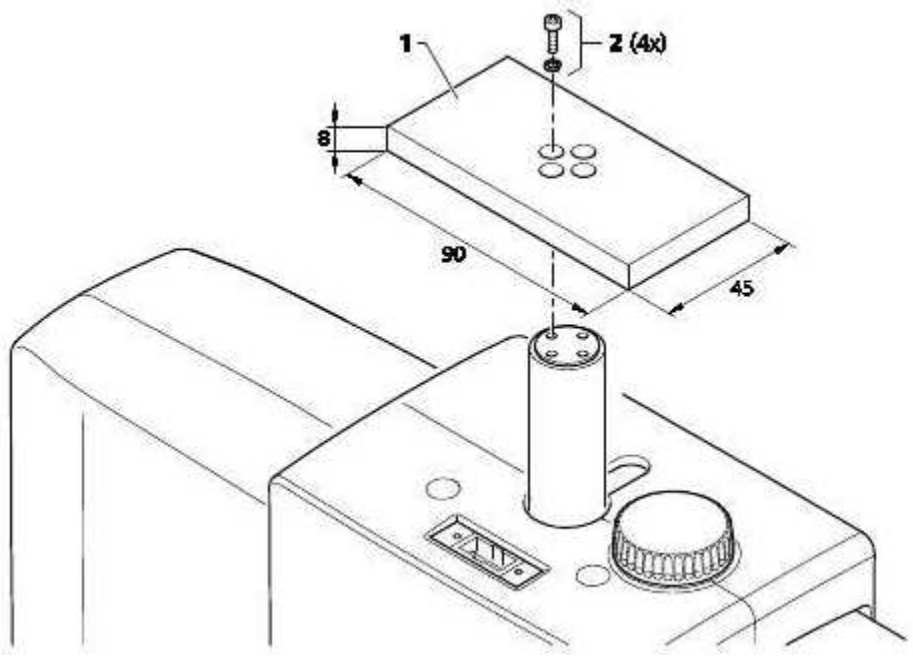
1 Assembly adapter ZDR15
2 Screws and E-rings from mounting set 1
3 Screws not included in the package (use screws (M4) fitting to supporting arm)

Fig. 11 Interface dimensions for mounting the phoropter head with the assembly adapter ZDR15



1 Assembly adapter ZDR16
2 Screws not included in the package (use screws (M4) fitting to supporting arm)
3 Assembly adapter ZDR14
4 Screws and E-rings from mounting set 1
5 Screws and E-rings from mounting set 2

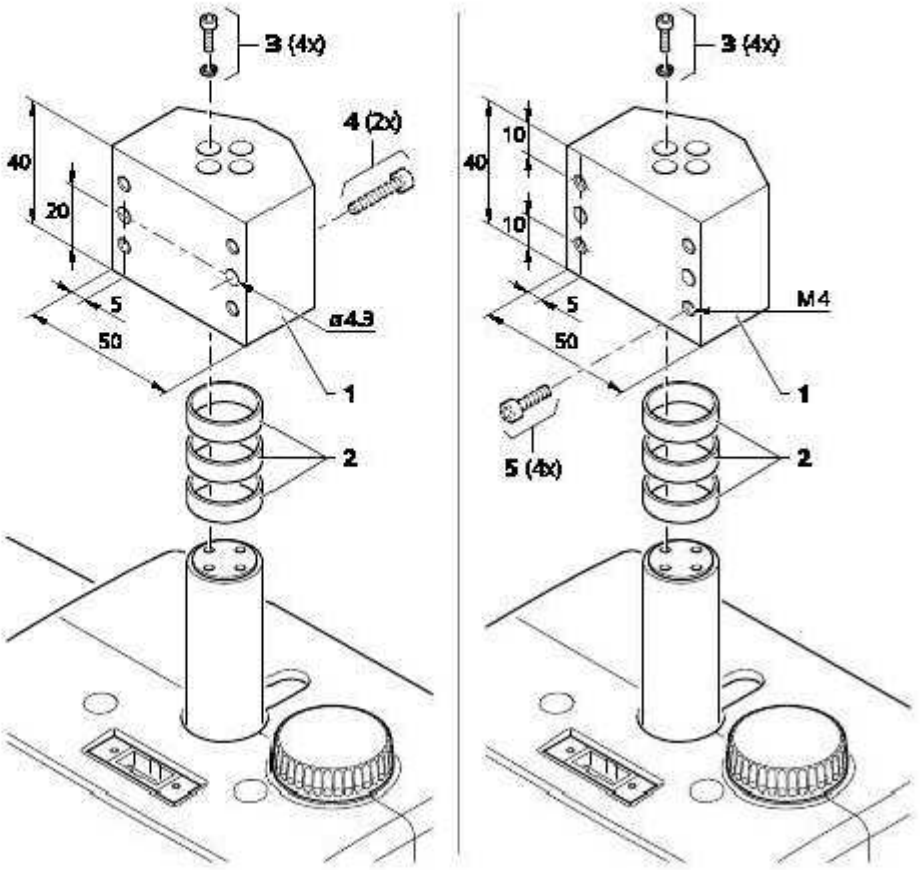
Fig. 12 Interface dimensions for mounting the phoropter head with the assembly adapters ZDR14 and ZDR16



1 Assembly adapter ZDR17
2 Screws and E-rings from mounting set 1

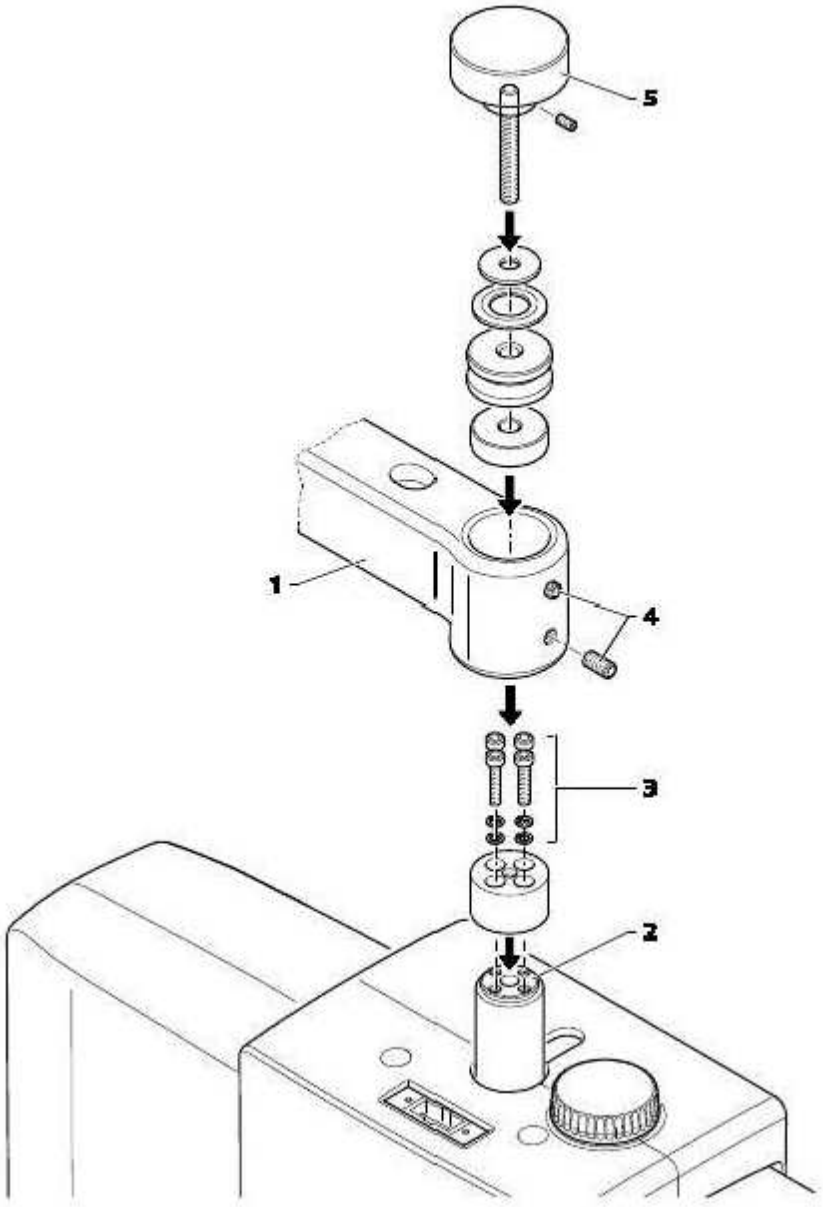
Fig. 13 Interface dimensions for mounting the phoropter head with the assembly adapter ZDR17

For assembly, add corresponding drill holes and threads into the supporting arm.



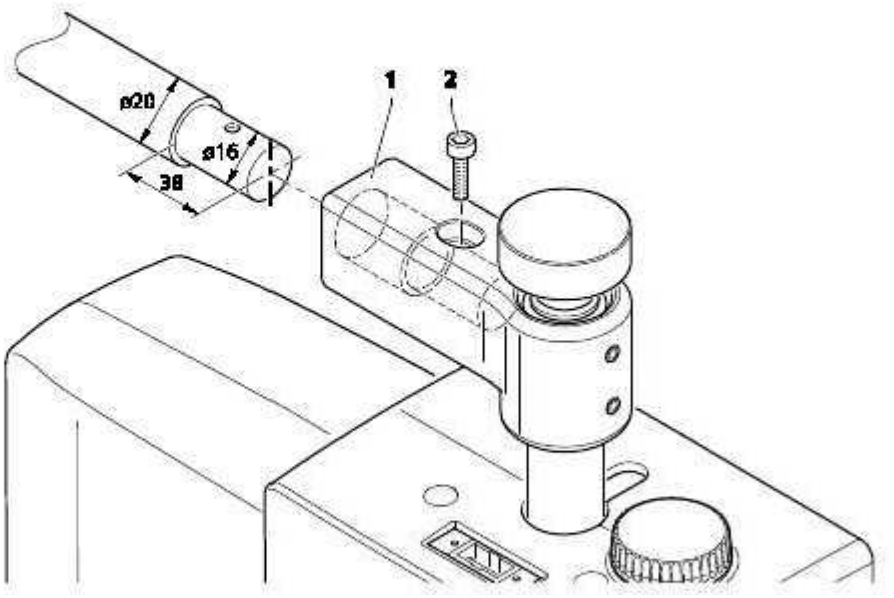
1 Assembly adapter ZDR18
2 Spacers (3 pc.)
3 Screws not included in the package (use corresponding screws (M3))
4 Screws not included in the package (use corresponding screws (M4))
5 Screws not included in the package (use corresponding screws (M4))

Fig. 14 Interface dimensions for mounting the phoropter head with the assembly adapter ZDR18



1 Assembly adapter ZDR19 or ZDR20
2 Fixing bolts
3 Screws M3x14 mm and E-rings D 5.4 mm to screw the adapter to the fixing bolt
4 Screws for vertical fixing of the phoropter head
5 Knurled screw

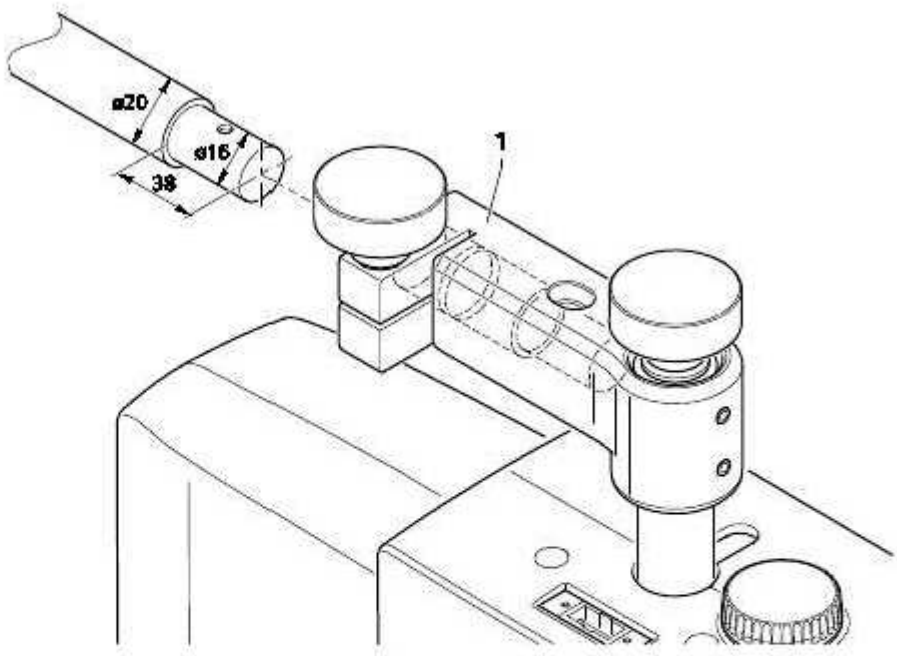
Fig. 15 Fixing of ZDR19 and ZDR20 adapter on fixing bolt of phoropter



1 Mounting for fixing rod

2 Screw for horizontal fixing of phoropter head (use one of the screws from mounting set 3 depending on the thread)

Fig. 16 Interface dimensions for mounting the phoropter head with the assembly adapter ZDR19



1 Mounting for fixing rod

Fig. 17 Interface dimensions for mounting the phoropter head with the tiltable assembly adapter ZDR20 (optional)

Interfaces to connect external devices

The following devices can be connected to the ports Com1 (**5**, Fig. 6) and Com2 (**4**, Fig. 6):

- VISULENS 500 Digital Lensmeter from software version v1.2.3
- VISUREF 100 Autorefractometer/Keratometer from software version v2.1.7

Proceed as follows:

- Please turn all of the equipment involved off.
- Connect the data interfaces for the devices listed above with the connections in the junction box to be used for this purpose. In this regard please use the interface cable supplied and select the following allocation:
  - VISULENS 500 to interface Com1
  - VISUREF 100 to interface Com2
- Attach both ends of the interface cable to the respective device and tighten the screws on the cable plugs and cable sockets.
- Please ensure that the interface parameters for the external devices have been reset to their factory settings.

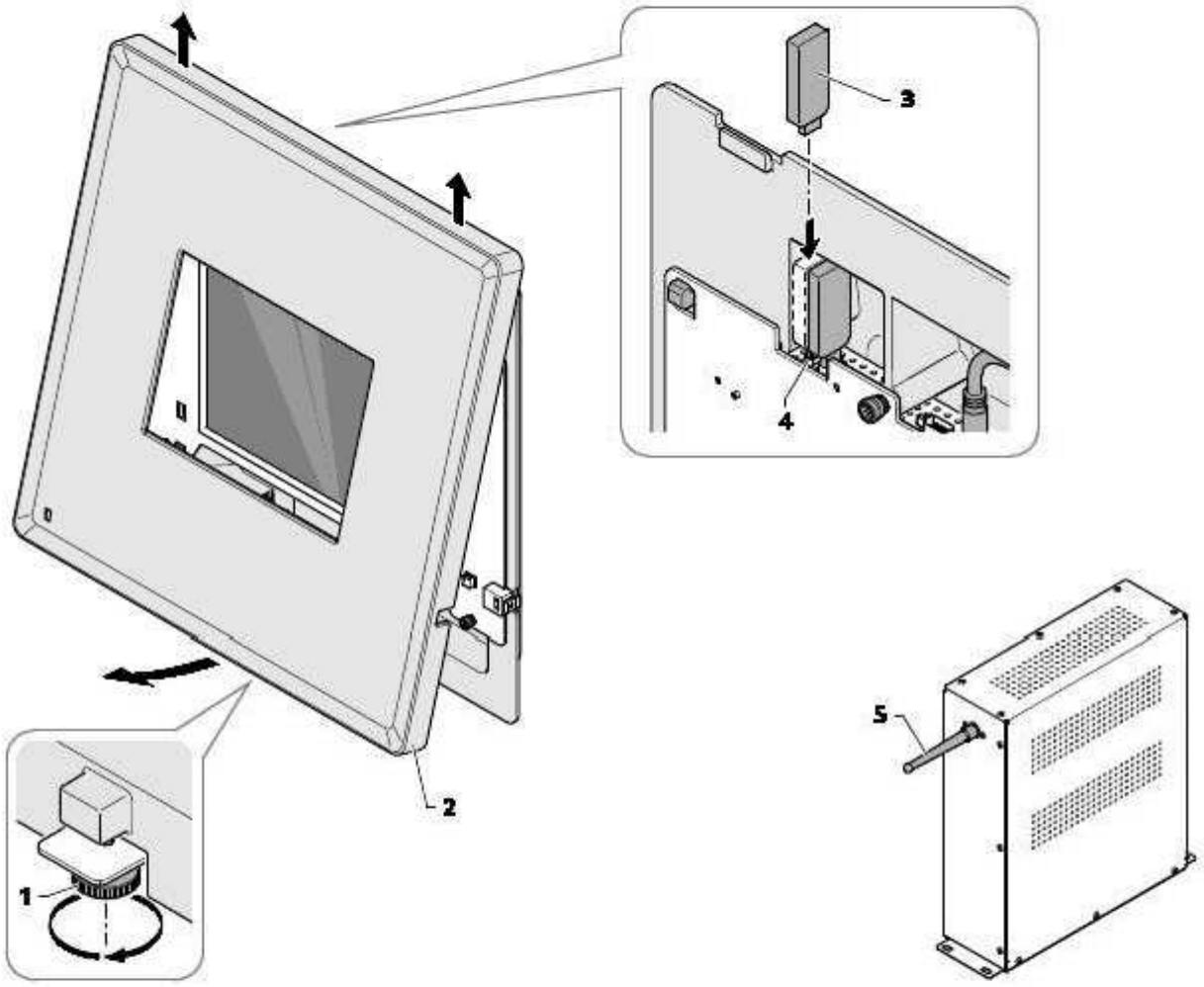
Interface to VISUSCREEN control unit

The interface to the VISUSCREEN control unit is a wireless connection using Bluetooth technology. The junction box broadcasts and receives data via the antenna (**5**, Fig. 18).
The Bluetooth/USB adapter (**3**, Fig. 18) in the USB interface for the VISUSCREEN control unit is employed as the remote station.

Proceed as follows:

- Loosen the knurled screw (**1**, Fig. 18) on the underside of the housing.
- Remove the cover (**2**, Fig. 18) by pulling it gently forward, and then upwards out of the retaining tabs of the housing.
- Plug the Bluetooth/USB adapter into a free USB port in the left upper corner of the unit (**3**, Fig. 18).

- Close the unit again by slightly tilting the cover onto the retaining tabs of the housing, and then pressing the lower side inwards.
- Retighten the knurled screw (**1**, Fig. 18).



1 Knurled screw
2 VISUSCREEN housing cover
3 Bluetooth/USB adapter
4 USB port
5 Antenna at junction box

Fig. 18 Interface to VISUSCREEN control unit

Daily startup

WARNING - GENERAL HAZARD

Prior to using the device, the user must ensure that it is in a good condition and fully functioning. Furthermore, the user must follow the instructions in the user manual.

The following inspections must be carried out each working day prior to use:

- Visual inspection of the housing, exterior markings, user manual, accessories and power cable to ensure that they are present and intact. If parts are missing or damage is visible, the device should not be used and should be taken out of service.

WARNING - RISK OF ELECTRIC SHOCK

Please take care that the following operational requirements are met before using the device each time:

- Use the power cable supplied with the device.
- The power cable has been plugged into a power outlet which is properly grounded.
- All cables and plugs must be in perfect working condition.

CAUTION - DANGER FROM FALLING PARTS

Patients could be injured if the phoropter head falls. Please thus ensure that the head is properly held in the respective mounting for your refraction unit.

- Use the integrated spirit level (**2**, Fig. 5) to check the horizontal orientation of the phoropter head. If necessary use the leveling screw (**3**, Fig. 5) to ensure horizontal alignment.

Switching on

WARNING - GENERAL HAZARD

If you notice smoke, strong smells, or suspicious noises, turn the device off immediately and remove the electrical plug. Contact your dealer.

The power switch can be turned off at any time. The device requires no time to shut down.

To remove the power cable, grip the plug. Do not pull the cable.

Do not touch conductive components and the patient at the same time.

CAUTION – HAZARD DUE TO MOVING PARTS

After being switched on, the phoropter head automatically performs a self-test, during which both wings move to the left and right. Please keep the patient away from the device during the self-test.

- First, turn the VISUPHOR 500 device on, then the VISUSCREEN control unit.
- To do so, use the power switch (**3**, Fig. 6) on the junction box.

Operation of the device

CAUTION - PROPERTY DAMAGE

Do not hit or drop the device. Impacts may damage the device and lead to a malfunction.

Pay attention to ensure that the device does not become dirty, and do not expose it to any metallic dust or chips.

CAUTION – HAZARD DUE TO MOVING PARTS

Do not place your hands or fingers between the left and right wings of the phoropter head, and pay attention to ensure that your patients also do not place their hands or fingers there.

Do not use the device with wet hands.

In particular, keep the surface of the examination window clean.

Before the patient takes his place at the device, or before you bring the digital phoropter into position in front of the patient, please perform the following stages in preparation:

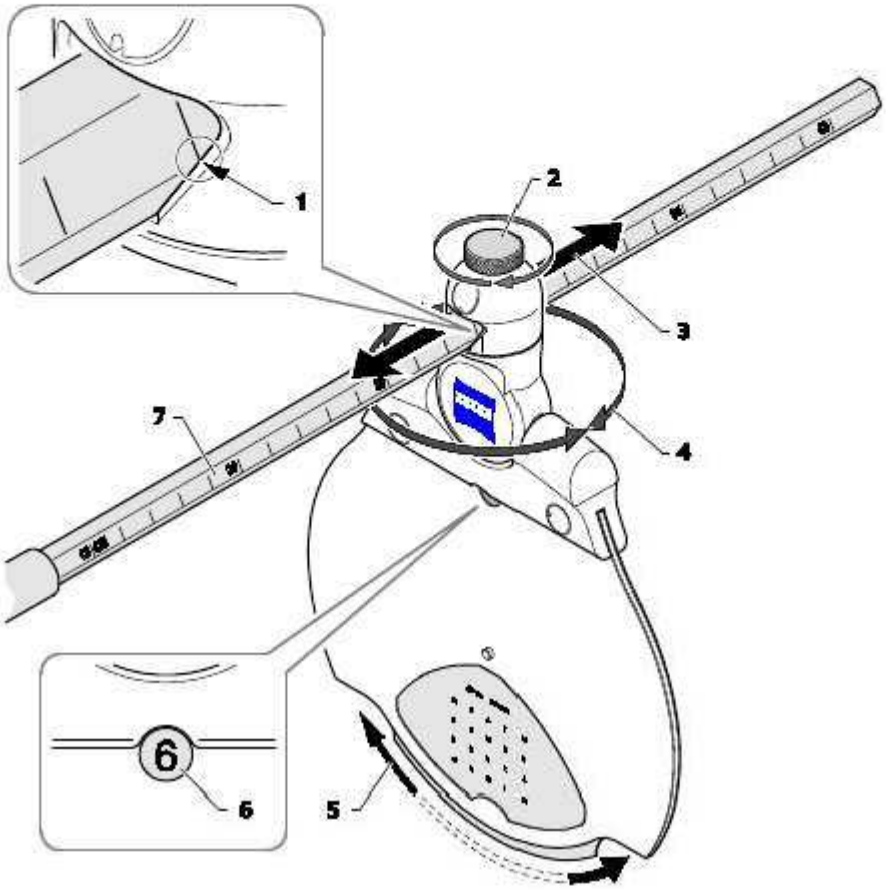
Preparation of the device:

- Leveling
  - Check the horizontal mounting of the phoropter head using the spirit level (**2**, Fig. 5).
  - If necessary use the leveling screw (**3**, Fig. 5) to align the head.
- Cleaning
  - Clean the face shield, the forehead rest and the examination window. Please note the information given in section *Care and cleaning* on page 48.
- Use the near-point chart.

If you want to perform a near-point examination:

- Mount the fixing rod (**3**, Fig. 1) to the phoropter head by inserting the rod into the respective mounting on the phoropter head (**7**, Fig. 5).
- Plug the near-point chart (**4**, Fig. 1) onto the fixing rod.
- Position the near-point chart in front of the patient's eye at the desired distance (**3**, Fig. 19).
  In order to set the desired value on the scale (**7**, Fig. 19), push the near-point chart until the edge of the head piece forms an intersection with the scale foot (**1**, Fig. 19).
  Finally mount the near-point chart using the screw (**2**, Fig. 19).

  The distance between the patient's eye and the near-point chart can be measured in centimeters, inches or diopters.



1 Intersection between the head piece and the scale foot
2 Mounting the near-point chart to the fixing rod
3 Moving the near-point chart to set up the distance from the eye
4 Turning the chart to select the front or rear
5 Turning the turntable to select the optotype card
6 Field for showing card number
7 Fixing rod with scale

Fig. 19 Set up near-point chart

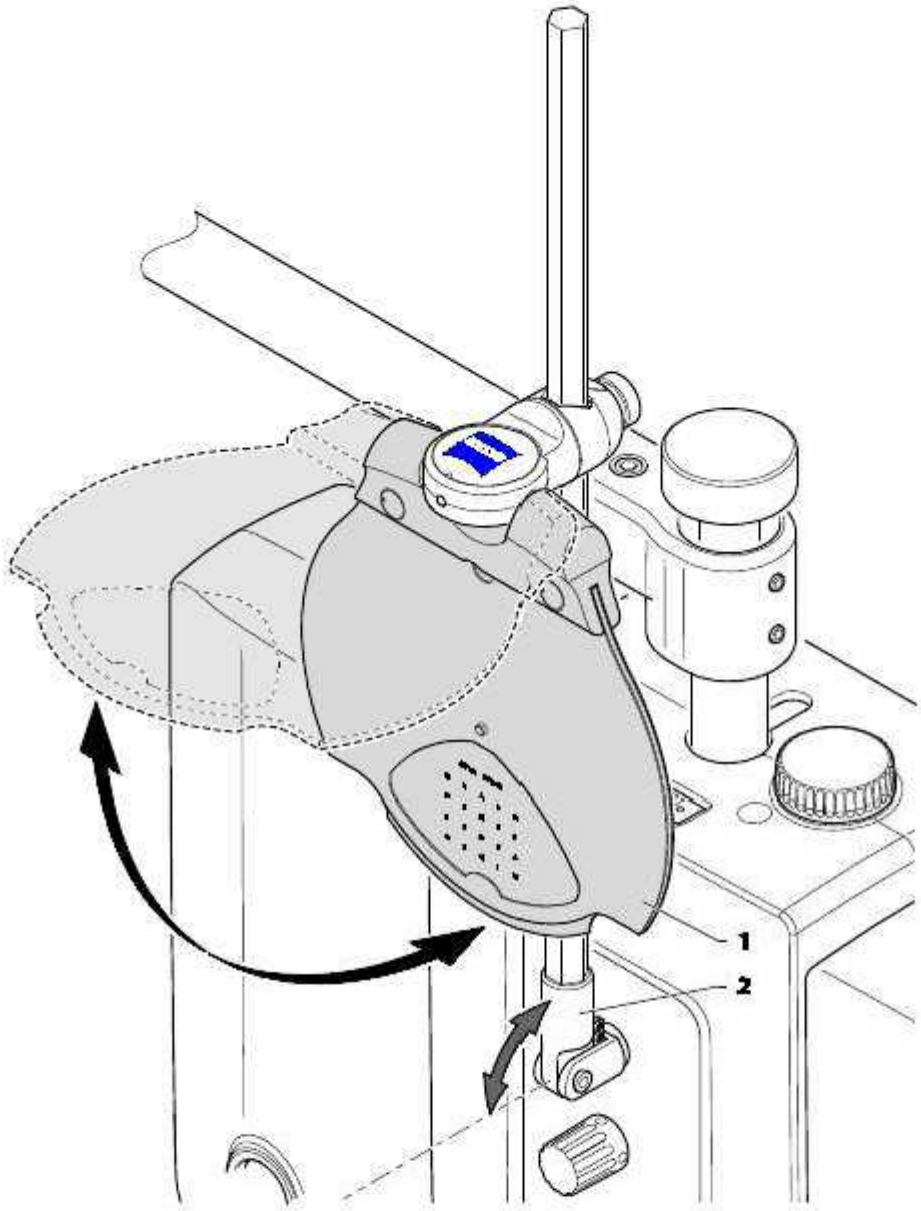
- Select the desired optotype card.
  To select the card turn the chart to select the front or rear (**4**, Fig. 19) and then the turntable (**5**, Fig. 19) until the respective card number (**6**, Fig. 19) can be seen in the display field.

Selection table for optotype card

	Card number	Description	Number shown on the examiner's side
Frontside	1	Landolt rings	8
	2	Optotype sequence for visual acuity 0.1, 0.2, 0.25, 0.32	7
	3	Optotype sequence for visual acuity 0.4, 0.5, 0.63, 0.8, 1.0	6
	4	Grid	5
Rearside	5	Fan chart	4
	6	Vertical number series	3
	7	Horizontal number series	2
	8	Optotype sequence for visual acuity 0.63	1

After using the near-point chart, this can be separated from the phoropter head again together with the fixing rod.

As an alternative, it is possible to fold up the fixing rod via the joint (**2**, Fig. 20) and to fold in the near-point chart towards the rod (**1**, Fig. 20) via the joint in its spacer.



1 Near-point chart (collapsible)
2 Joint to fold up the fixing rod.

Fig. 20 Fold up the near-point chart and fixing rod

Transferring data

- Take over the objective refraction data for the patient from FORUM, iCom or your practice management system into the control software.
- When the data is transferred, the pupil distance (PD) for the patient is pre-set on the digital phoropter, and reticules for monitoring or fine comparison of this set-up are swung into in the examination window (**11**, Fig. 5).

Positioning the patient

- Ask your patient to sit down in front of the phoropter or bring the phoropter into position in front of the patient.

  The patient has to be sitting comfortably and lean his head onto the middle of the forehead rest (**9**, Fig. 5). Pay attention to ensure that the head is in an upright position.

- Adjust the corneal vertex distance (CVD) to 17 mm.

  To do this, look through the control window (**1**, Fig. 21).
  Position yourself so that the solid reference line (**3**, Fig. 21) for the scale included in the deflecting mirror rests between the two triangles (**4**, Fig. 21).

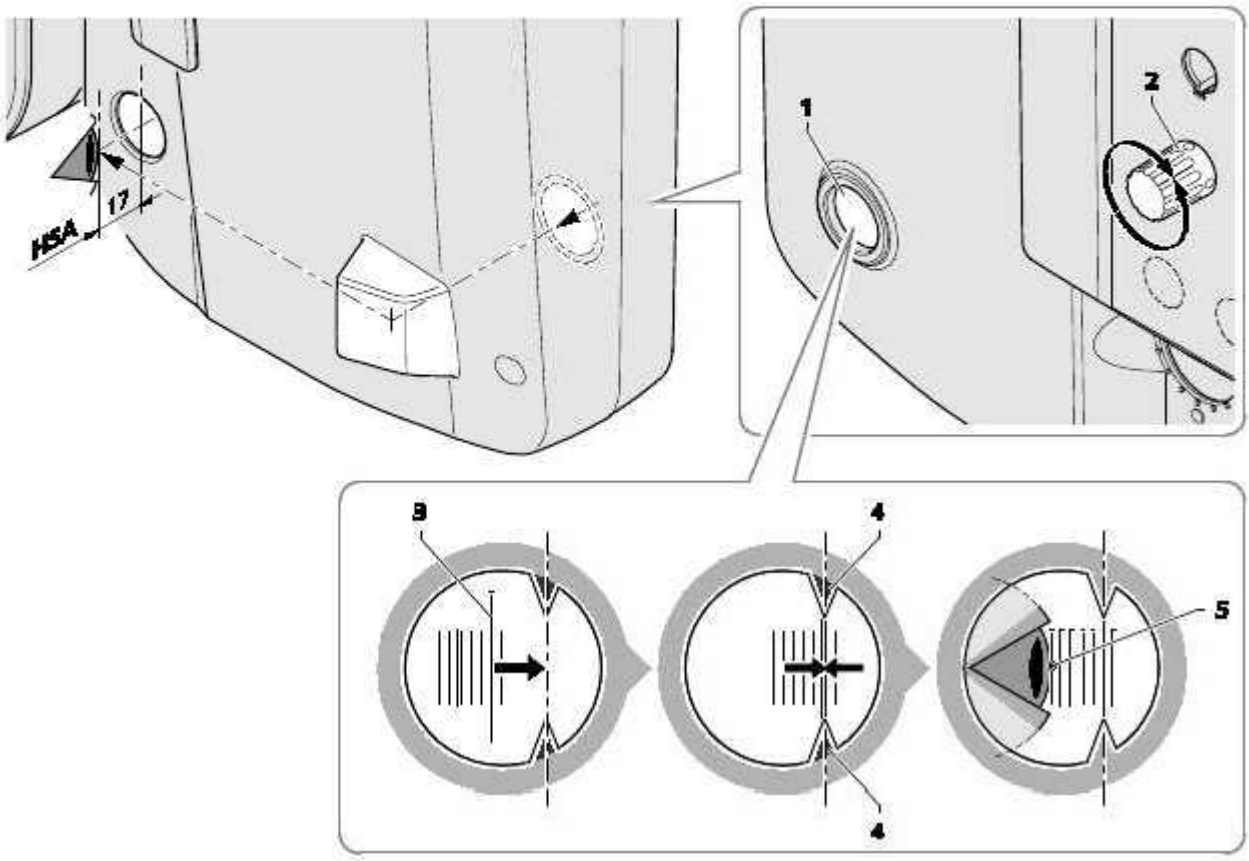
  Correct the position of the forehead rest using the adjusting screw (**2**, Fig. 21) until the vertex of the patient's eye (**5**, Fig. 21) rests on the left line of the displayed scale.

- Also check the corneal vertex distance for the other eye.

  It may be that you have to ask the patient to move his/her head several times.

- Check the pupil distance (PD) that has been set up using the reticules that have been swiveled in.

  If necessary, correct the PD using the control software.



1 Control window
2 Adjusting screw to set the CVD
3 Reference line
4 Reference triangles
5 Vertex of the patient's eye

Fig. 21 Positioning the patient and setting up the CVD

Perform examination

When the PD data that have been set up are taken over into the control software, the illumination of the patient's eyes ceases and the set-up for the objective refraction data (sphere, cylinder and axis) taken over from the PMS are used in place of the reticules. This is the starting point for the following determination of the subjective refraction.

Shutting down

Switching off the device

If one of the following events should occur, switch the instrument off immediately at the power switch and disconnect the cable from the power supply.

- Electric shocks
- Penetration of substances
- Smoke, sparks or strange noises
- Faults that cannot be remedied based on the information provided in this user manual.

Label the instrument clearly as being out of service and report the problem to the ZEISS service (contact details see reverse).

- Switch off the device at the power switch.

  The power switch can be turned off at any time. The device requires no time to shut down.

- Be sure to unplug if the system is not used for a longer period of time.

  Be sure to turn off the power switch before connecting to or disconnecting from a power supply.

  Before connecting or separating all plug-in connections in the structure, ensure that the power cable is unplugged.

- Use the supplied cover to protect the device from dust when not in use.

Maintenance and care

WARNING - GENERAL HAZARD

The device may only be opened, put into operation, modified and repaired by the manufacturer's customer service technicians or specialists expressly authorized in writing by Carl Zeiss Meditec. If in doubt, insist on seeing the written authorization or contact Carl Zeiss Meditec directly.

The manufacturer is not liable for damage caused by unauthorized tampering with the device. Such actions will render any warranty claims invalid.

Troubleshooting

Problem	Possible cause	Corrective measure
The digital phoropter does not work at all.	The device is not switched on.	Check the position of the on/off switch.
	The device is not connected to the supply voltage.	Check to ensure the power cable is correctly plugged in, and that there is electricity on the socket.
	The phoropter head is not connected to the junctino box.	Check to ensure that the connecting cable is connected properly.
The phoropter head makes loud noises during the self test.	One of the fuses has blown.	Check the fuses.
The device does not work correctly after initializing the phoropter head.	Communication with the VISUSCREEN control unit does not work.	Check the Bluetooth status LED. If the LED is green, restart the entire structure.

Replacing the forehead rest

- Remove the forehead rest by pulling this away from the device.

  Avoid pushing the forehead rest up further than its stopping point. This could cause the holding bridges on the back of the forehead rest to break off.

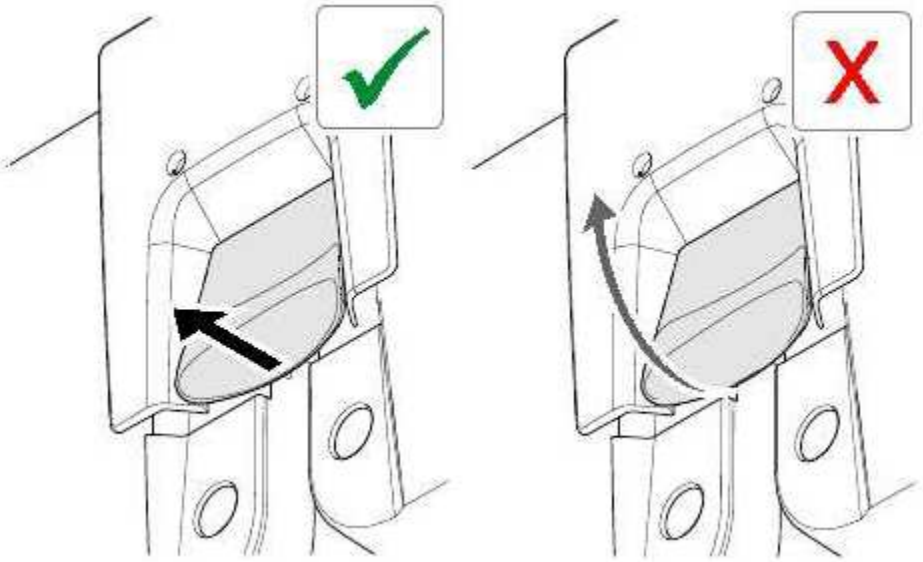
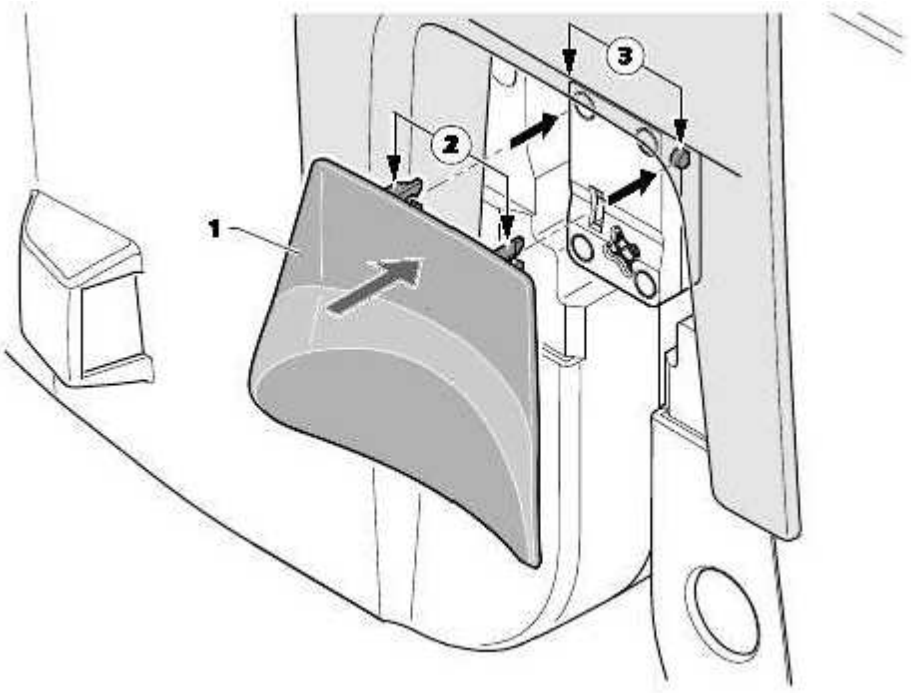


Fig. 22 Removing the forehead rest

- To insert the forehead rest (**1**, Fig. 23) place the holding bridges (**2**, Fig. 23) on the back of the forehead rest on the forehead rest insertion point on the device side (**3**, Fig. 23).



1 Forehead rest
2 Holding bridges
3 Mount for forehead rest

Fig. 23 Inserting the forehead rest

- Press lightly against the forehead rest, until this clicks into place.

Replacing the face rest

- To remove the face rest, press its lower edge up slightly and remove the face rest carefully as shown in Fig. 24.
- To insert the face rest, place this into position and let it go.

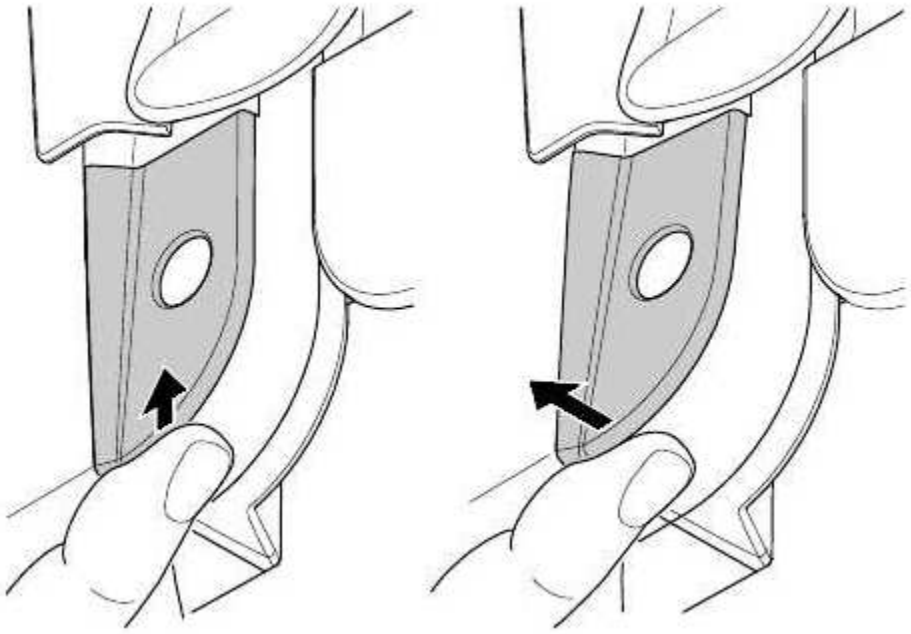


Fig. 24 Replacing the face rest

Replacing the fuses

WARNING - RISK OF ELECTRIC SHOCK

The VISUPHOR 500 must be switched off and disconnected from the power supply before being cleaned or serviced.

Before changing the fuses, disconnect the device from the power supply to prevent the risk of serious injury or death.

WARNING - RISK OF ELECTRIC SHOCK

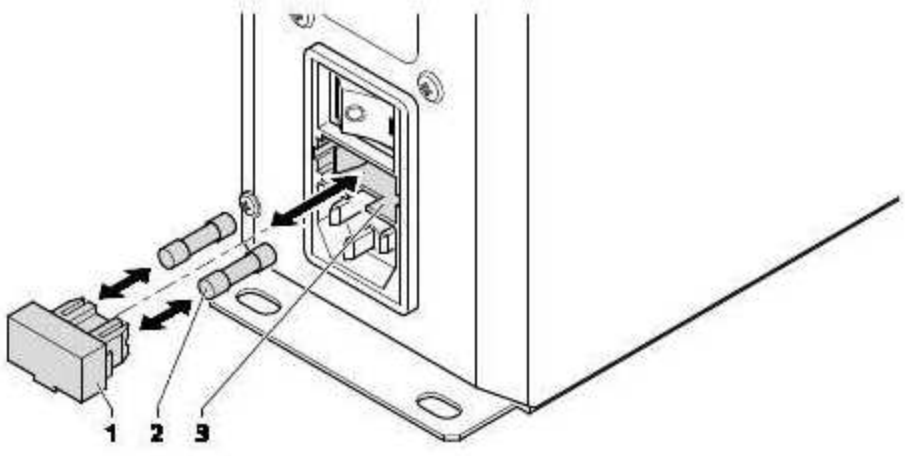
Internal fuses may only be changed by service staff specially trained in maintenance and service work.

Opening up the casing while the unit is turned on exposes the operator to the risk of a fatal electric shock.

WARNING - FIRE HAZARD

Replace the fuses in the power input module with fuses which conform with the specifications in Section *Technical data*, page 56 of this user manual.

- Disconnect the device from the power supply.
- Release the lock mechanism at the sides of the fuse compartment (**3**, Fig. 25) and remove the fuse carrier (**1**, Fig. 25).



1 Fuse holders
2 Fuse
3 Fuse compartment

Fig. 25 Replacing the fuses

- Remove the defective fuse (**2**, Fig. 25) from the fuse carrier (**1**, Fig. 25) and replace it with a new fuse.
- Replace the fuse compartment (**1**, Fig. 25) and ensure the locking mechanism clicks in.

Maintenance

Care and cleaning

WARNING - RISK OF ELECTRIC SHOCK

Repair and maintenance work may only be carried out by authorized service staff.

Do not remove any parts of the casing or carry out any repairs yourself, especially not on the interior parts of the device.

To avoid overheating or the risk of fire, only replace spent fuses with new ones of the same type.

Removing parts of the casing exposes you to the risk of an electric shock.

– There are no parts inside the device which can be serviced by the user.

– Any service work which needs to be performed must be carried out by trained personnel.

CAUTION - PROPERTY DAMAGE

The national disinfecting regulations must be observed in the choice of disinfectants and disinfection procedures. Please note that some cleaning agents and disinfectants may have an adverse effect on plastic components. Damage caused by such disinfectants is not covered by our warranty. The surfaces of the device have been tested and are guaranteed to resist frequent treatment with alcoholic disinfectants and cleaning agents in the long term.

Do not use any aggressive or abrasive cleaning agents.

Do not use acetone and acetone-based cleaning agents to clean the device, as they could damage the surfaces.

Contaminated parts with which the patient has come into contact during the examination (forehead rest and face shield) should be cleaned with a disinfectant approved for the purpose. These parts are designed to be wiped down using mild cleaning agents and disinfectants such as suds, disinfectants based on quaternary ammonium compounds (0.2 %), glutoral (2 %) or isopropanol (60 %).

Cleaning the exterior components

- All parts of the housing may be wiped off with a moist but not drip-wet cloth. Wipe off any marks or stains with distilled water containing a drop of household detergent.

Do not use any volatile cleansers, solvents or benzene, etc.

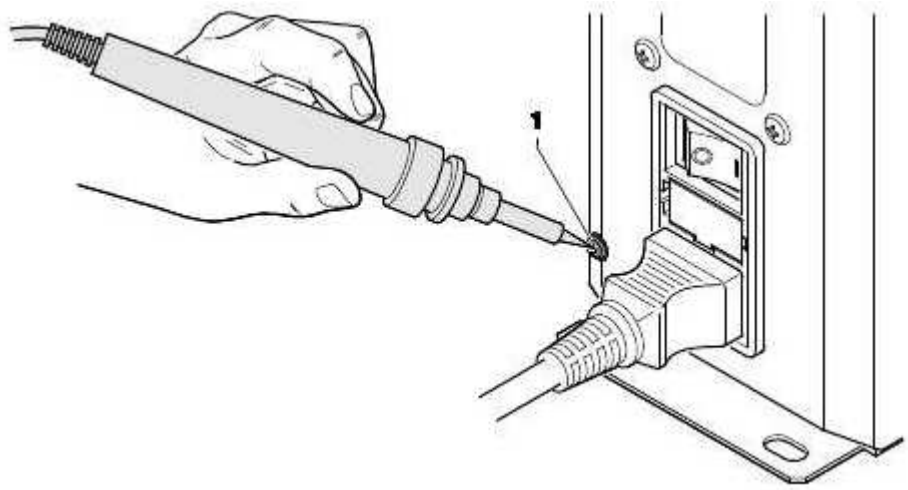
Ensure that no moisture penetrates the device during cleaning and disinfection.

Please use a soft, dry cloth to clean glass surfaces after having blown off any dust and other dirt.

Safety inspections

Proceed as follows to perform a safety check of the device:

- Check the protective earth conductor resistance. For this purpose, connect the device to the measuring instrument using the power cable. To perform a measurement, press the measuring tip to the screw (measurement point) shown in Fig. 26 on the left side of the power switch (on/off button). The measured value may not exceed 0.3 Ω.



1 Measuring point

Fig. 26 Measurement of leakage current

- After successful measurement, the device leakage current must be measured. Preferably, the differential current method should be used. the device is in its operating state. Press the measuring tip onto the measuring point again (**1**, Fig. 26). The measured value may not exceed 0.5 mA.
- Finally, measure the insulation resistance using a test voltage of 500 V. The measured value may not fall below 2 MΩ.
- Note down the measured values.

Replacement of components

If, after discussion with your dealer, it should be necessary to replace a device or a component, please proceed as follows:

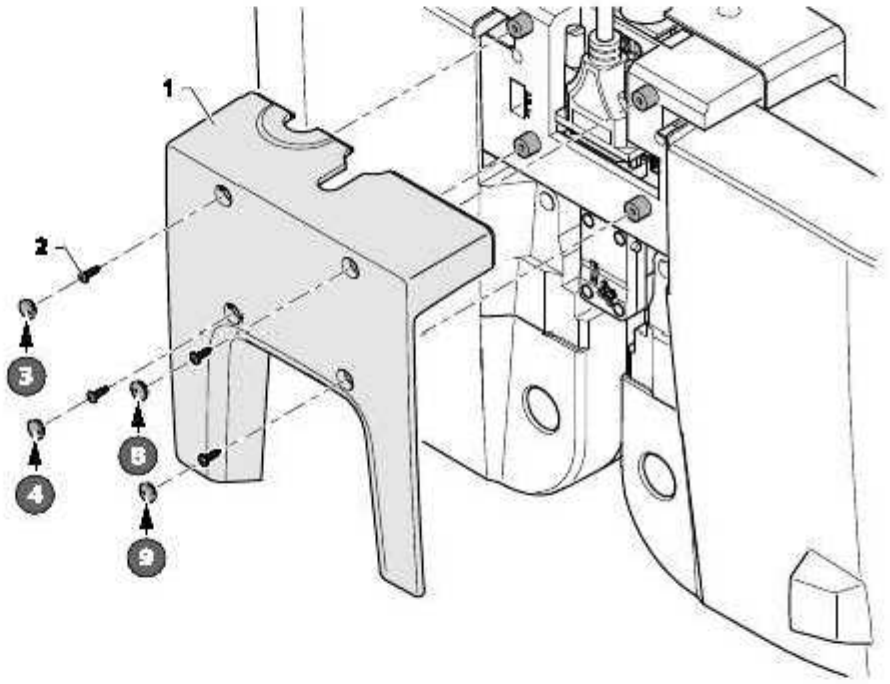
Document your structure carefully before removing a component. In so doing, pay particular attention to the specific points for your installation. Your records must enable you, together with the following notes, to recreate the current status of your installation.

- Switch off all devices and disconnect the power cables.
- Keep all of the small parts which arise during dis-assembly (screws, caps, etc, ...) for later assembly.
- Only use original packaging for transport.

Replacing the phoropter head

Disassembly

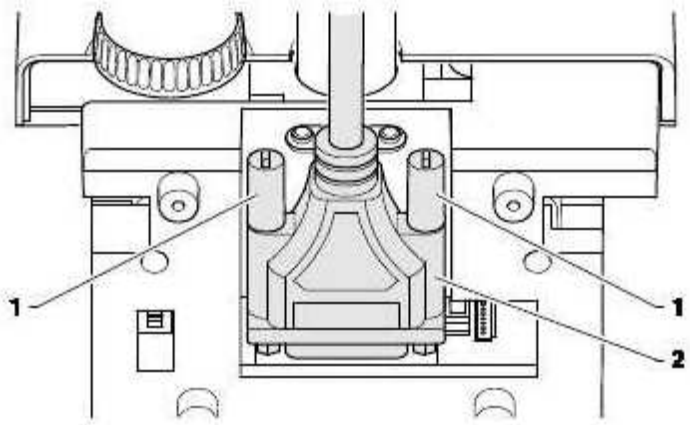
- Remove the forehead rest, see chapter *Replacing the forehead rest on* page 44.
- Remove the four screw covers (, , , , Fig. 27).
- Loosen and remove the four fixing screws (**2**, Fig. 27).
- Take the cover off the connector compartment (**1**, Fig. 27).



1 Cover for the connector compartment
2 Fixing screws
Upper left screw cover
Lower left screw cover
Upper right screw cover
Lower right screw cover

Fig. 27 Removal of the cover for the connector compartment

- Loosen the two fixing screws (**1**, Fig. 28) for the connector cable.
- Pull the connector cable off upwards (**2**, Fig. 28). In so doing, hold the cable directly at the plug.
- Hold the phoropter head firmly during removal to prevent this from falling.
- Loosen the fixing screws on the assembly adapter for your installation (see chapter *Interfaces to mount the phoropter head* on page 23).



1 Fixing screws for the connector cable
2 Connector cable with plug

Fig. 28 Removing the connector cable

Mounting

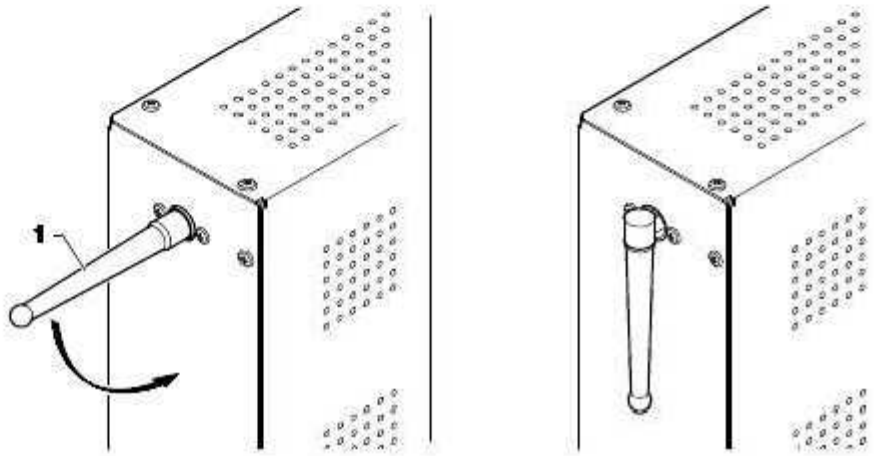
- Attach the phoropter head to the respective attachment point in your installation.
- Connect the connector cable (**2**, Fig. 28).
- Fix the two fixing screws (**1**, Fig. 28) for the connector cable.
- Put the cover on the connector compartment (**1**, Fig. 27).
- Insert the four fixing screws (**2**, Fig. 27) and tighten these.
- Assemble the four screw caps (, , , , Fig. 27).

  In so doing, note the numbers of the caps and their allocation to their respective positions and orientation of the caps shown in Fig. 27.

Replacing the junction box

Disassembly

- Loosen all of the cables attached to the junction box and fold in the antenna (**1**, Fig. 29).
- Unscrew the screws fixing the junction box to the installation environment.



1 Antenna

Fig. 29 Disassembly of junction box

Mounting

- Attach the junction box to its installation environment using the screws.
- Connect all of the associated cables to the junction box and unfold the antenna (**1**, Fig. 29).

After going live, it may also be necessary to update the system configuration (see *"VISUSCREEN 100/500 - Subjective refraction with VISUPHOR 500" user manual*).

Optional accessories

WARNING - GENERAL HAZARD

If the device has been modified, it must be tested and checked in order to ensure the safe operation of the device after its modification.

Use only accessories and spare parts approved by Carl Zeiss Meditec.

A current and complete list of accessories can be obtained from your retailer.

Technical data

Dimensions (W x D x H)	
Digital Phoropter	361 mm x 108 mm x 280 mm
Junction box	71 mm x 240 mm x 251 mm
Weight	
Digital Phoropter	4.74 kg
Junction box	1.88 kg
Mains voltage	100 V to 240 V AC
Line frequency	50/60 Hz
Power consumption	1.0 A to 0.5 A AC

Classification of the device

Fuse	T2.50AH, 250 V
Protection class	1
Ingress protection rating	IPX0
Device type	B (DIN EN 60601-1)
Operating mode	continuous operation
Bluetooth	Class I: 100 mW (20 dBm), 100 m

Ambient conditions for intended use

Temperature	+10 °C to +35°C
Relative humidity	30 % to 90 %
Ambient air pressure	690 mbar to 1060 mbar
The device may not be operated using air, oxygen or nitrous oxide in the proximity of a flammable mix of anesthetics.	

Ambient conditions for storage and transport

Ambient temperature	-10 °C to +55 °C
Relative humidity	30 % to 95 %
Ambient air pressure	700 hPa to 1060 hPa

Setting range	
Spherical lenses	-29.00 D to +26.75 D.
	-19.00 D to +16.75 D (when using a cross cylinder or a prism) (steps of 0.125 D)
Toric lenses	
Cylinder power	0.00 D to 8.75 D (steps of 0.25 D)
Cylinder axis	0° to 180° (steps of 1°)
Cross cylinder	± 0.25 D
	± 0.50 D
	±0.25 D (dual cross clyinder)
Prismatic lenses	0 Δ to 20 Δ (steps of 0.1 Δ)
PD	48 mm to 80 mm (steps of 0.25 mm)
Near-point examination	
PD	50 mm to 74 mm
Working distance,	35 cm to 70 cm
Retinoscope lenses	+1.5 D, +2.0 D (distance, 67 cm, 50 cm)

Special lenses

Aperture diaphragm	∅ 2 mm
Maddox filter	right eye: red/horizontal, left eye: red/vertical
Red/green filter	right eye: red, left eye: green
Polarization filter	Right eye: (135°, 45°), left eye: (45°, 135°)
Dissociating prism	Right eye: 6 Δ BU
	Left eye: 10 Δ BI (up to 5 Δ complement)
Cross cylinder, fix	(±0.50 D, axis 90°)
Visual field	40° (CVD: 12 mm)

HF transmitter specifications

Frequency range	2400 MHz to 2483.5 MHz
Transmission power	max. 4.7 dBm
Modulation type	FHSS
Channel	79 channel
Antenna amplification	max. 2.0 dBi
Working temperature	-10 °C to +35 °C
Supply voltage	100 V to 240 V AC
Line frequency	50/60 Hz
Power consumption	1.0 A to 0.5 A

Electromagnetic compatibility

ZEISS VISUPHOR 500 satisfies the requirements of electromagnetic compatibility pursuant to IEC 60601-1-2:2014.

CISPR 11: Group 1

CISPR 11: Class B

Ambient conditions for intended use

With regard to electromagnetic compatibility, ZEISS VISUPHOR 500 is intended for use in a domestic professional healthcare environment pursuant to IEC 60601-1-2:2014.

ZEISS VISUPHOR 500 is not intended to be used in special environments such as military facilities, heavy industry, medical facilities with high-current devices or radiology facilities such as MRTs.

Limitations on essential performance features

ZEISS VISUPHOR 500 has no performance features which are defined as essential performance features according to IEC 60601-1. Therefore, no impairment of the essential performance characteristics of ZEISS VISUPHOR 500 is expected due to electromagnetic interference.

CAUTION - GENERAL HAZARDS

If operation in private healthcare or special environments or in hospitals together with HF devices such as diathermy devices or MRTs is required, the distance between the ZEISS VISUPHOR 500 and the HF devices must be in accordance with the specifications in Table 9 of the IEC 60601-1-2:2014 or calculated according to the specifications of the standard. Furthermore, ZEISS VISUPHOR 500 must be closely observed to monitor its proper functioning in this configuration.

CAUTION - GENERAL HAZARDS

Portable and mobile RF communications equipment may affect the device.

When operating radio devices or components for radio transmission, observe a distance of at least 30 cm to all parts of ZEISS VISUPHOR 500, including cables specified by the manufacturer. Otherwise, a malfunction or reduced performance of the device is to be expected.

CAUTION – RISK OF ELECTROMAGNETIC RADIATION

The ZEISS VISUPHOR 500 may not be placed next to or stacked together with other equipment, except in the device configurations described in this user manual. If operation close to or with other devices is necessary, the ZEISS VISUPHOR 500 must be closely observed to monitor its proper functioning in this configuration.

CAUTION - GENERAL HAZARDS

Medical electrical equipment is subject to special EMC precautions and must be installed and commissioned in accordance with the EMC instructions included in the accompanying documentation.

Replacement cables may only be purchased at Carl Zeiss Meditec or at dealers authorized by Carl Zeiss Meditec.

The use of accessories, all types of transducers and cables not specified in this user manual or not sold by Carl Zeiss Meditec as replacement parts may result in higher emissions or reduced immunity of the device.

Relevant accessories:

- Serial connection cable RS232 SUB-D, 3 m, 1:1 seria cable, male <-> female
- WLAN access point for VISUSCREEN/VISUPHOR/Access point Lancom L-321agn Wireless US
- Power cables
- Bluetooth/USB adapter

CAUTION - GENERAL HAZARDS

If the device shows obvious damage (e.g. on housing or cables), ZEISS Service should be informed. It is possible that ZEISS VISUPHOR 500 may still function if damaged, but is much more susceptible to electromagnetic radiation.

Emission

Emission	Standard	Compliance
Conducted emission	CISPR 11	Group 1
Radiated emission	CISPR 11	Class B
Harmonic emissions	IEC 61000-3-2	Class A
Voltage fluctuations/flicker emissions	IEC 61000-3-3	Complies

Immunity

Phenomenon	Standard	Test level
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air (housing, connections)
Radiated RF EM fields	IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz
Electrical fast transients/bursts	IEC 61000-4-4	±2 kV, 100 kHz repetition rate (power cable) ±1 kV, 100 kHz repetition rate (data cable)
Surges line·to·line	IEC 61000-4-5	±0.5 kV, ±1 kV (power cable)
Surges line-to-ground		±0.5 kV, ±1 kV, ±2 kV (power and data cables)
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V 0.15 MHz to 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz (power and data cable)
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz
Voltage dips	IEC 61000-4-11	0% U_T; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % UT; 25 cycles @ 50 Hz/30 cycles @ 60 Hz Single phase: at 0°
Voltage interruptions		O % U,; 250 cycles @SO Hz/300 cycles @60 Hz

Phenomenon	Standard	Test frequency (MHz)	Radio service	Immunity test level (V/m)
Immunity to radiated radio frequencies, caused by wireless communications equipment in accordance with IEC 60601-1-2	IEC 61000-4-3	385	TETRA 400	27
		450	GMRS 460, FRS 460	28
		710	LTE Band 13,17	9
		745		
		780		
		810	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	28
		870		
		930		
		1720	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	28
		1845		
		1970		
		2450	Bluetooth, WLAN 802.11b/g/n, RFID 2450, LTE Band 7	28
		5240	WLAN 802.11 a/n	9
		5500		
		5785		

Abbreviations/Glossary

ARK	Automatic refractometer / keratometer
CISPR	Comité international spécial des perturbations radioélectriques (Special International Committee on Radio Interference)
CVD	Vertex distance
D	Diopters
dBi	Decibel isotropic
dBm	Decibel relative to 1 milliwatt
DIN	Deutsches Institut für Normung (German standards association)
EC	European Community
EMC	Electromagnetic compatibility
EN	Europäische Norm (European standard)
ESD	Electrostatic discharge
ESDS	Electrostatic sensitive devices
EU	European Union
EEC	European Economic Community
FHSS	Frequency Hopping Spread Spectrum
FI	Ground fault circuit interrupter
Fig.	Figure
HF	High frequency
IEC	International Electrotechnical Commission
IP	Ingress protection rating
LED	Light emitting diode
MAC	Media Access Control
MDD	Medical Device Directive
PD	Pupil distance
REF	Catalogue/part number
RS232	Serial interface
SN	Serial number
UMDNS	Universal Medical Device Nomenclature System (nomenclature for medical products)
U_T	AC mains voltage prior to application of the test level.

Figures

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000000-2075-933-GA-en-GB-230822 VISUPHOR 500
Subject to change

Your contact

The address of your contact person may be found in a separate document or on a label attached to the device.

CE

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