refraction unit
cubeONE

Directions for use

GA2024_04_ENG

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WAGNER & GUDER
MEDICAL GMBH

To this manual

The instructions for use are part of the scope of delivery.

- Please read manual before use refraction unit
- Make yourself familiar with the safety regulations
- Store at the place of use of the appliance
- Keep for the lifetime of the appliance
- Pass on to any subsequent owner or user of the equipment

We reserve the right to make changes to the design and scope of delivery in the course of technical developments.

Guidance

– The table of contents at the beginning of the instructions for use gives you an overview of the topics contained
– Pictures and signs warn of dangers or point out special features

Manufacturer

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Table of contents

Content

Safety instructions

Description of symbols

sign “Follow instructions for use“
especially read the safety instructions and follow the enclosed documents

Equipment labelling „nameplate“

	Manufacturer		
	Date of manufacture	GTIN	Global trade item number
ED10%	Duty cycle lifting unit	UDI	Unique device identifier
CE	EU- conformity		Type of device B
	Fuse	SN	Serial number
MD	Medical device	~	Alternating current
REF	Series		Disposal note
	Data Matrix Code according to GS1		Weigth of the product

Warning note „risk of trapping“
Pay attention to moving or motorised parts which, due to their design, could present a risk of trapping for the patient.

Warning note indicate a potential risk to the health and safety of users and/or patients. The warnings explain the nature of the hazard and how it can be avoided.

Mains voltage/ mains input
Please disconnect the unit from the mains when opening the housing.

Grounding
Indicates grounding (protective conductor) for safety reasons.

WEEE- marking „disposal“
Electrical or electronic devices or assemblies must not be disposed of as normal household waste.

Application area

Intended use (use as directed)

The cubeONE examination unit is an ophthalmological examination unit and is used exclusively for accommodating testing and measuring examination equipment for ophthalmic optics.

Any use other than that specified is not permitted.

Intended use

The cubeONE examination unit is a versatile device for positioning a sitting patient and/or customer in front of ophthalmic examination equipment. Both manual and electromotive adjustment options are available for positioning.

Medical device law

According to the directive of medical devices guideline 2017/745 (MDR), ophthalmologic examination unit cubeONE a non-invasive, active medical device in category I.

Reporting obligations of operators and users

Operators and users are obliged to report serious incidents to the manufacturer or distributor immediately and without culpable hesitation. Reportable incidents are malfunctions that could affect the features and performance of the product in terms of its suitability for use, as well as lead to a hazard for the patient and/or operator. In countries of the European Union, observe the reporting obligations to the competent authority as well as your national jurisdiction.

Device class	I
Basic UDI-DI	426076094UNITET
EMC	Electromagnetic compatibility page 33 following.

Approvals and requirements

Description	Marking
Electrical version	DIN EN 60601-1:2006 + A1:2013 + A2:2021 Protection class I
EMC requirements	The device complies with the EMC requirements of DIN EN 60601-1-2:2021, class B
CE- marking	The device complies with the essential safety requirements according to EU Regulation 2017/745 on medical devices The unit is marked CE

Informations for the operator

- Before using the device, make yourself thoroughly familiar with the contents of the operating instructions. Also observe the operating instructions for accessories and other system components.
- The examination unit may only be installed and commissioned by qualified personnel who are familiar with the installation, commissioning and operation of the product. For the purposes of these operating instructions, qualified personnel are persons who, on the basis of their technical training, knowledge and experience and their knowledge of the relevant standards, are able to assess the work assigned to them and recognise possible risks.
- Keep the operating instructions ready to hand at all times for the operating and service personnel.
- Observe the legal regulations for accident prevention and work safety valid in the respective country.
- Changes and repairs to the examination unit may only be carried out by our service personnel or by designated authorised dealers. The manufacturer is not liable for possible damage caused by unauthorised interventions on the unit. In this case, all warranty claims are void.
- The examination unit must not be installed and operated in damp rooms. Avoid dripping and splashing water.
- The examination unit must not be operated in a potentially explosive environment.
- The examination unit was adjusted to a level when it was installed. If the unit has to be moved, please make sure that all adjusting elements of the base plate touch the floor. This is the only way to ensure the stability of the unit and the examination equipment.
- In order to guarantee the specified working position of the examination equipment, it is necessary to swivel and move the telescopic table and the phoropter arm. Please make sure that the patient does not come into contact with moving parts. There is a risk of injury!
- The maximum load capacity of the instrument table is 40kg, while instrument position 1 may be loaded with a maximum of 30kg.
- Pay attention to the maximum load capacity of the patient chair of 135 kg.
- The lifting column of the patient chair is not designed for permanent operation. After an operating time of more than 1 minute, the lifting column of the patient chair requires a cooling time of 9 minutes.

- The examination unit may only be put into operation at a correctly installed grounded contact socket 230V/AC mains voltage with the mains cable supplied or in connection with the wall connection box.
- Extension cords and portable multiple sockets must not be used to operate the refraction unit.
- Interruption of the protective conductor is not permitted, as this can lead to danger for the user/patient and damage to installed equipment.
- If the protective conductor is damaged or electrical lines are damaged, the examination unit must be disconnected from the electrical connection and secured against unintentional operation.
- Never open the device! There are voltage-carrying parts inside.
- The examination unit may only be opened by authorised specialist staff.
- Only the main power fuses accessible from the outside may be changed.
- Please disconnect the mains power plug before cleaning. Please make sure that no detergent or water enters the examination unit.
- Additional devices that you connect to the examination unit must demonstrably be in compliance with the relevant IEC standards. Furthermore, all configurations must comply with the normative requirements for medical systems
  (see IEC 60601-1 and IEC 60601-1-2). The system configurator is responsible for ensuring that the system complies with the normative requirements.
- Each device has a protective conductor resistance and a leakage current. These add up if you connect mains-operated devices directly to the examination unit. According to IEC/VDE, the limit values are max. 0.1mA for the touch current, 5mA for device leakage current and max. 0.2Ω for the protective conductor resistance.
- Possible risks for the operation of the examination unit and the installation of further devices are considered in the product FMEA and in the risk management.

Requirements for operation

Before the first operation

- Check the stability of the examination unit
- Check the fixing points of the installed equipment
- Pay attention to the maximum permissible weights of the devices
- All cables and plug connections are in perfect condition
- The mains plug is plugged into a socket with a working protective conductor.
- Check safety-relevant circuits

Before the operation

- Check the fixing points of the installed devices
- Clean the permissible surfaces of the examination unit and contact surfaces of the installed devices.
- Advise patients/customers of possible risks

During the operation

- Never leave patients/ customers unattended at the devices
- Do not leave an instrument unattended with the light source switched on.
- The lifting element of the patient chair has a maximum load capacity of 135kg and is not designed for continuous operation.

After the operation

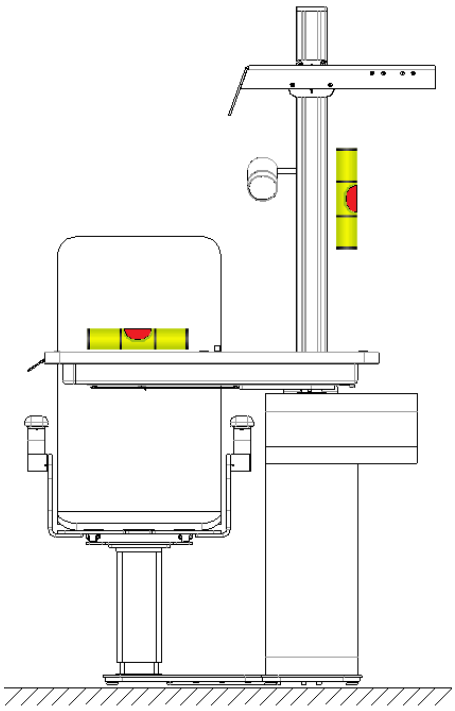
- Switch OFF the examination unit or installed devices if they are not in use
- Insufficient hygiene or incorrect cleaning contrary to the instructions for use can contribute to the risk of infection for the patient/customer and damage surfaces of the examination unit or lead to discoloration

Liability and warranty

Warranty and liability are based on the conditions specified in the contract

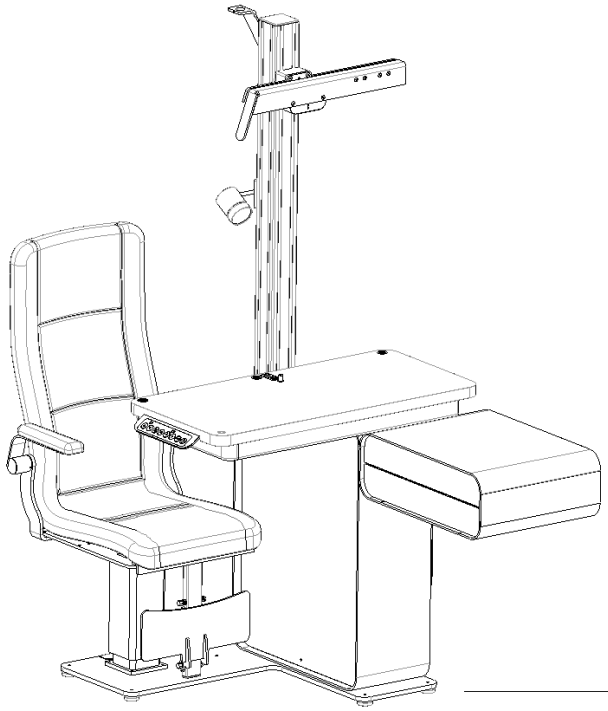
NOTCIE **Loss of warranty**
The manufacturer is not liable for damage caused by unauthorised intervention in the device or improper handling. In addition, all warranty claims are void.

Positioning and installation instructions



Correct adjustment of the refraction unit

Tough floor

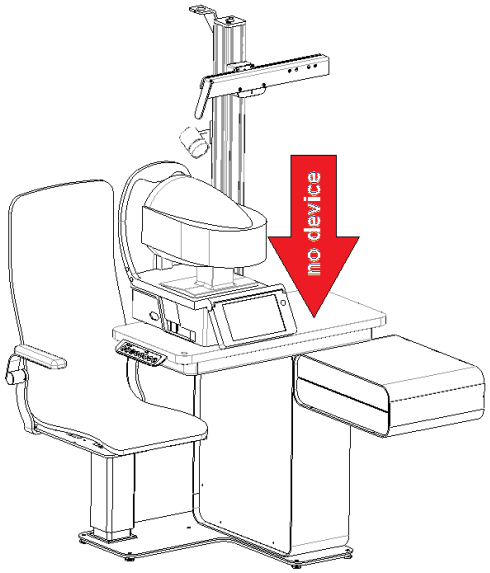


6x adjustable legs

Create stability

After transport,
Remove safety caps from legs

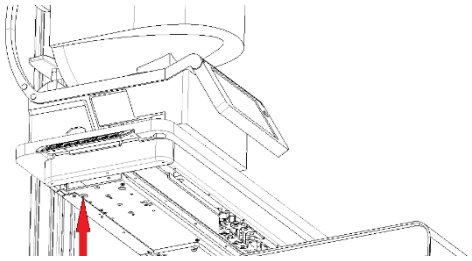
Notes on device installation



Refraction unit with single device working

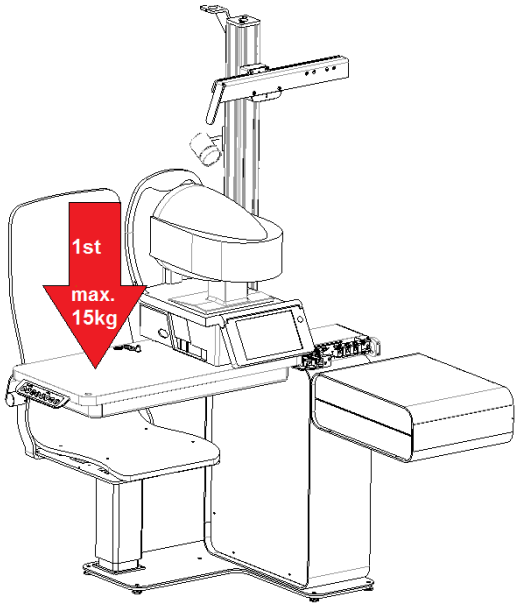
1. Working position 1: max. **30kg**

2. Working position 2: **Keep space free**



Attention! Single device working

Fix the 2nd table position with a suitable fixing screw M4x25mm

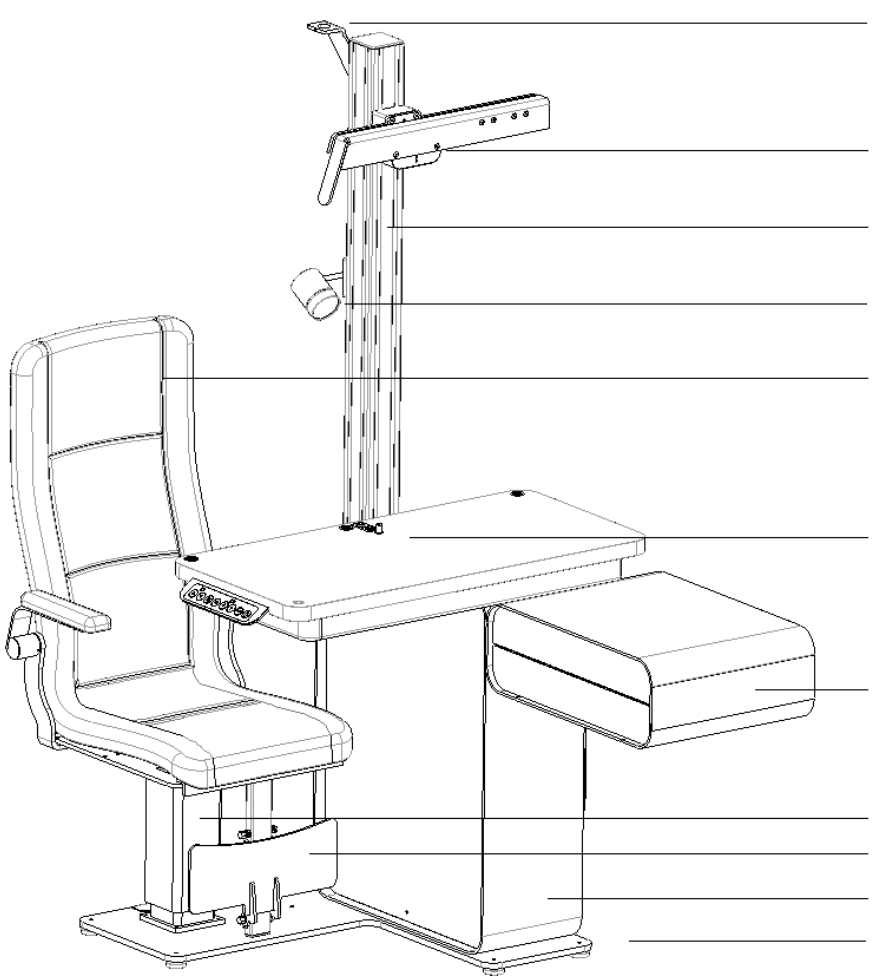


Refraction unit with multiple device working

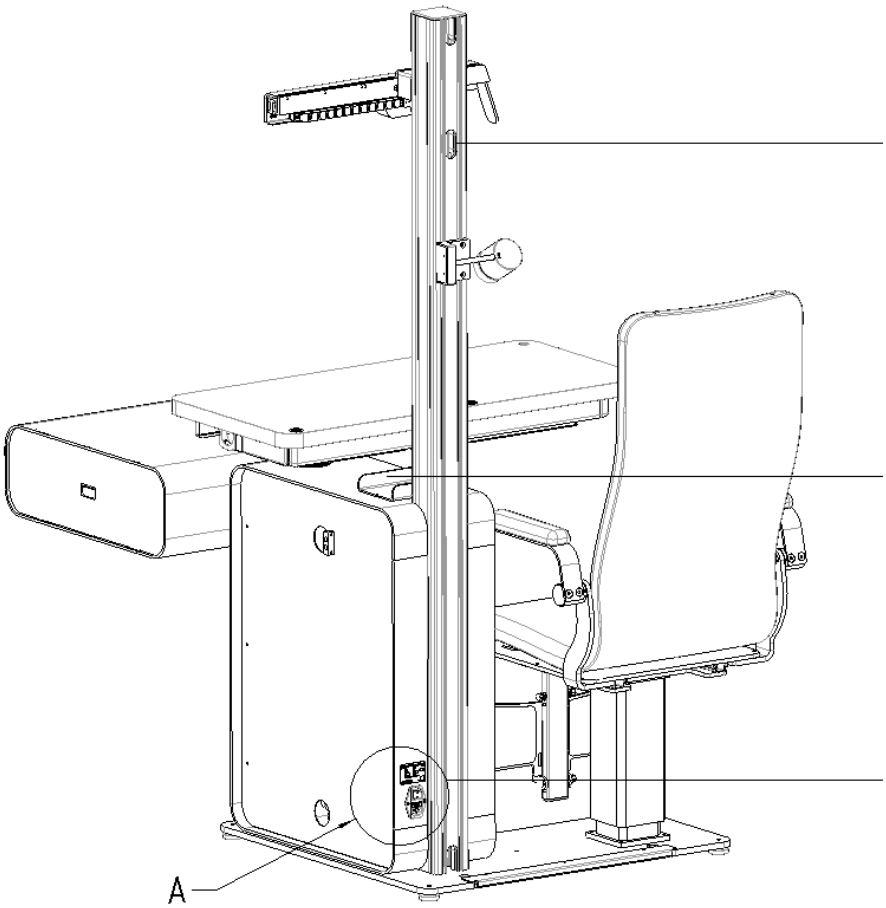
1. Working position 1: max. **15kg**
2. Working position 2: max. **25kg**

Failure to observe the permissible loads may result in a hazard!

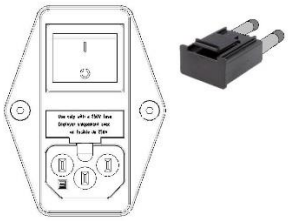
General structure



1	Mounting of projector, D=30mm
2	Reading Spot/ reading lamp
3	Phoropter rail with mounting hole, D=22mm
4	Functional column with slot system
5	Working table with control panel, application part
6	Lens case
7	Patient chair with tiltable armrests
	optional: sliding seat position, seat turning, foot rest, backrest inclination
8	Lifting pillar
9	Basic frame
10	Base plate with adjustable legs



12 cable exit functional column
13 eyewear desposit
14 Mains connection refraction unit,
In case of error disconnect **HERE**!



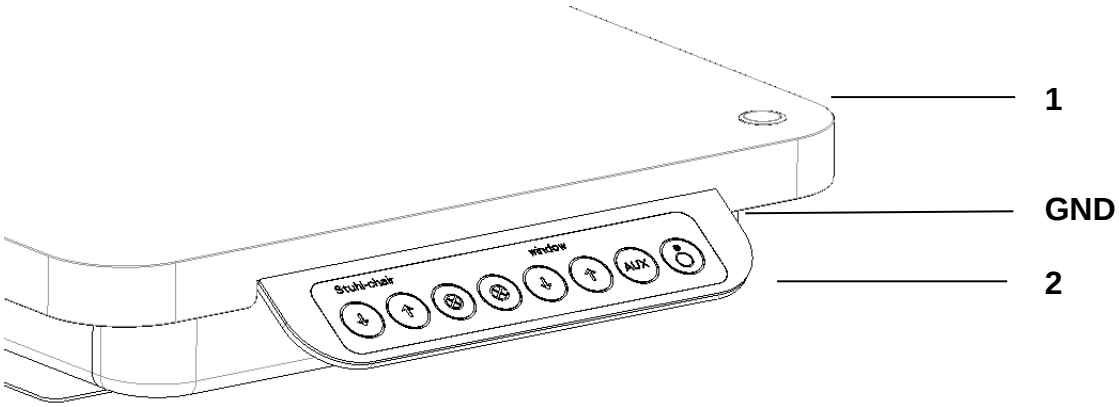
Mains connection
with fuses

2x T 6,3 A / H

Nameplate
Manufacturer
Specification

Working table

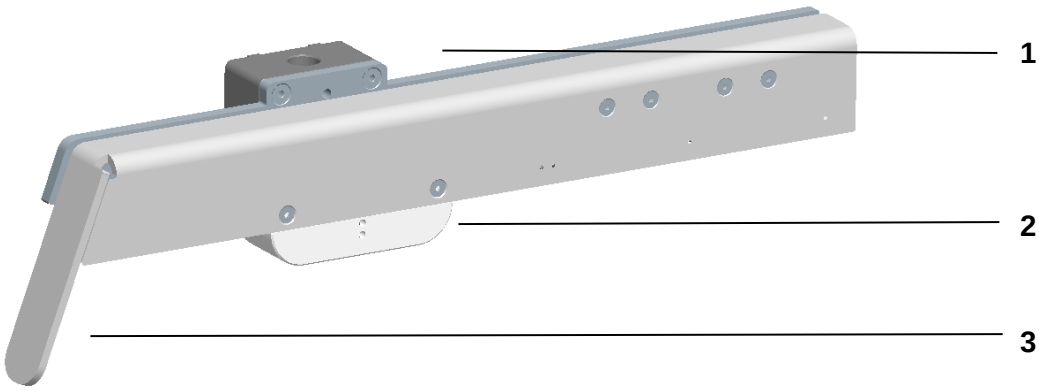
The instrument table enables smooth and safe swivelling in front of the patient. When the end position is reached, an electromagnet locks automatically. The table is swivelled back by releasing the holding magnet by pressing the table button. When changing the examination device to the second holding position, the table is moved to the second table position by passing a mechanical lock. Patient and user can keep their sitting position. The maximum permissible load of the two-device table is 40kg.



1 Press button to release the holding magnet
2 control panel

Phoropter arm

Telescopic rail system

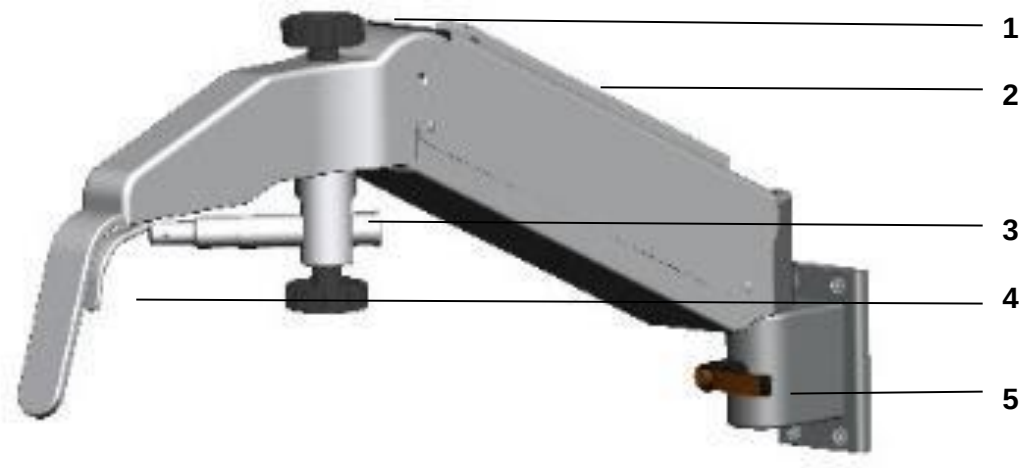


1 adapter phoropter rail with mounting hole

2 mounting hole phoropter d=22mm with clamp screw 2x M5 Inbus

3 handle phoropterarm

Swivel mounted phoropter arm



1 Clamp handle

2 Cable guide

3 Phoropter mount
Make sure that the phoropter head with the corresponding safety screw is fixed correctly!

4 Handle to loose and adjust working heigh (gas spring system)

5 Clamp handle and swivel mount

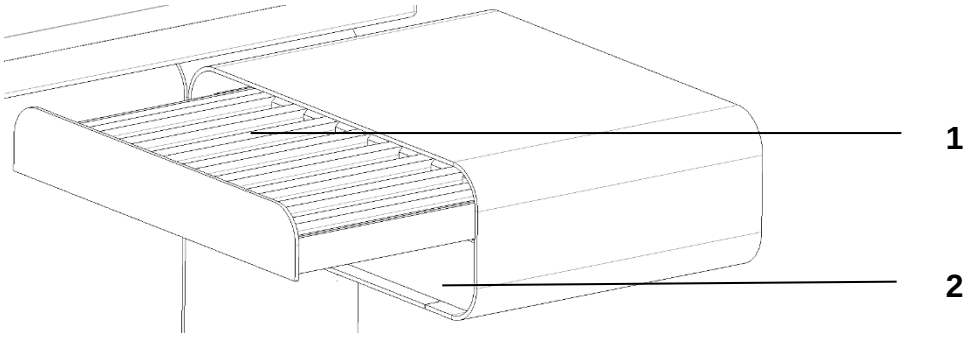
Mounting bracket projector mount

1 Projector mount, D=30mm Mounting with screw lock, M5 Inbus

2 Fixing point on the function column with sliding blocks

Drawers with lens case holder

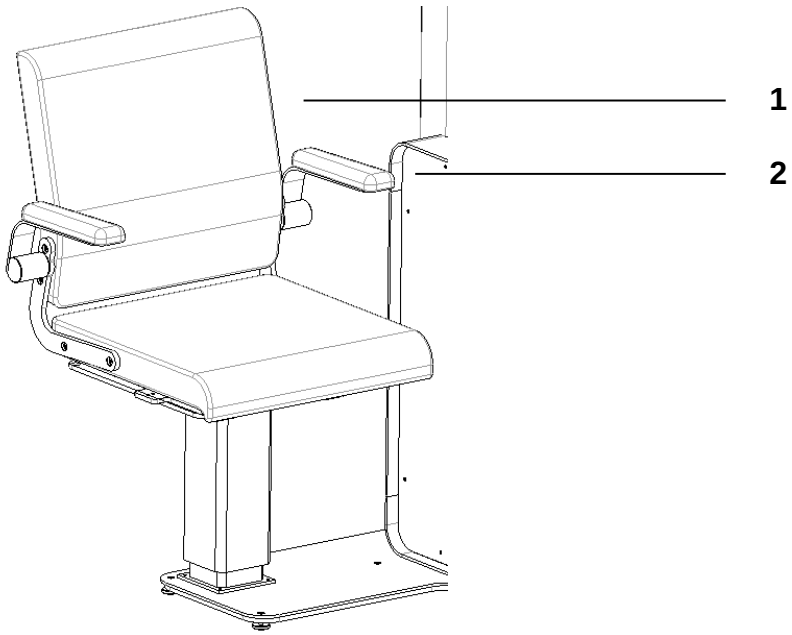
The drawer is designed in such a way that it can contain a measuring glass insert.
This is included in the scope of delivery (space for 238 glasses).



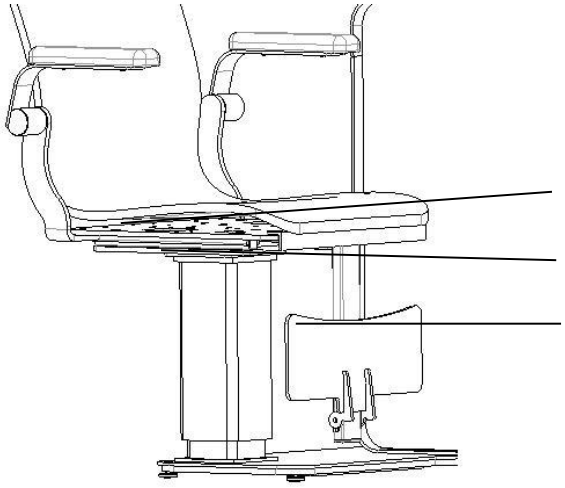
1 Lens case for measuring glases (238pcs)
2 drawer

Patient chair

The patient chair is fixed to the unit and has an electromotive height adjustment. The maximum permissible lifting load of the patient chair is 135kg.



1 Seat shell
2 Turnable arm rest



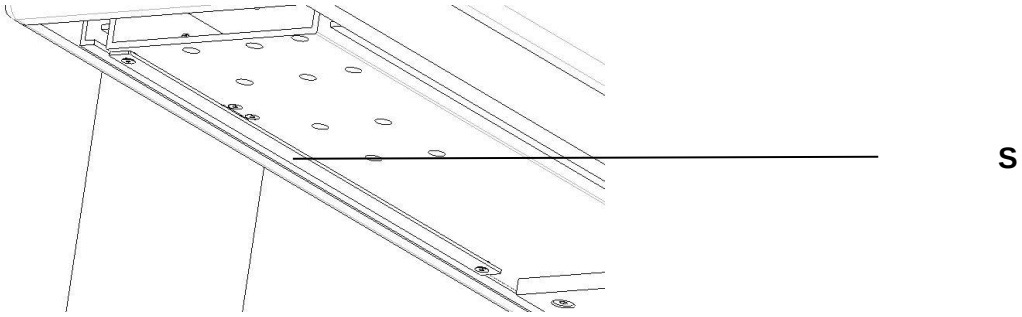
1 Sliding seat position
2 Seat rotation, 4x 90°=360°

Please note that the optional seat rotation can only be used to a limited extent in certain seating positions!

3 Foot rest, tiltable

Please make sure that the patients do not put their feet under the footrest! The lifting column does not recognize any obstacle as a result of the construction!

Safety switch, Emergency Stop patient chair

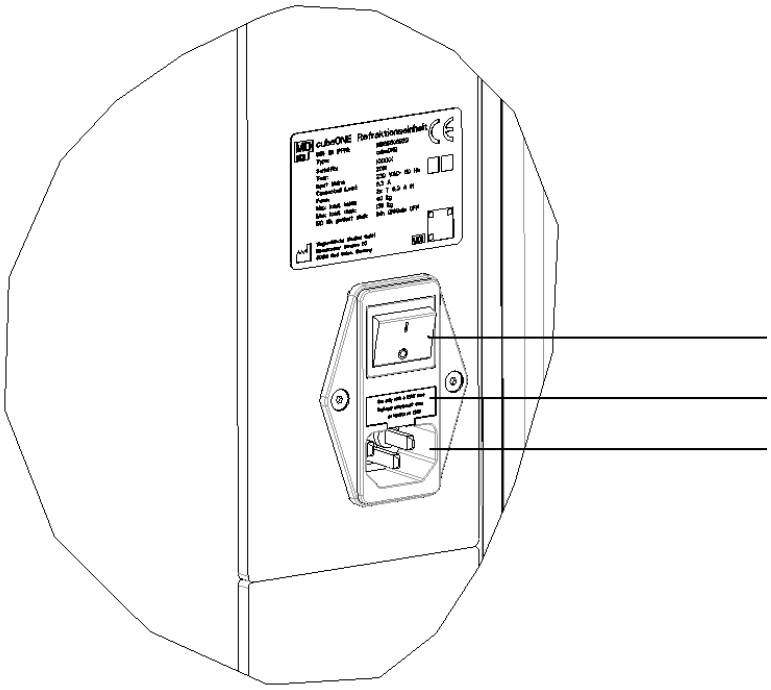


S Safety switch

Make sure that all adjustable accessories do not endanger the patient. Especially seat displacement, footrest and rotation are a source of danger for the patient when the patient chair is moved in height. Although the unit has a safety switch strip under the instrument table, this is not always in operation because of its design.

Electric connection

The electrical connection of the examination unit is made to a properly installed grounded contact socket or the wall mounting box included in the delivery. Please use only the included power cable, connection length 2,5m, cable cross-section 1mm^2 or the connection cable of the wall connection box.



Mains switch

Fuse box
2x T 6,3A / H
Power input
(2,5m, 1mm^2)

In case of error
disconnect **HERE**!

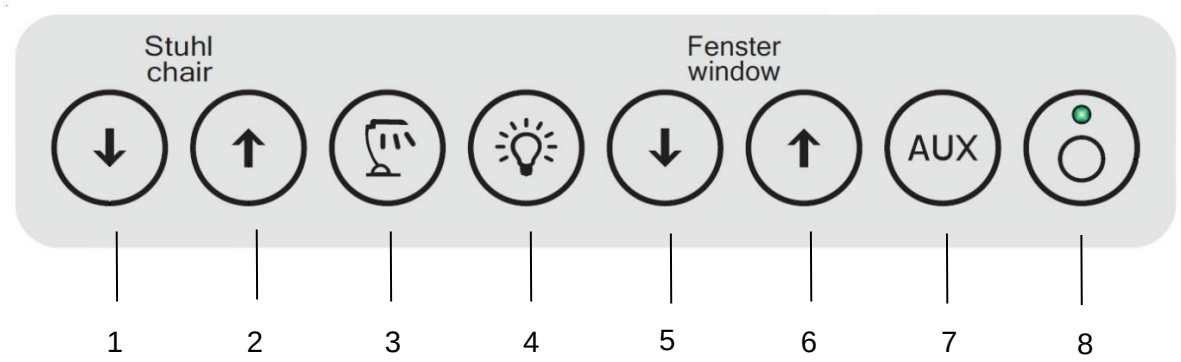
Initial operation

- Plug the enclosed power cord into the power input socket provided
- Connect the power cord to a properly installed grounded outlet.
- Set the power switch to "I".
- Press the operating switch on the device table, the control lamp lights up green, Page 19 (Position 8)

Operation

Control panel

The operating switch with the control lamp is located at the instrument table, see page 14 (position 15). The examination unit is ready for operation as soon as the button is pressed and the lamp lights up green. This also applies to already installed examination units or additional components, if they are supplied with voltage via the switchable socket strip 230VAC/4A. The examination devices on the telescopic table are automatically ready for operation when table position 1 or table position 2 is reached. Next to the operating button there are further control functions.



1 Patient chair DOWN

2 Patient chair UP

if you put both buttons, patient chair will move „Automatic down“ to lowest position

this function is working by a time delay of 10sec. After finish this time patient chair is able to move UP again

3 Button reading lamp ON/ OFF

4 Button roomlight control

5 Blind control Down

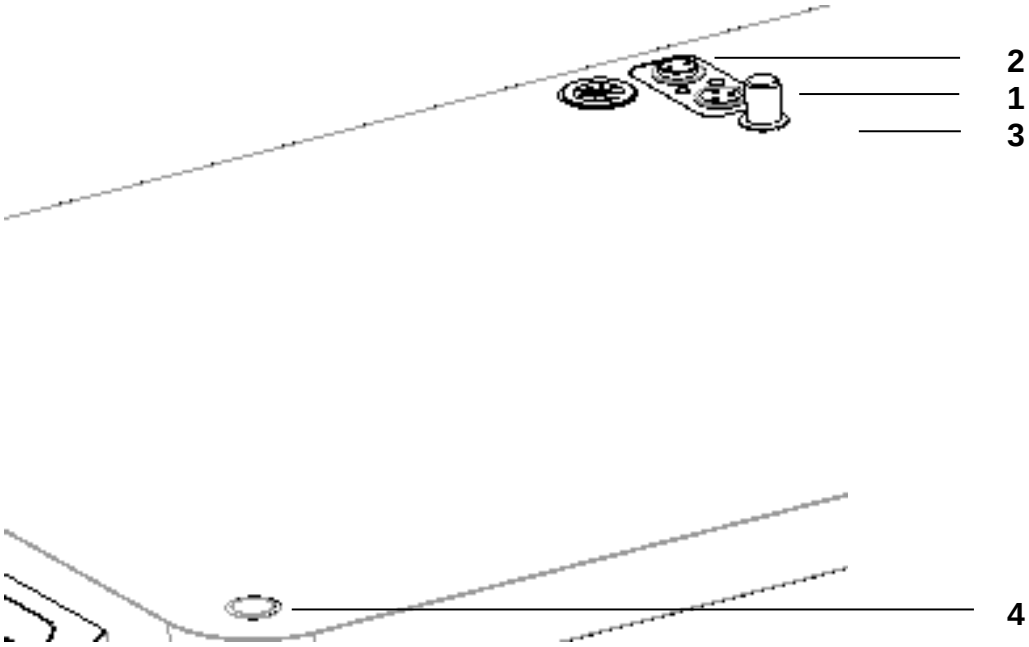
6 Blind control UP

7 AUX, free button

8 operation button with LED light (green), Stand- By- Mode

Device installation

Instrument table - electric connection



5- pole cable, marking 1 to 4 and GND (PE)

1 3pol **working table position 1** for device connection (cable marking 1+2)
PIN 2: GND- protective earth
PIN 1+3: 6 VDC or 12 VDC (on basic board – page 26)

K11 Outlet 6V: PIN 25/ 27

K11 Outlet 12V: PIN 25/ 26

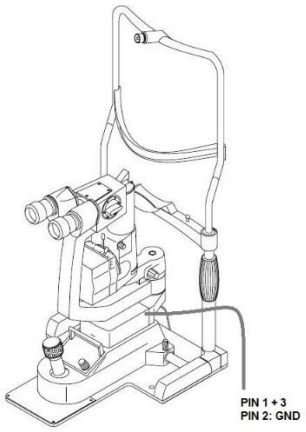
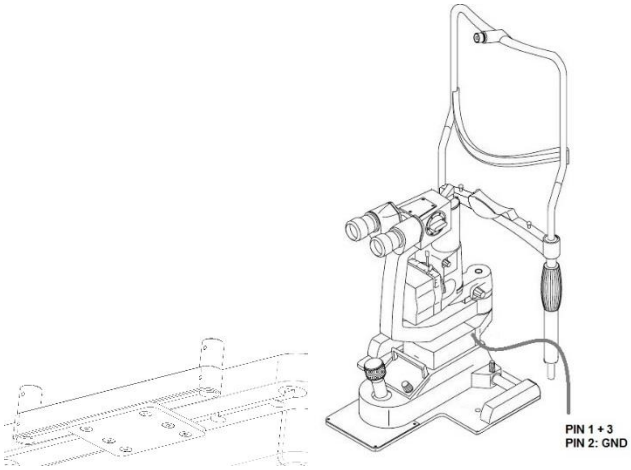
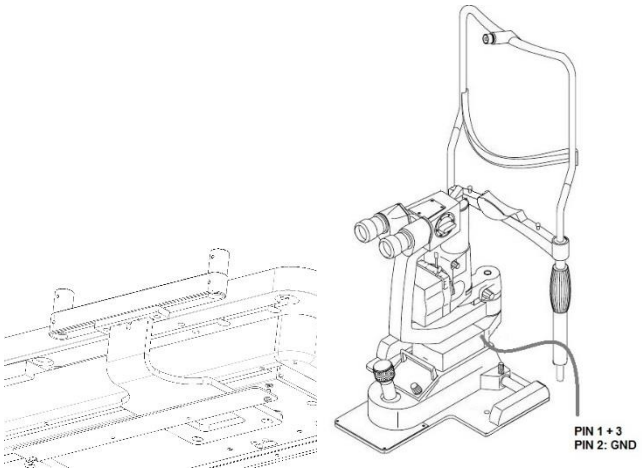
2 3pol **working table position 2** for device connection (cable marking 3+4)

PIN 2: GND- protective earth

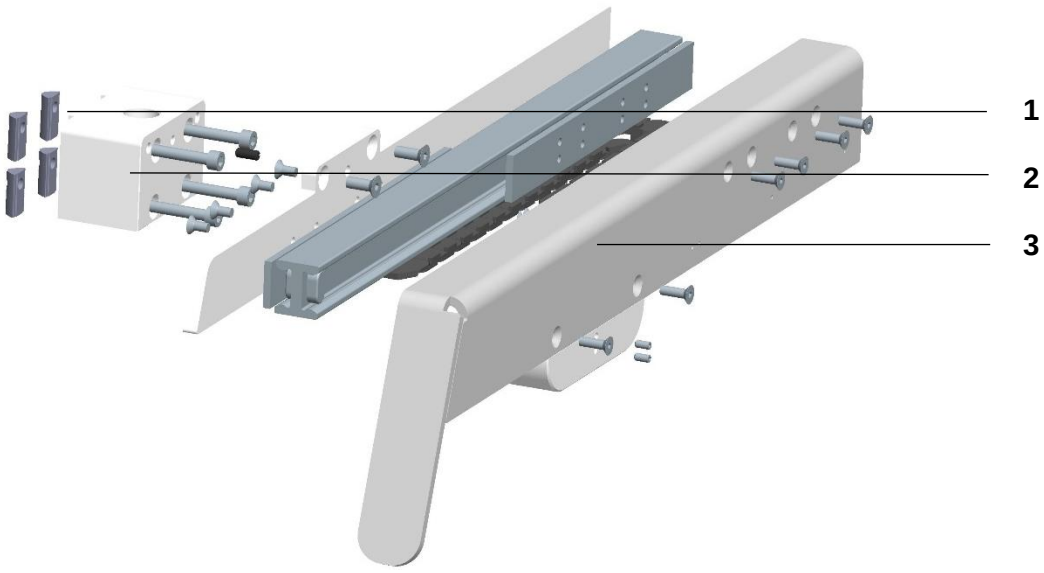
3 Brightness control, dimmable for instrument table

4 Button to loose electromagnetic brake

Slit lamp installation

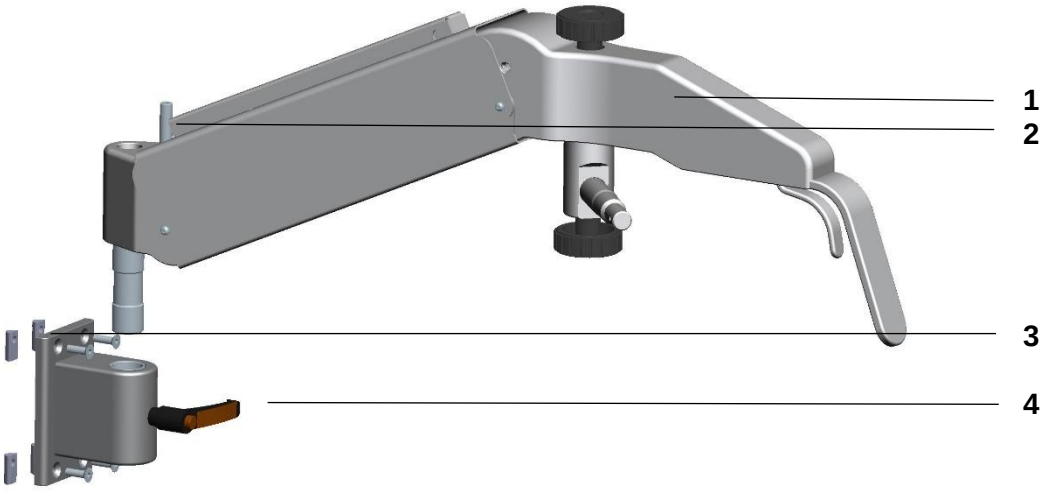
No.	Example	description
1		Slit lamp assembly on base plate with integrated chin rest **table position 1**
2		Slit lamp assembly on base plate with or without integrated chin rest **table position 1**
3		Slit lamp assembly with or without base plate and 2nd moveable device Chin rest is fixed on 1st position **table position 1**

Phoropter arm



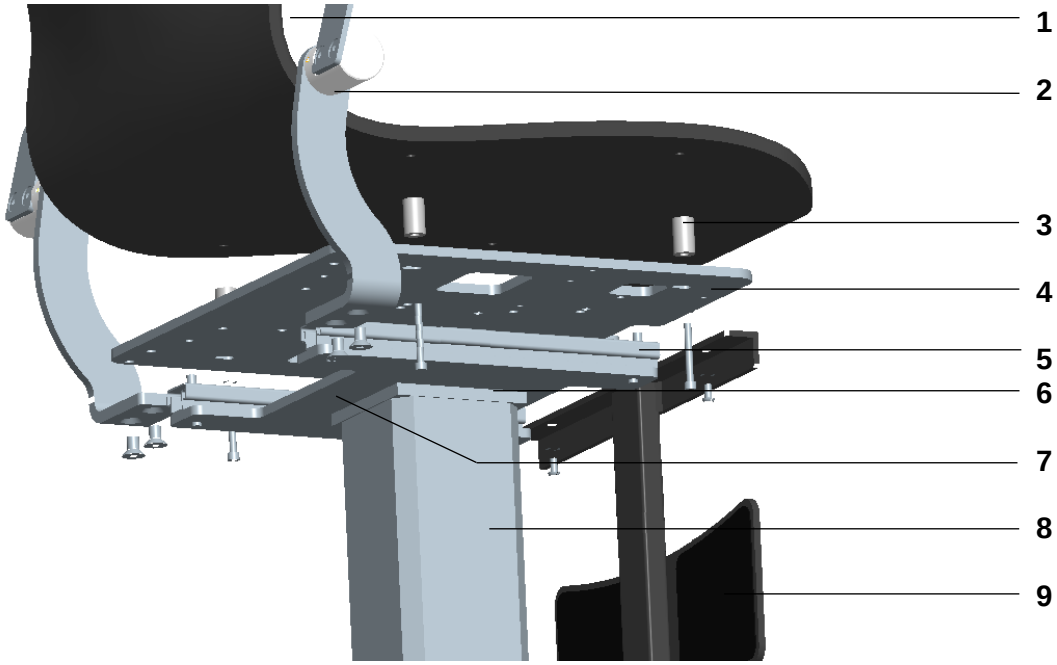
1 Slot nut, to mount phoropter rail on function pillar
2 Mount
3 Phoropter rail

Swivel mounted arm



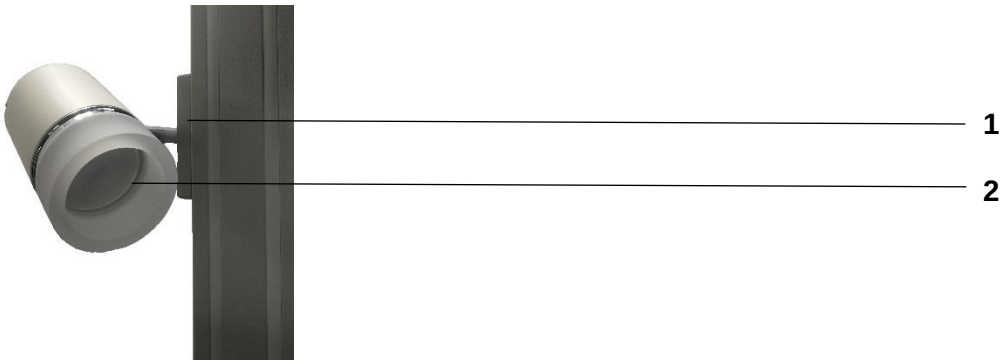
1 Basic mount
2 Adjustable screw for weight control
3 Slot nut, to mount phoropter rail on function pillar
4 Clamping lever for rotation

Patient chair



1 Seat shell
2 Arm rest mount
3 Spacers
4 basic base plate for seat shell
5 seat moving forward/ backward (option)
6 Turning seat position (optional)
7 Base plate sliding seat shell
8 Electric pillar
9 Foot rest

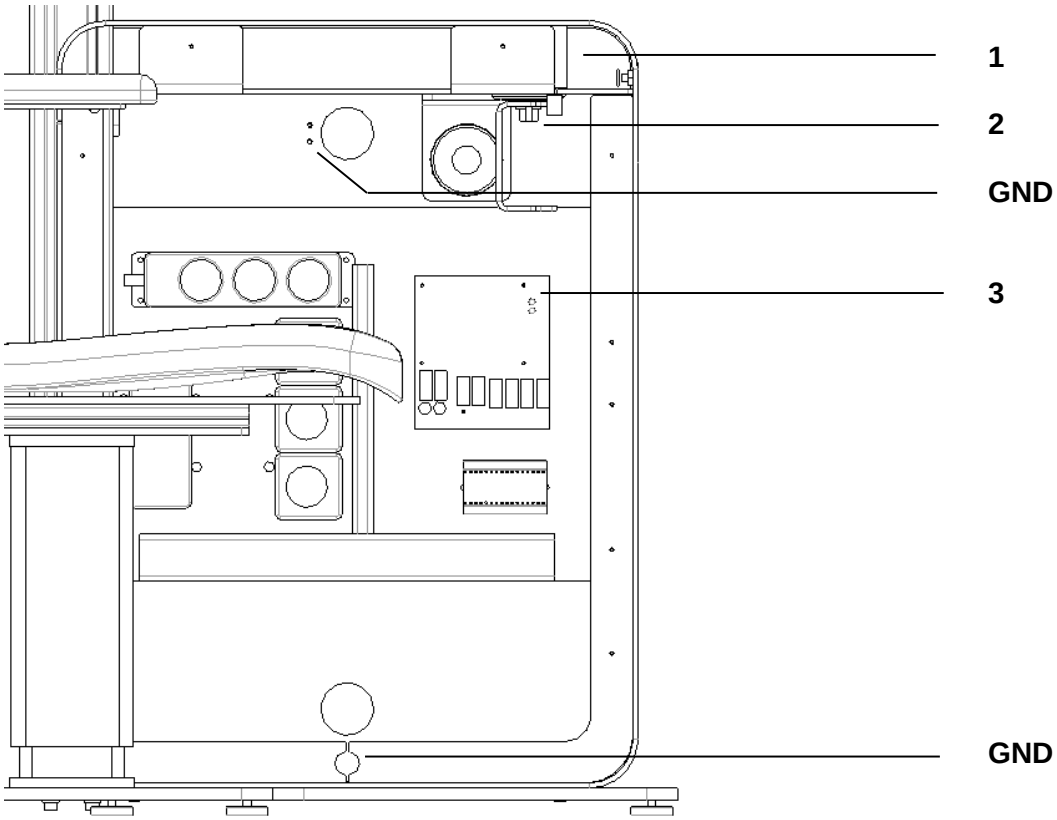
Reading light/ Reading spot



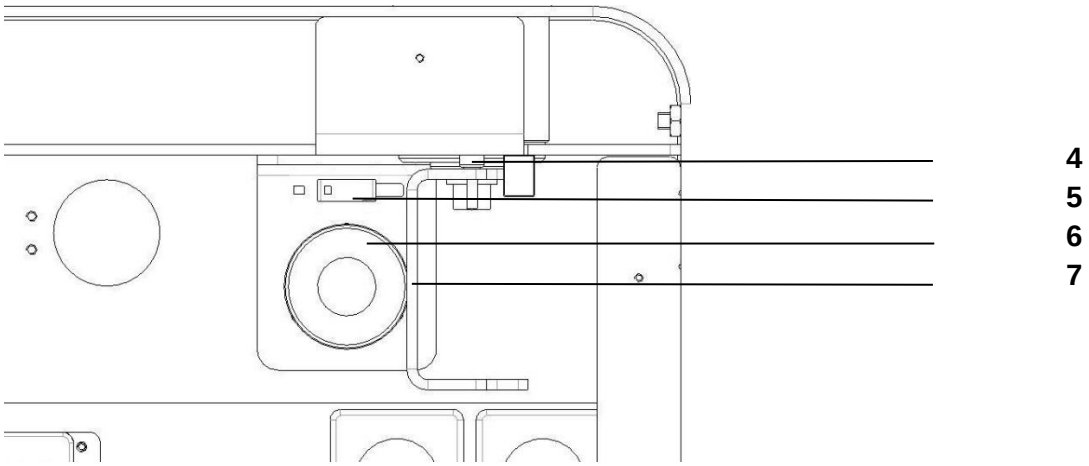
1 Mount of reading lamp – adjustable in high and turnable
2 illuminants, GU5,3 – 4,6VA – 4000K

Technical structure

Basic frame

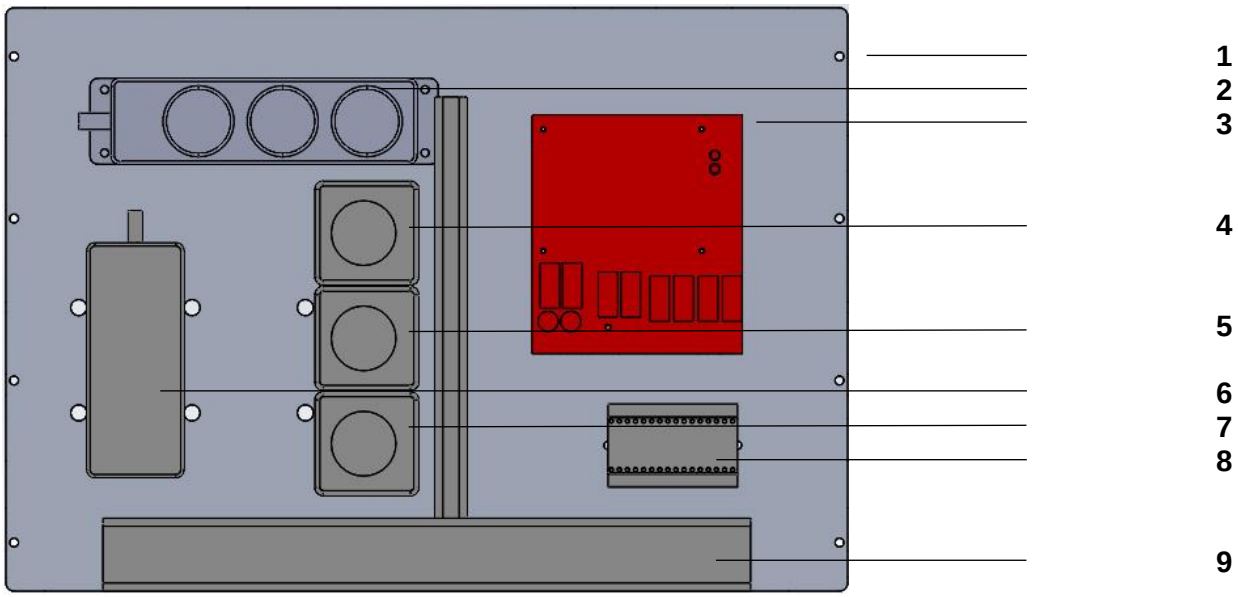


1 Table bearing
2 Holding magnet instrument table in working position
3 plate of control unit (page 25)

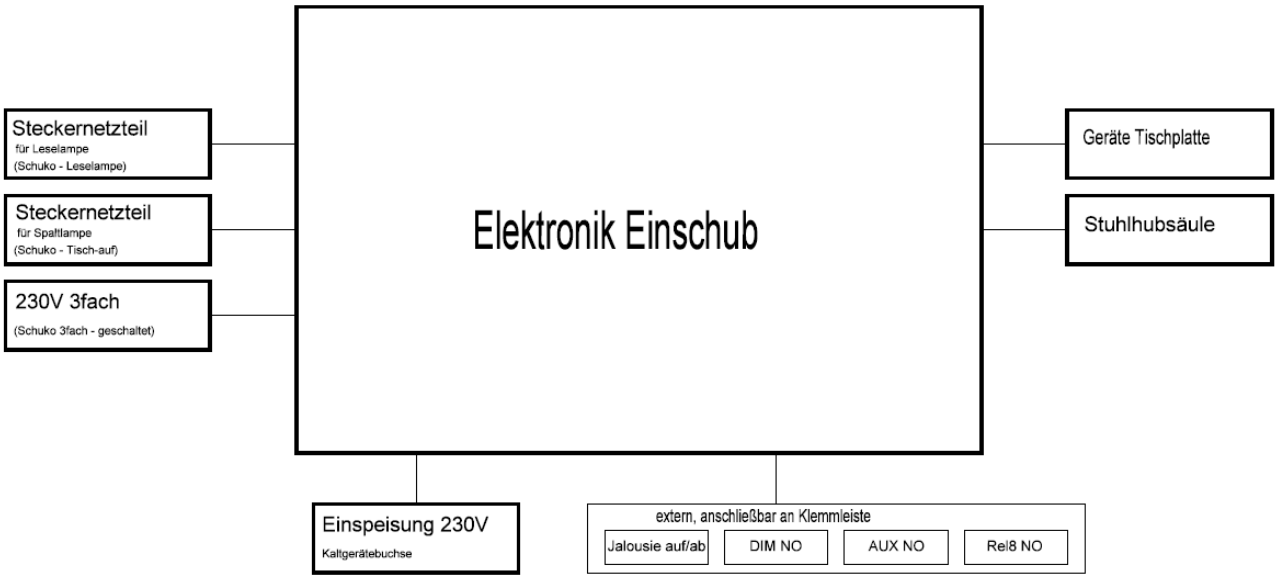


4 spring loaded thrust piece
5 End switch
6 Holding magnet
7 fixation plate – turning instrument table

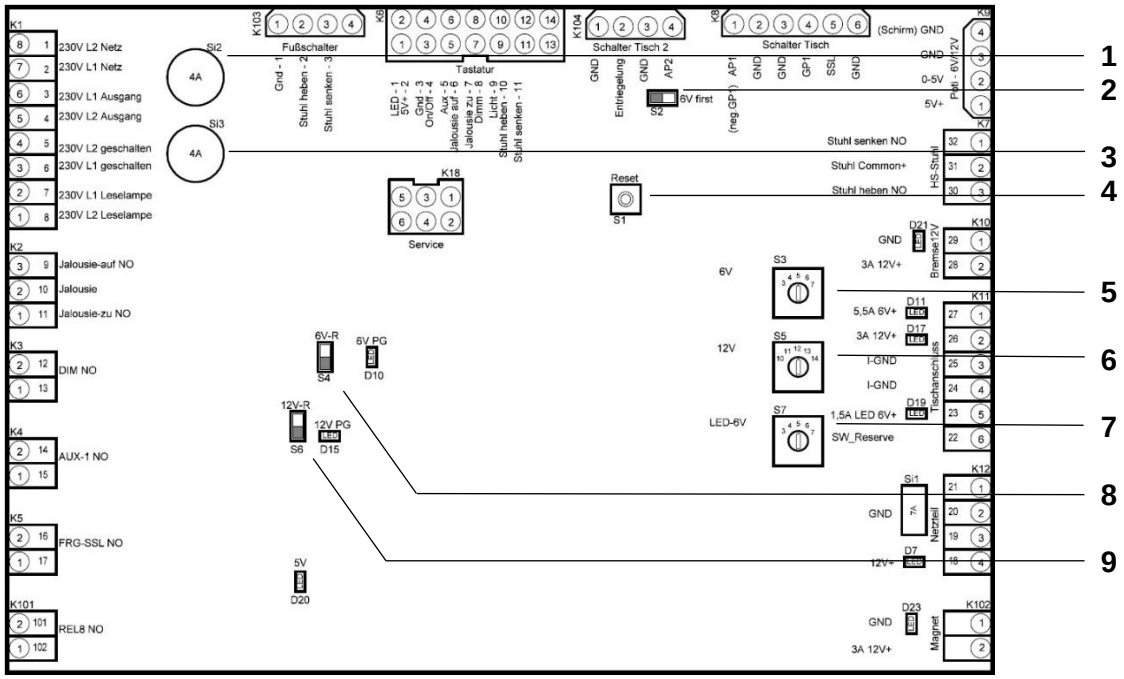
Control unit



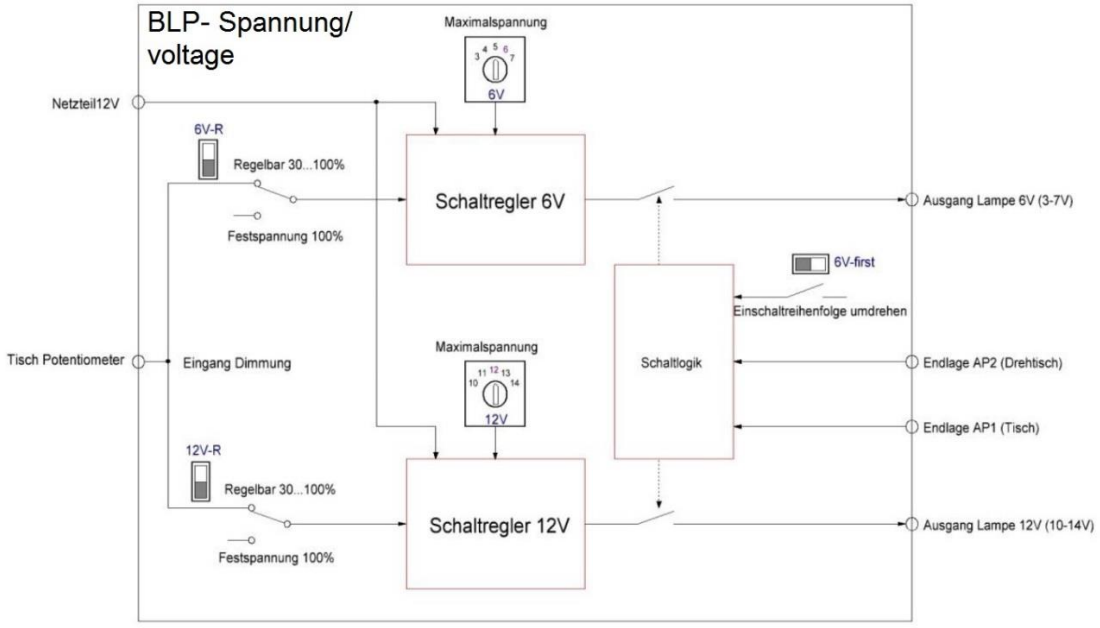
1	Base plate control unit cubeONE
2	3times power socket, current power, 230VAC – max. 4A
3	Basic board - BLP
4	Reading spot 230VAC, switched over control panel
5	power socket 230VAC, switched by working position
6	power supply 12VDC
7	power socket 230VAC switched, max. 2A
8	external connection
9	cable guide



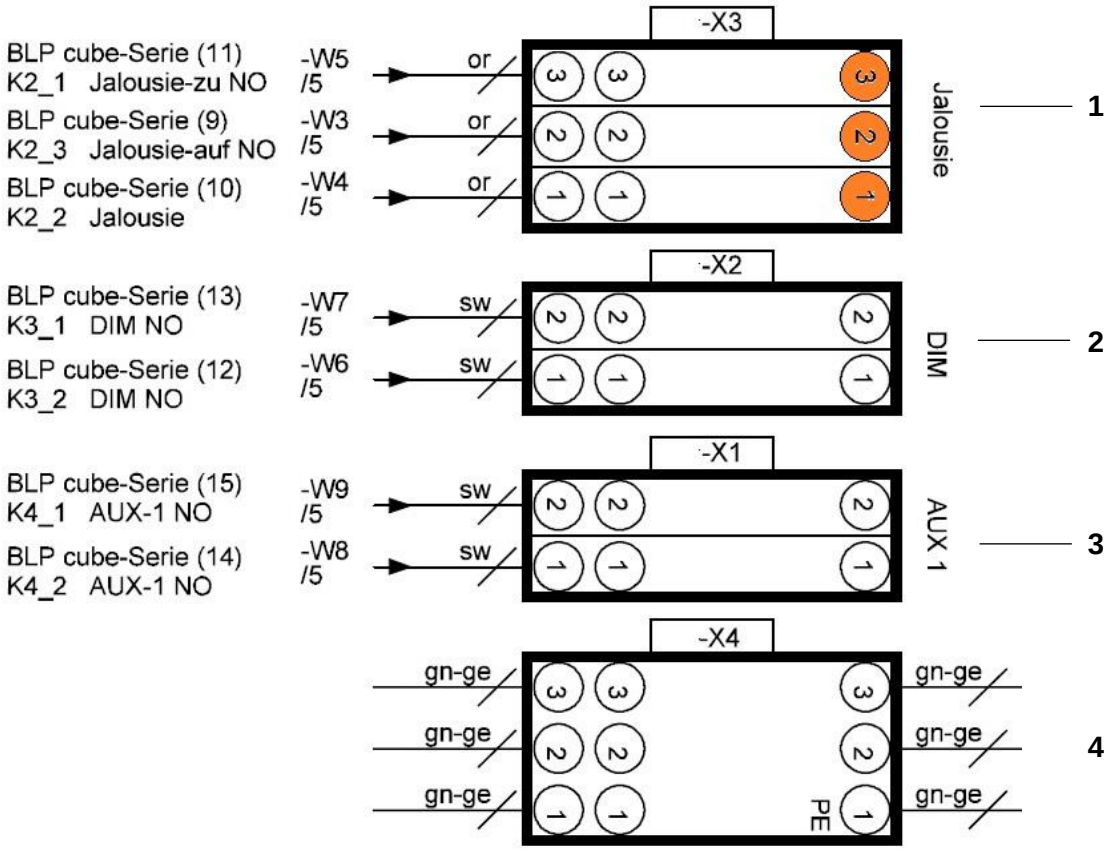
Basic board - BLP



1 fuse Si2 (230V T 4 A / H)
2 switch between first and second instrument position of outcomming voltage
3 fuse Si3 (230V T 4 A / H)
4 RESET - buttom
5 6V outlet (max.5,5A), switch position 1,2,3,4,5 according to: 3V, 4V, 5V, 6V, 7V
6 12V Ausgang (max. 3A), switch position 1,2,3,4,5 according to: 10V, 11V, 12V, 13V, 14V
7 LED- 6V (Fixierleuchte), switch position 1,2,3,4,5 according to: 3V, 4V, 5V, 6V, 7V
8 switchover 6V-R dimmable/ 6V fixed voltage
9 switchover 12V-R dimmable/ 12V fixed voltage

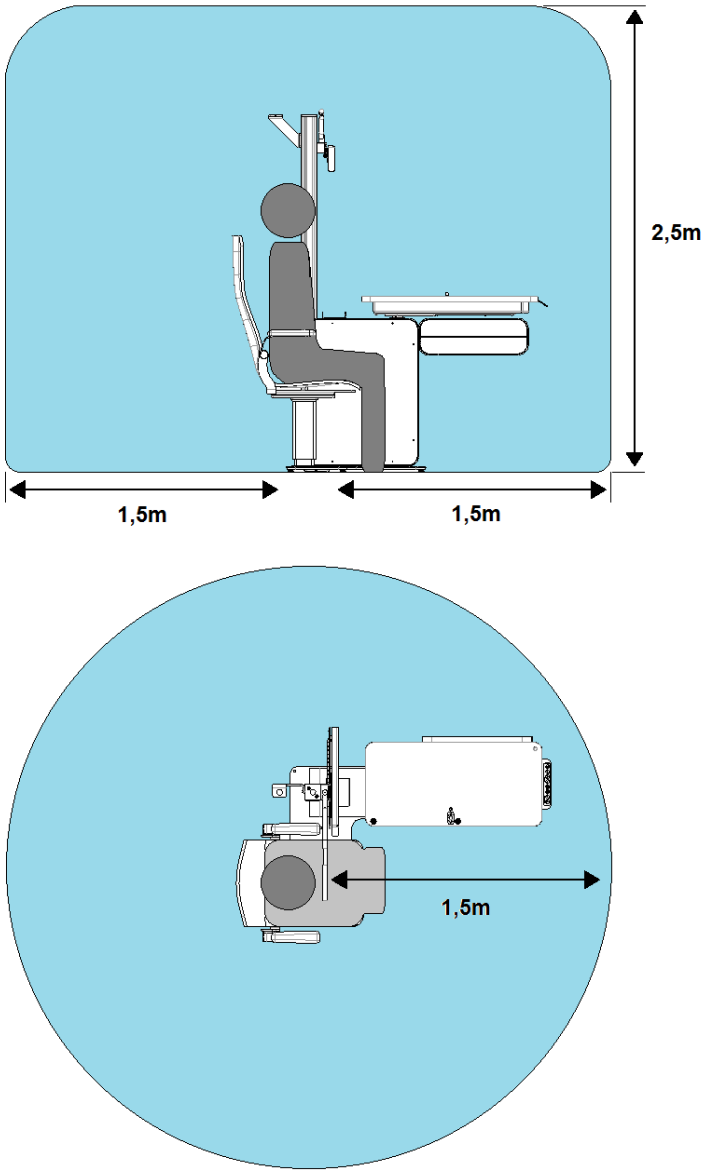


External termial block



1 connection to blind control, External voltage switchable to 8 A
2 connection to rommlight control
3 connection to free switch AUX, Potential free Push button or switch (by software)
4 GND – ground terminal

Patient Surrounding



The area marked above is considered the patient surrounding. In this area, the patient is guaranteed the maximum possible protection. In the area of the patient's environment dangerous spots can occur. Here the treating physician or optician has a special duty of care, especially in connection with the installed devices. In this area, a patient may intentionally or unintentionally create an electrically conductive connection. This must be prevented by suitable protective measures!

Maintenance of the device

Safety check

The examination unit is maintenance-free and designed for a service life of 6 years. To ensure safe and proper operation and a long service life at all times, regular preventive maintenance must be carried out. The electrical safety of the device may deteriorate due to aging and usage.

At least the following safety checks should be done for the system by the manufacturer or qualified persons.

- Check the directions for use is available
- Visual inspection of device and accessories for damage
- Legibility of the labels
- Check the function of safety relevant circuits!
- Function test of the operating functions
- Leakage current test
- Protective conductor test
- Documentation of the results

Failure to observe the inspection intervals may result in a risk of healthy.

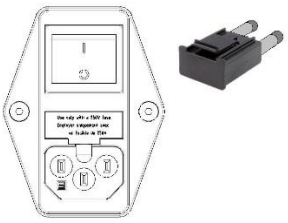
Attention! Duty cycle patient chair

The lifting system of the examination unit is not suitable for designed for continuous operation.

Operating time:	1 min, continuous operation with full load
Resting time:	9 min

Change of the main fuses

The main fuses may only be changed when the mains plug is disconnected. You should only consider changing the fuses if the control lamp does not light up despite the power and operating switch being switched on.



- The mains fuses can be found in the fuse box at the mains connection of the examination unit.
  Press the plastic tongue attached to the box (e.g. with a screwdriver or similar). This will release the lock of the fuse box.
- Pull the fuse box out of the opening by hand.
- Replace the defective fuses with new fuses (marking: T 6,3 A / H).
- Slide the fuse box back into the provided opening until the plastic spring locks into place.

Maintenance of the device

Disconnect the examination unit from the power switch and pull the power plug! Avoid that cleaning material or other liquids can get into the examination unit or on installed examination devices during cleaning work.

Cleaning

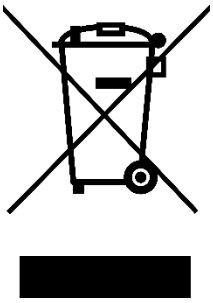
Instrument table and patient chair with armrests

The instrument table top is provided with a plastic surface. It has a plastic-coated surface in accordance with EN 14322, is biocompatible in accordance with ISO 10993-1 and is correspondingly resistant. Disinfectants may also be used for cleaning.

Clean the paint parts and the seat upholstery on the examination unit exclusively with a damp cloth and mild cleaning agents. Stubborn soiling on varnished surfaces can be removed with petroleum ether or methylated spirits. Repeated use can lead to colour changes of the components!

Environmental protection regulations

Disposal



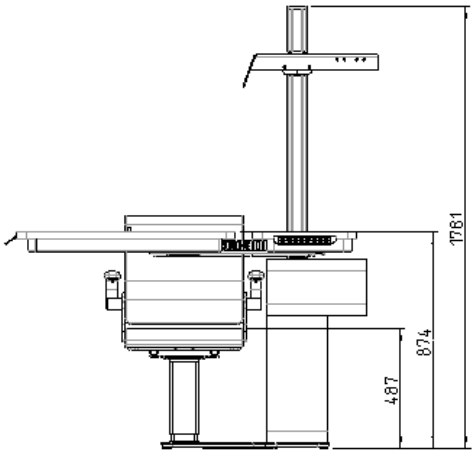
This symbol indicates that the electrical or electronic equipment must not be disposed of as normal household waste.
This symbol is only valid for EU member states.
To avoid possible negative effects on the environment and possibly on human health, this equipment must be disposed of (i) in EU Member States in accordance with the EU Directive on Waste Electrical and Electronic Equipment WEEE and (ii) in all other countries in accordance with local regulations for the disposal and recycling of hazardous waste.

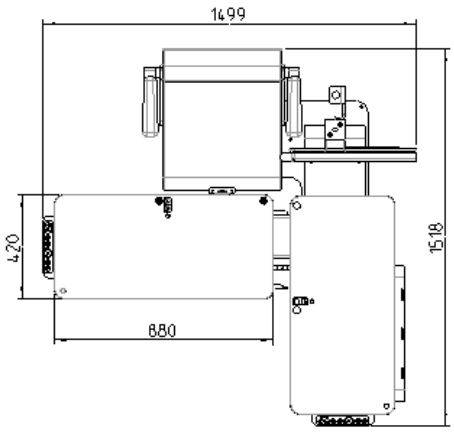
WEEE-Reg.-No. DE 67707987

Device details

Technical Data

Feature	Permitted values
Nominal power input	230 VAC ±10%
Frequency	50 Hz
Protection class	I
Type of device	B
Connection load	6,3 A
Reading lamp	6 VA
Low voltage	6 VDC / 5,5 A 12VDC / 3A
Working high	875 mm
Maximum high	1780 mm
Duty cycle ED 10% Patient chair	1 min ON / 9 min OFF
Lifting speed	10 mm/s
Net weight	140...170 kg
Loading capacity patient chair	135 kg
Loading capacity instrument table	40 kg





Wagner & Guder Medical GmbH

Hermstedter Straße 57,
99518 Bad Sulza, Germany

Essential performance of the examination unit

The examination unit does not have an essential performance characteristic as defined in IEC 60601-1-6:2010 + A1:2015 + A2:2021.

However, it is possible for a system consisting of an instrument table and one or more medical devices to have one or more essential performance characteristics.

For example, an essential performance characteristic may be the unconditional holding of the stroke position during an ophthalmic procedure.

The existence of essential performance features must therefore be re-evaluated without fail when creating medical electrical systems!

Environmental conditions

1. For operations

Feature	Permited value range
Temperature	+5°C … +40°C
Relative humidity	30% … 75% no condensation
Operating height	till 2000m a.n.z

2. For Transportation

Feature	Permited value range
Temperature	-20°C … +70°C
Relative humidity	10% … 90% no condensation
Air pressure	500hPa … 1060hPa

3. For Storage

Feature	Permited value range
Temperature	-10°C … +55°C
Relative humidity	10% … 90% no condensation
Air pressure	700hPa … 1060hPa

Electromagnetic compatibility (EMC)

Medical electrical equipment is subject to special precautions with regard to EMC and must be installed and commissioned in accordance with the following guidelines. Portable and mobile HF equipment (e.g. cell phones) can affect medical electrical equipment. Third-party devices may only be connected in compliance with the EN 60601-1 standard. The refraction unit fulfills the requirements on electromagnetic compatibility according to EN 60601-1-2:2007 (IEC 3rd Edition) + EN 60601-1-2:2015 (IEC 4th Edition).

The following information is only valid in connection with the accessories supplied and included with the device.

- power cord (2,5m)

Guidance and manufacturer's declaration – Electromagnetic emissions		
This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment		
Emission test	**Compliance**	**Electromagnetic enviroment - guidance**
RF Emissions according to CISPR 11	Group 1	This product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions according to CISPR 11	Class B	This product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Emission of harmonics according to IEC 61000-3-2	Class B	
Voltage fluctuations / flicker emissions according to EN 61000-3-3	Matches	

Guidance and manufacturer's declaration – Electromagnetic immunity

This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.

Immunity test standard	EN 60601-test level	Compliance level	Electromagnetic environment - guidance
Electrostatic Discharge (ESD) according to EN 61000-4-2	± 8 kV contact ± 15 kV air	fulfilled	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. .
Electrical fast transient / burst according to EN 61000-4-4	± 2 kV Netzleitungen ± 1 kV für Eingangs- und Ausgangsleitungen	fulfilled	Mains power quality should be that of a typical commercial or hospital environment.
Surge according to EN 61000-4-5	± 1 kV Leiter-Leiter ± 2 kV Leiter-Erde	fulfilled	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines According to EN 61000-4-11	0% U_T 10ms 0% U_T 20ms 70% U_T 0,5s	fulfilled	Mains power quality should be that of a typical commercial or hospital environment. If the user of this product requires continued function even in the event of interruptions in the energy supply, this product should be powered from an un-interruptible power supply or a battery.
Magnetic Field Immunity (50 or 60Hz) EN 61000-4-8	30 A/m	fulfilled	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T = the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – Electromagnetic immunity

This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.

Immunity test standard	EN 60601 test level	Compliance level	Recommended distance [c]
Conducted disturbances induced by RF fields EN 61000-4-6	3 Vrms 150kHz - 80MHz 6 Vrms 150kHz - 80MHz	3 Vrms 6 Vrms	$d=0{,}35\sqrt{P}$ $d=0{,}7\sqrt{P}$ 80MHz – 800MHz
Radiated RF EM fields EN 61000-4-3	3 V/m 80MHz - 2,7GHz 10 V/m 80MHz - 2,7GHz 80%@ 1 kHz AM Modulation	3V/m 80Mhz- 1 Ghz 10 V/m 80Mhz- 1 Ghz 80%@ 1 kHz AM Modulation	$d=1{,}4\sqrt{P}$ 800MHz – 2,7GHz
Proximity Field from HF transmitter	9 V/m to 28 V/m	fulfilled	
Where ***P*** is the maximum output power rating of thet ransmitter in watts **(W)** according to the transmitter manufacturer and ***D*** is the recommended separation distance in metres **(m)**. Field strengths from fi xed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range b Interference may occur in the vicinity of equipment marked with the following symbol:			

NOTE 1:	At 80 MHz and 800 MHz the higher frequency applies.
NOTE 2:	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a.	Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broad-cast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this product is used exceeds the applicable RF compliance level above, this product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this product.
b. c.	Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m. Possible shorter distances outside the ISM bands do not contribute to improved application in this table.

Recommended safe distances between portable and mobile HF communication devices and this device.

This product is designed to be operated in an electromagnetic environment in which radiated HF interference is controlled. The customer or user of this product can help to prevent electromagnetic interference by maintaining minimum distances between portable and mobile HF communication systems (transmitters) and this product, as recommended below in accordance with the maximum output of the communication system.

Nominal output of the transmitter (W)	Safe distance according to transmission frequency (m)		
	150kHz - 80MHz $d=0{,}35\sqrt{P}$	80MHz - 800MHz $d=0{,}7\sqrt{P}$	800MHz - 2,7GHz $d=1{,}4\sqrt{P}$
0,01	0,035	0,07	0,14
0,1	0,11	0,2	0,44
1	0,35	0,7	1,4
10	1,11	2,2	4,4
100	3,5	7	14

For transmitters with a nominal output not listed in the table above, the distance ***D*** can be calculated in meters **(m)** using the equation for the respective column, in which ***P*** is the nominal output of the transmitter in watts **(W)** according to the specification of the transmitter manufacturer.

NOTE 1:	At 80 MHz and 800 MHz the higher frequency applies.
NOTE 2:	To calculate the recommended safe distance of transmitters in the frequency range of 80 MHz to 2.7 GHz an additional factor of 10/3 was used to reduce the probability of a mobile/portable communication device causing interference if inadvertently brought into the patient area.
NOTE 3:	These guidelines may not apply in all situations. Electromagnetic wave propagation is influenced by absorption and reflection of buildings, objects and people.

Technical error in the system

Solve technical errors

If an error occurs, shut down the system and use the following error list to correct the error. If this does not remedy the error, mark the device as non-functional and inform the person who put your entire system into operation.

For your safety

Malfunction	Possible cause	Remedy	Link
No function	Power cord not connected	Check connection between power outlet and refraction unit	page 13/ 18
	Power failure	Notify home electrican	-
	Power supply defective	Contact distributor	page 24
	Main fuse defective	Change mains fuse	page 18
Devices on instrument table without working	Installed instruments disconnected or disabled	Enable device or check connection	Operating manual of devices
	Instrument table not in working position	Move table in end position	page 14
	End switch defective	Contact distributor	page 21
	Cable connection to the examination device disconnected (cable break)	Contact distributor	page 20
	Power supply defective	Contact distributor	page 24
Patient chair without working	Look, no working	-	-
	Cable break control panel	Contact distributor	page 19
	Electric pillar defective	Contact distributor	-
	Safety switch activated or blocked	Check safety switch and control correct working	page 17

Malfunction	Possible cause	Remedy	Link
Installed 230VAC device without working	Look, no working	-	-
	Fuse on circuit board defective	Contact distributor	-
	Fuse of device defective	Change fuse for device	Operating manual of devices
Device on instrument table- no dimming working	Potentiometer defective	Contact distributor	page 20
	Cable break	Contact distributor	-
	Disconnection to circuit board	Contact distributor	page 25
Reading lamp do not work	Power supply or illuminants defective	Contact distributor	-
	Power output reading lamp defective	Contact distributor	page 25
Safety switch not working	switch defective	Contact distributor	page 17
	Safety switch damaged	Schaltkontakt wieder herstellen	page 17
	Cable break	Contact distributor	page 17
	Disconnection to circuit board	Contact distributor	page 25
2nd working position not accessilbe	2nd working position fixed with screw	Disassemble screw	page 11
	Cable guide blocked moving	Contact distributor	-
	Dirt in rail system	Clean sliding system	-

Malfunction	Possible cause	Remedy	Link
Instrument table not in moveable in working positon	Ball locking jams or is incorrectly adjusted	Contact distributor	page 21
	Table bearing damaged	Contact distributor	page 21
Instrument table not fixed in working position	Holding magnet damaged	Contact distributor	page 21
	Switching relay damaged	Contact distributor	page 25
	End position switch damaged	Contact distributor	page 21
Electro-magnetic	See below (Table E- interference)	Increase distance, Potential equalization	

Eliminating electromagnetic interference

Service	Band (MHz)	Test frequency (MHz)	Max. power P(W)	Distance d (m)
Different services (TETRA 400)	380-390	385	1,8	1
FRS-460, GMRS 460	430-470	450	2	1
LTE Band 13/17	704-707	710/745/780	0,2	1
GSM800/900 LTE Band 5 Mobile phone CT1+, CT2, CT3	800-960	810/870/930	2	1
GSM1800/1900 DECT (mobile phone) LTE Band 1/3/4/25 UMTS	1700-1990	1720/1845/1970	2	1
Bluetooth, WLAN 802.11b/g/n LTE Band 7 RFID 2450 (active, passive)	2400-2570	2450	2	1
WLAN 802.11a/n	5100-5800	5240/5500/5785	2	1

Caution!

Portable HF telecommunication devices may not be used at a distance of less than 1 meter from the device including the cables.

System combination medical and non- medical device

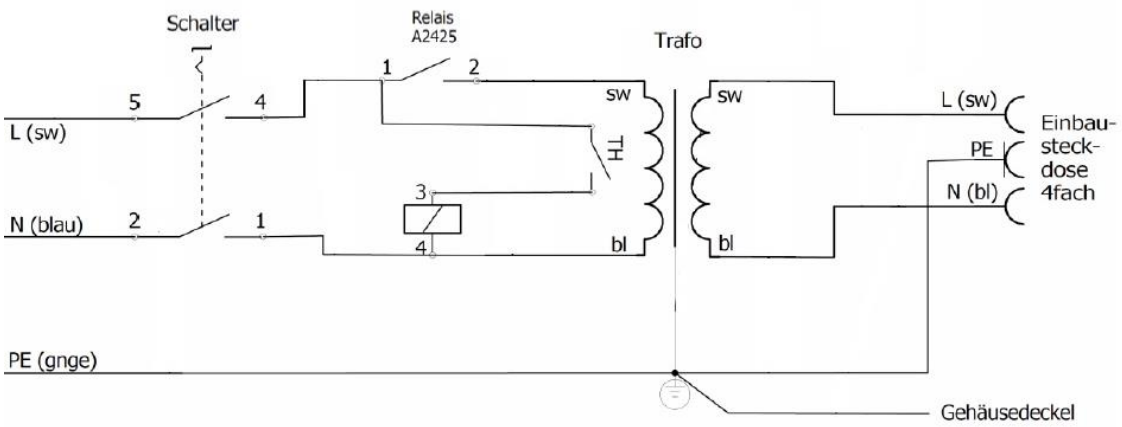
In order to guarantee the electrical safety of medical devices and non-medical devices (e.g. printers), a safe separation according to IEC 60601-1 with 2x MOPP is required.

The following precautions may be necessary for this purpose.

1. Isolation transformer (option)

To guarantee the electrical safety of medical devices and non-medical devices (e.g. printers), operation in medical protected areas is intended with an isolating transformer (accessory).

The isolating transformer to be used is supplied with mains voltage, must meet the DIN EN 60601-1 standard and have protection class I.



Power input: 1x 230 VAC

Power output: 4x 230 VAC

2. Network isolator (option)

The network isolators prevent galvanic connection between MED and non-MED devices in the signal line (e.g. network feed-through) and the transmission of unwanted voltages and currents. The network isolator is connected directly into the network connection and must meet the specifications according to DIN EN 60601-1!

NOTE: Decoupling between the Ethernet connection and the medical device is a legal requirement according to DIN 60601-1.

Warranty and warranty conditions

If defects due to material or processing faults occur within 24 months after delivery, we guarantee the fastest possible and free repair of the refraction unit or, at our decision, a free exchange. For electronic components such as power supplies or motherboard, defects will be repaired free of charge within 12 months.

Requirements for a warranty case:

- The invoice with date of delivery is available
- The device was used correctly or for its intended use
- Repairs have only been done by customer service or by persons authorized by us

Warranty services do not extend the warranty period, or start a new warranty period. Consumables or normal traces of use are not subject to warranty claims.

The general terms and conditions of company

Wagner & Guder Medical GmbH

Purchase order details

Spare parts

Description	Order number
Power cord 2,5m	MC-B1D12500
Fuse T 4 A / H - Littelfuse	0215004.TXP
Fuse T 6,3 A / H - Littlefuse	021506.3TXP
Power supply 12VDC	GSM90B12-P1M
Control panel instrument table	2014-400-065
Cable control panel	MAT904134158
Pillar patient chair 230VAC	E100
Pillar patient chair 110- 240VAC	E101
Isolating relais with freewheeling diode for E101	E102
Basis board BLP	E150
Illuminants LED – GU10	E194
Seat shell ONE	S1500
Seat shell highline	S1100
Armrest	18825
Sheet metal armrest	2014-400-041
Potentiometer with cable 3m, instrument table	MAT904134159
Adjustable leg (STRM)	02000
Directions for use	WG-UGA