Refraction unit cubeEVO

Directions for use

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WAGNER & GUDER MEDICAL GMBH

Contents

Safety instructions
Description of symbols

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

Equipment labelling „nameplate“

- MD medical device I
- Unit name
- UDI-DI
- Type
- Serial number
- Date of production
- Mains input voltage
- Power input
- Main fuses
- Load capacity instrument table
- Operating cycle patient chair
- Manufacturer
- Address
- Type of device
- CE- marking
- Note of professional disposal
- UDI (QR code)

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.

CE- marking
Indicates compliance with standards for medical devices.

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 cubeEVO 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 cubeEVO 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 cubeEVO a non-invasive, active medical device in category I.

Device class	I
Basic UDI-DI	PP10431UNIT15
EMC	Electromagnetic compatibility page 38 following.

Approvals and requirements

Description	Marking
Electrical version	DIN EN 60601-1: 2006 + Cor.:2010 + A1:2013 Protection class I
EMC requirements	The device complies with the EMC requirements of DIN EN 60601-1-2: 2016, 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.

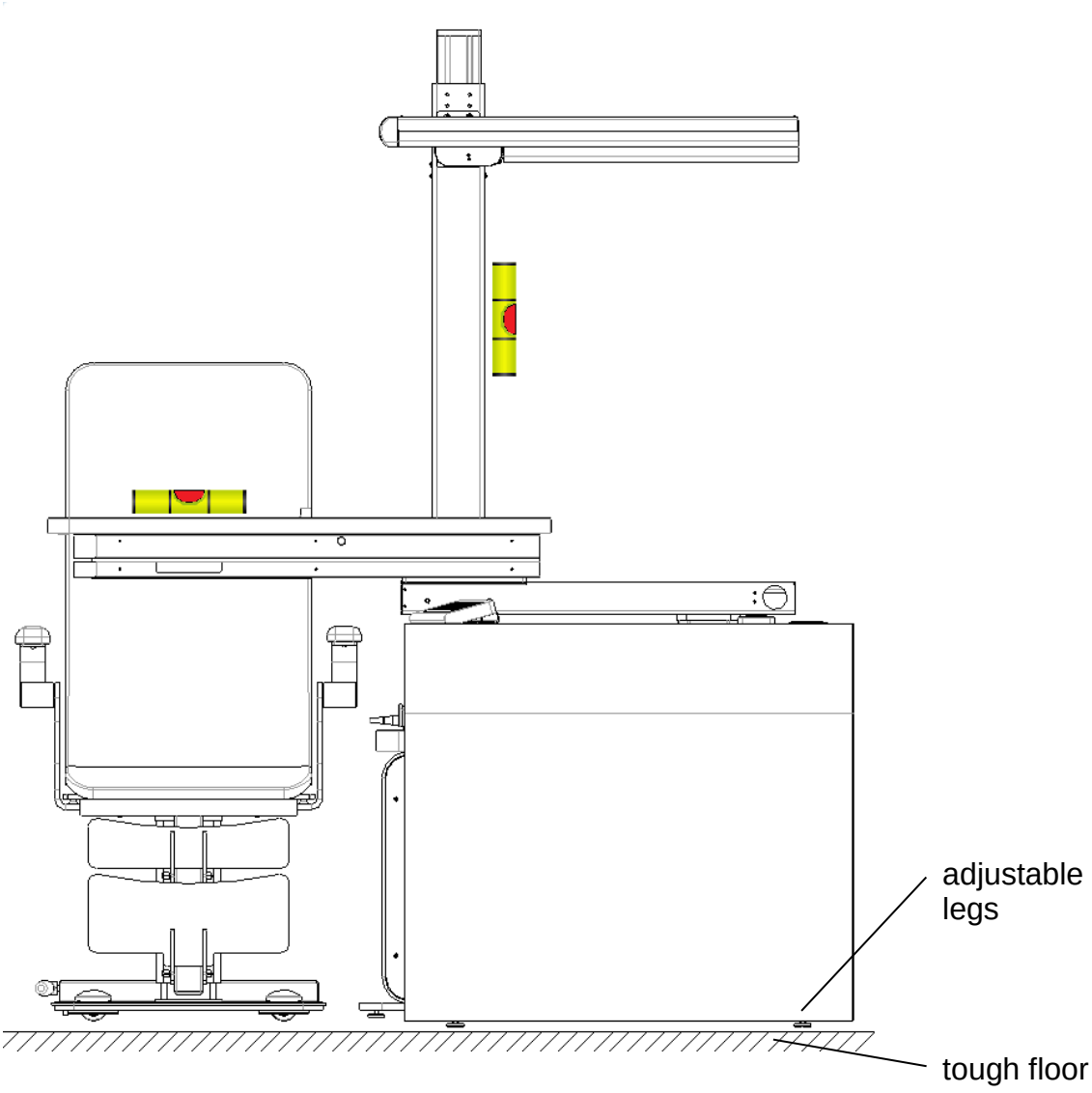
- Please disconnect the mains power plug before cleaning. Please make sure that no detergent or water enters the examination unit.

- 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

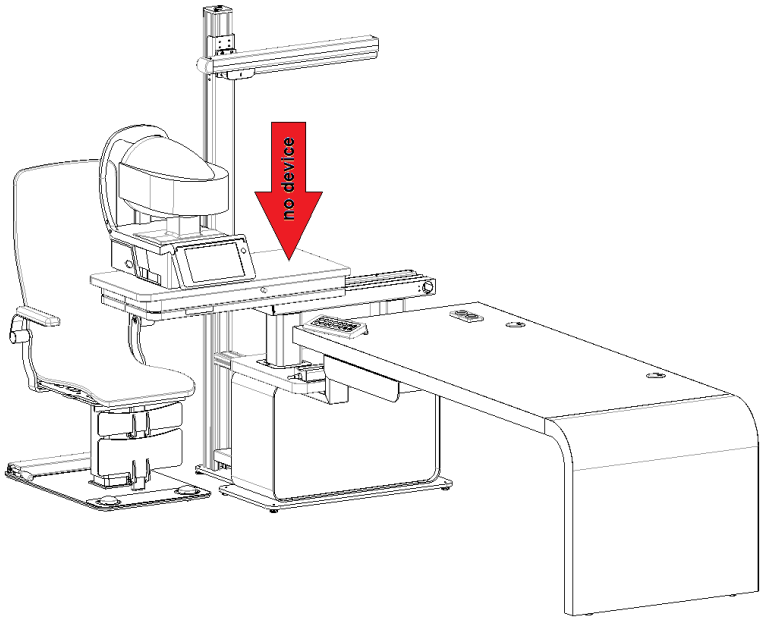
(see IEC 60601-1 and IEC 60601-1-2). The system configurator is responsible for ensuring that the system complies with the normative requirements.

- 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. 0.5mA for the touch 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.



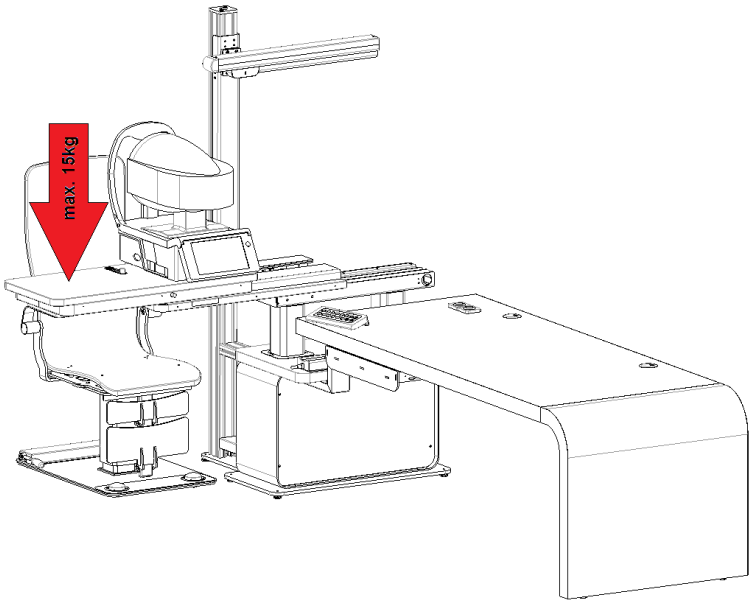
Notes on device installation



Refraction unit with single device working

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

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



Refraction unit with multiple device working

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

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

Electric safety

- Medical devices are subject to special precautionary measures according to the electromagnetic compatibility EMC. Please pay also attention on this during the operation.
- The examination unit may only be plugged into shockproof sockets installed according to the regulations and with the line cable which is supplied.
- Before establishing the connection, please control the line voltage 230V/AC.
- Extension wires and non-stationary multiple sockets must not be used for the operation of the refraction unit.
- It is not allowed to interrupt the protective conductor, for this can cause danger to the user/ patient as well as damages on installed devices.
  The examination unit has to be detached from the electrical connection and protected against accidental use, if the protective conductor is affected or electric cables are damaged.
- Every unit has a grounding and a housing leakage current. These mount up, if you connect line-operated devices directly to the examination unit. The limit value according to IEC/VDE for the grounding leakage current is 500µA and for the housing leakage current is 100µA. For the specific values of your examination unit please consult the protocol.
- Only the change of the main power fuses, which are accessible from the outside, is allowed.
- Only as authorized stated specialist staff is allowed to open the examination unit. Please pay attention to the advices in the chapter Instruction for maintenance and repair.
- Before beginning cleaning works, please disconnect the mains. Please pay attention, that no cleansing agent or water gets into the examination unit.

Proper operation

The examination unit cubeEVO does duty as basic unit for the set-up of working places for determination and modulation of vision aids and for optical examination.

Another use as the specified one lies in the exclusive responsibility of the user. The manufacturer therefore will be released from legal liability.

The examination unit operated only by briefed and trained persons. Because of the diverse design and equipping alternatives specialist staff, which is authorized by us, performs a basically briefing to your individual examination unit.

This also applies to the installation and connection of optional equipment and extension modules. Please pay attention to the advices in the operating manuals of the equipment fabricators or ask our specialist staff for information.

The description of control modules like curtain or ambient light control is not included in this operating manual. Therefore an individual briefing to the screen procedures will be performed.

An additional instruction of the operating personal is in duty of the buyer.

For description of safety advices see above!

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

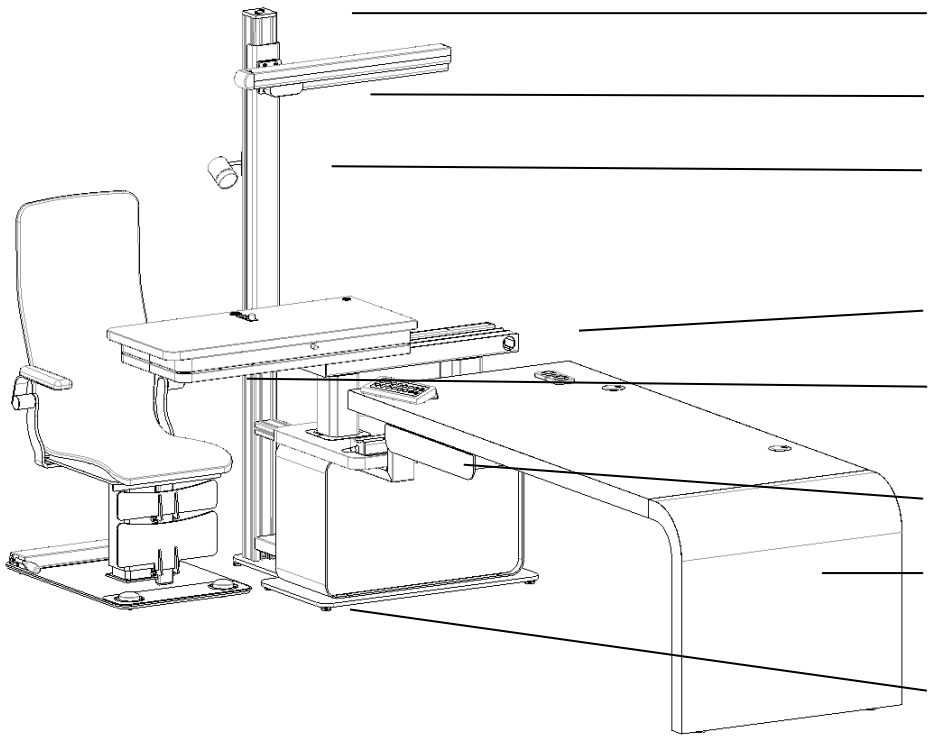
- Switch OFF the examination unit or installed devices if they are not in use
- Insufficient hygiene or incorrect cleaning contrary to the instructions for use can contribute to the risk of infection for the patient/customer and damage surfaces of the examination unit or lead to discoloration

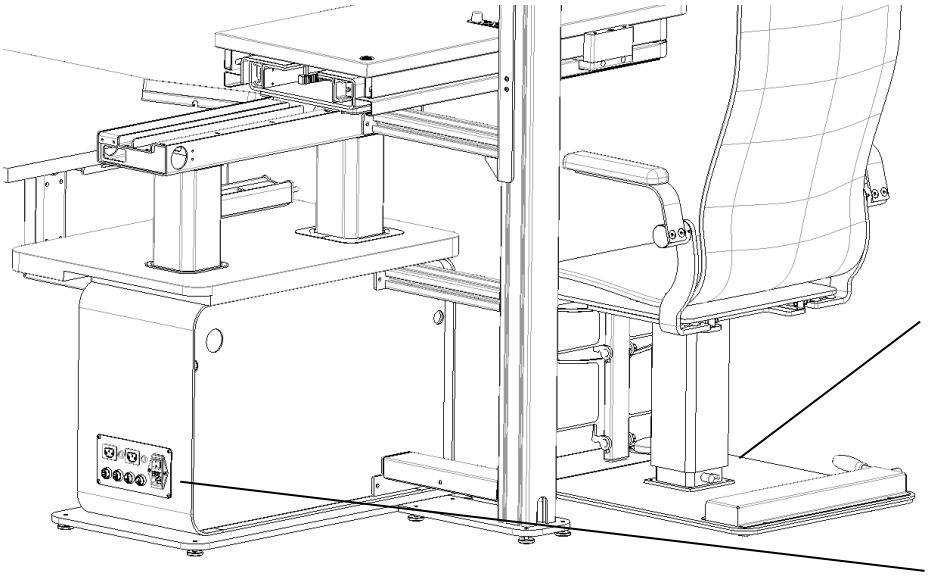
Liability and warranty

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

NOTICE **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.

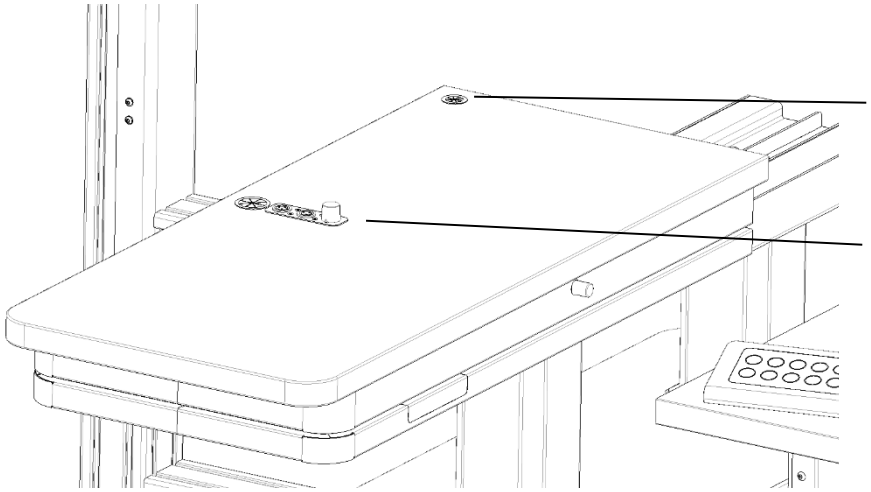
General construction cubeEVO





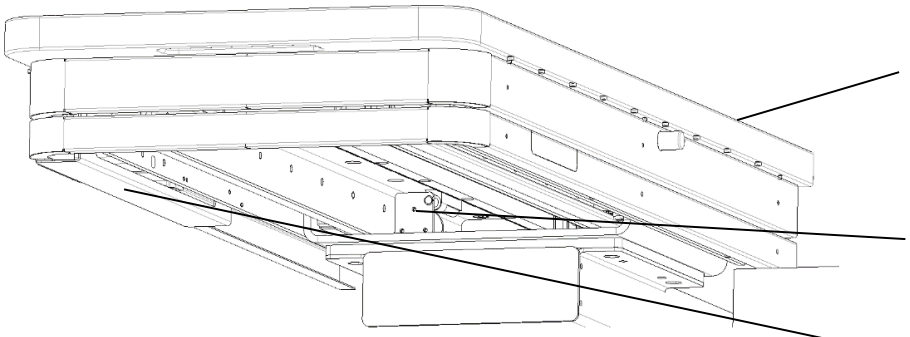
Working table – two devices

The two- device workable enables a smooth and safe proceeding in front of the patient. First movement is possible manual or by electromotoric drive. After reach his end position stops automatic and fixed with electromagnetic brake. To move in basic position put button under table or control panel.
The maximum load of the instrument table is 40kg. First position maximum load 20kg.



cable-outlet

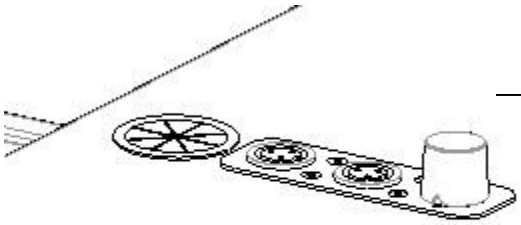
electric device connection 6/ 12VDC, dimm-able



locking 2nd Table position

electro magnet

safety switch-patient chair, table movement



1
2
3

4 under the table, manual version only

1 3pin connection socket **2**, free available
PIN 2: protective earth

2 3pol connection socket **1** for device
PIN 2: protective earth
PIN 1+3: 6 VDC or 12 VDC (on lower board – page 22)

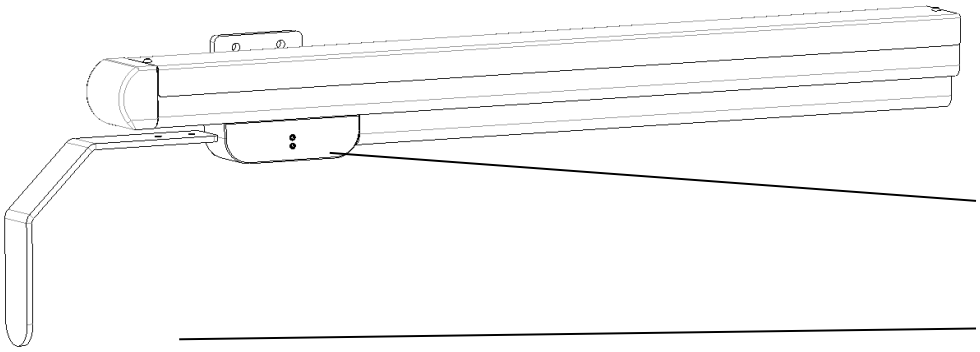
K11 Output 6V: PIN 25/ 27

K11 Output 12V: PIN 25/ 26

3 Potentiometer brightness control – for 3pin socket **(3)**

4 Button to release the holding magnet

Phoropter rail

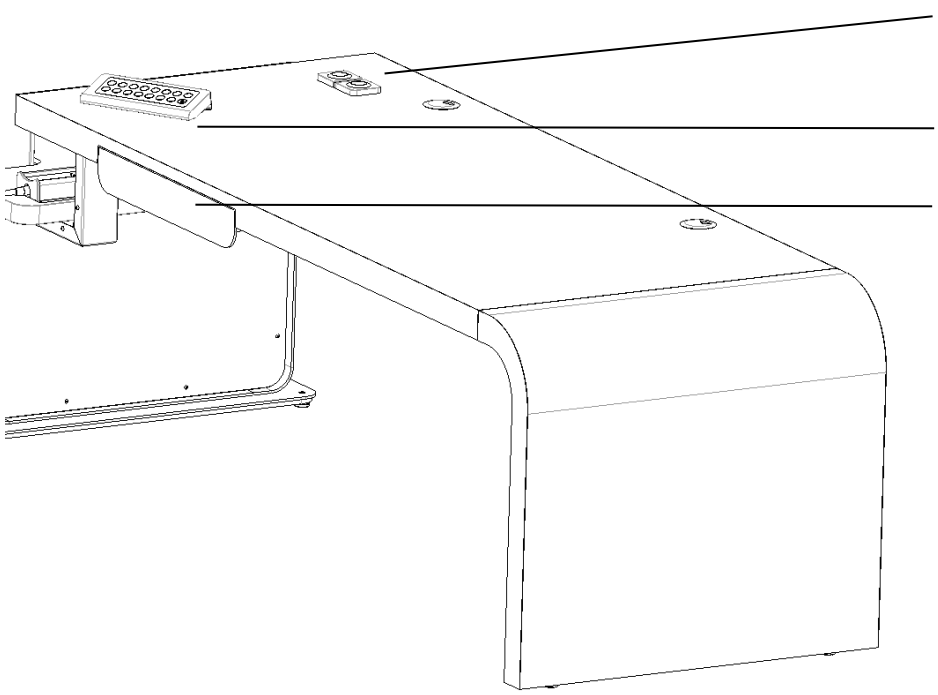


phoropter mounting D=22mm

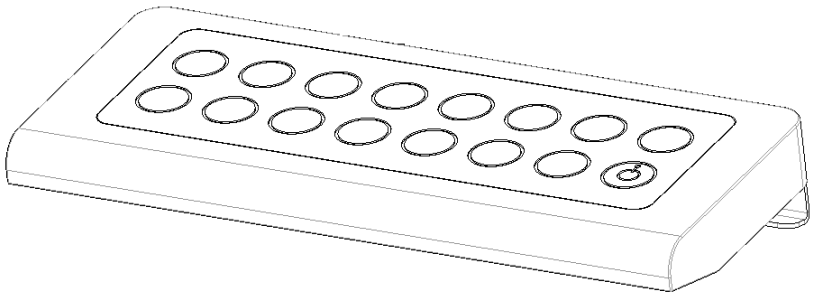
Handle (only mechanical version)

Writing desk with formed leg

The writing desk has a modular shape. Individual designed and flexible in furnishing this desk leaves no wish unfulfilled. Integrated NT-300 re- charger or types of different legs and a integrated drawer can be ordered.



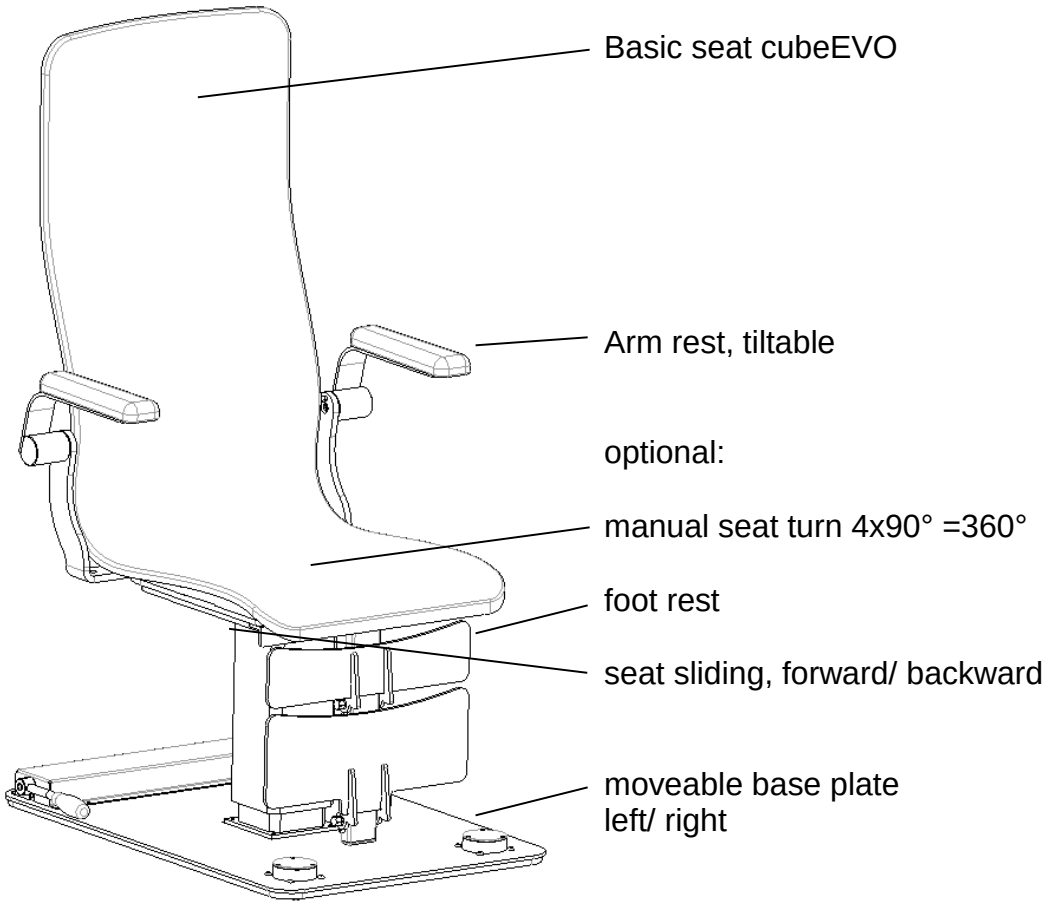
Control panel

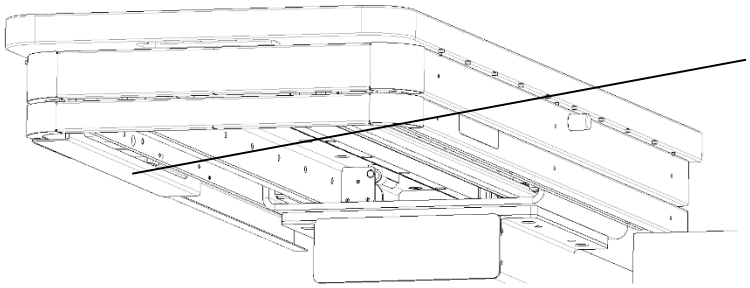


Control panel cubeEVO

Patient chair

The patient chair is solid connected to the unit and already has in the basic version an electromagnetic column with safety switching strip. This bar is designed to prevent a collision of the patient's leg with the device table. The chair is available with further adjustment functions and retrofitted. The allowable standard load of the patient's chair is 135kg.





Safety switch bar safety stop in the upward movement of the patient's chair or complete table system

Please ensure that the patient is not at risk for all adjustable accessories. The seat displacement and the footrest represent a source of danger for the patient when the patient chair is moved upwards when the seat module is actuated. The unit has a safety bar underneath the instrument table for the legs, but this is not in operation everywhere due to its construction.

Please ensure that the patient does not place the feet under the footrest! Due to the design, the lifting column does not register any obstacle!

Seat rotation: The seat rotation serves for better entry and exit for the patient, a detent holds the chair in its rest position 4x 90 = 360 °. When turning, make sure that the seat movement is in a forward position.

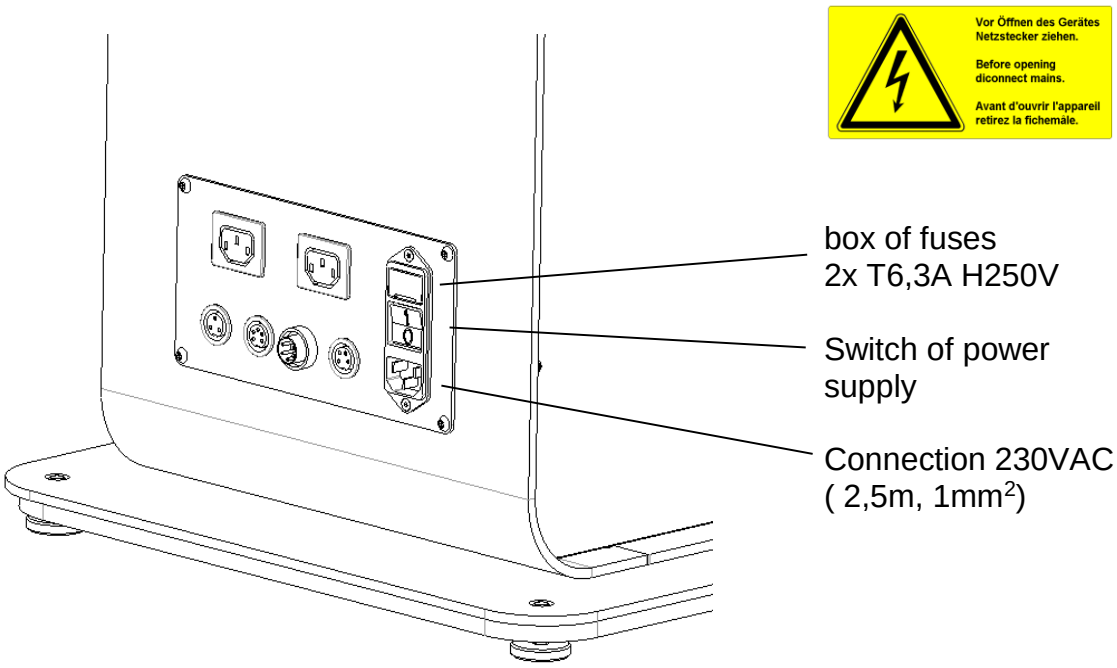
Operation

Electrical connection

The electrical connection of the test unit is made to a suitably installed protective contact socket or the wall connection box included in the scope of supply.
Please use only the supplied mains cable, connection length 2.5m, cable cross-section 1mm^2 or the connection cable of the wall connection box.

Inital operation

- Please connect the cable of mains connection with the power socket
- Connect the cable of mains connection with a installed safety socket
- Press the power switch on the device table, the control lamp is green, figure 9 (position 8)



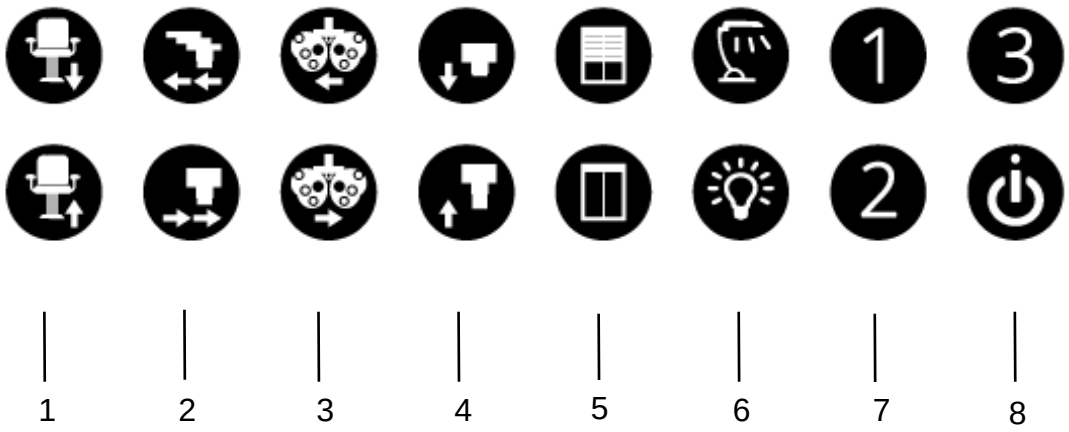
Mains connection with fuses

2x T 6,3 A / H

Nameplate
Manufacturer
Specification

The refraction unit is ready for operation as soon as the pressure switch has been actuated and the lamp is illuminated in green. This also applies to already installed test equipment or additional components if they are supplied with power via the switchable socket strip 230VAC/ 4A available on the installation side. The examination devices on the telescope table are automatically ready for operation when the instrument table has been reached first position. In addition to the operating switch, there are further control functions on the worktable.

control panel



1 Patient chair UP/ DOWN – push both button 10sec move down

2 Working table movement

3 Phoropter movement

4 Working table UP/ DOWN

5 WINDOW control UP/ DOWN

6 Reading lamp/ roomlight control

7 Switch 1 +2 +3, free features

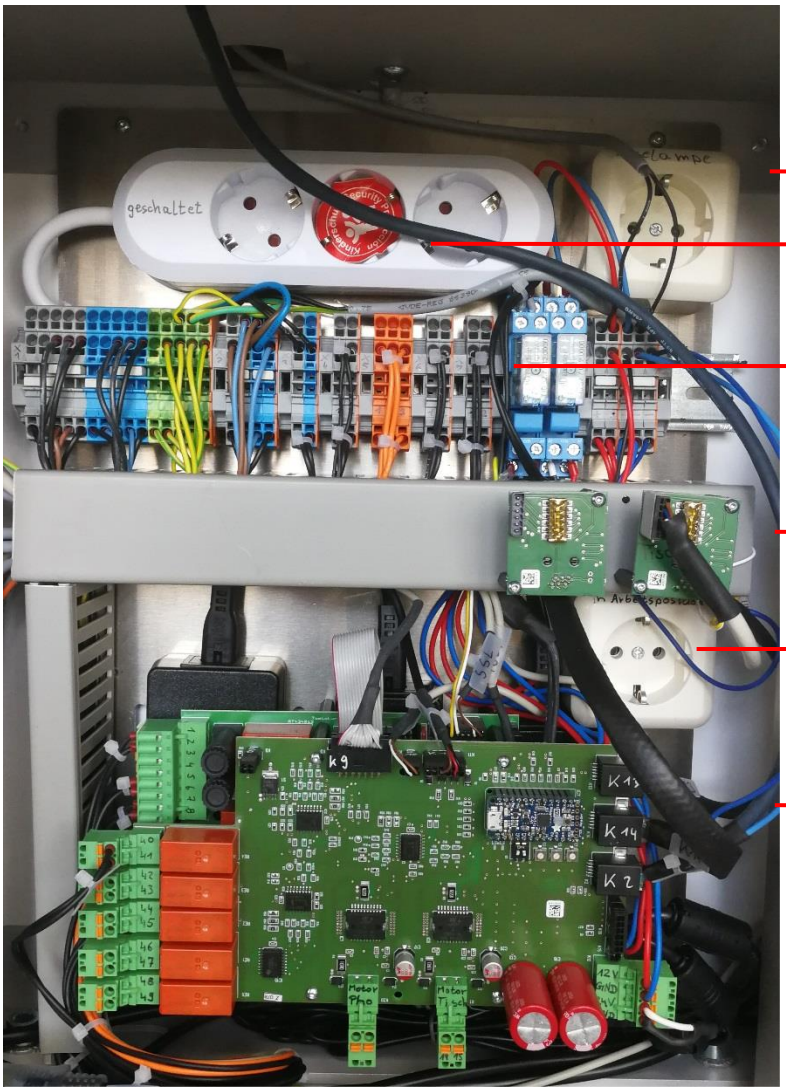
8 Operation switch, LED (green) ON/ OFF,
safety switch by motoric drive (STOP- emergency)

Electronic base plate

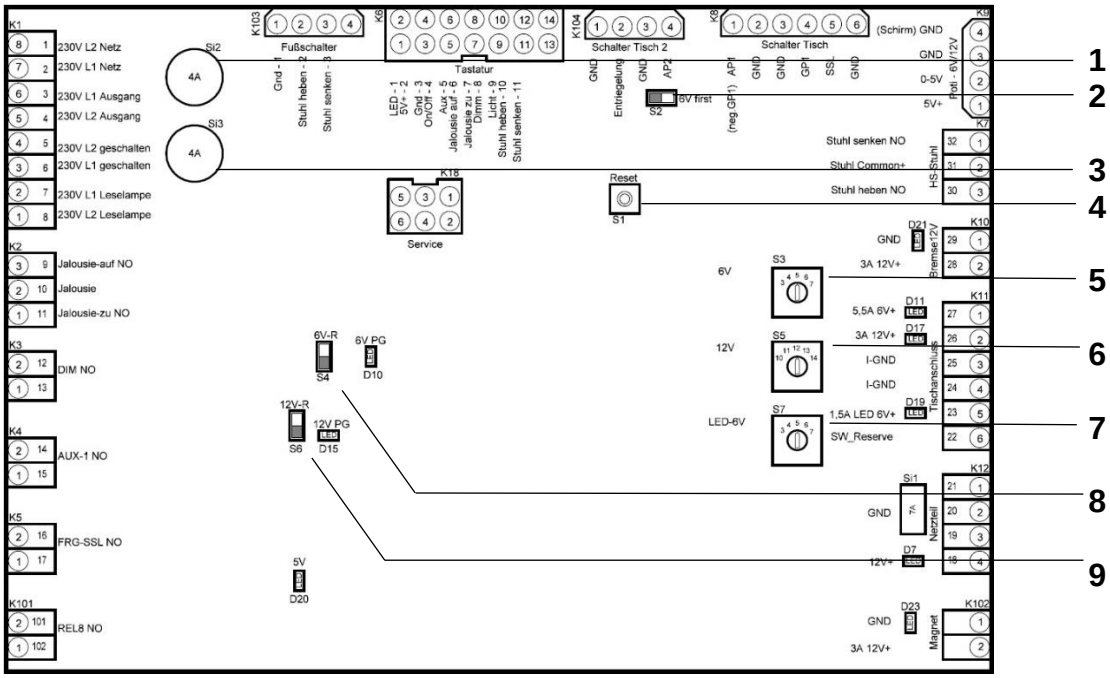
The refraction unit cubeEVO has a programmable control electronics with a special interface. The programs are stored on an EEPROM.

Owing to external disturbances, it is possible that not all functions of the examination unit are available or partial system malfunctions may occur. This malfunction can only be remedied if the unit is disconnected from the mains for at least 30sec. In this case, a RESET of the control electronics takes place and the state before the disturbance is restored.

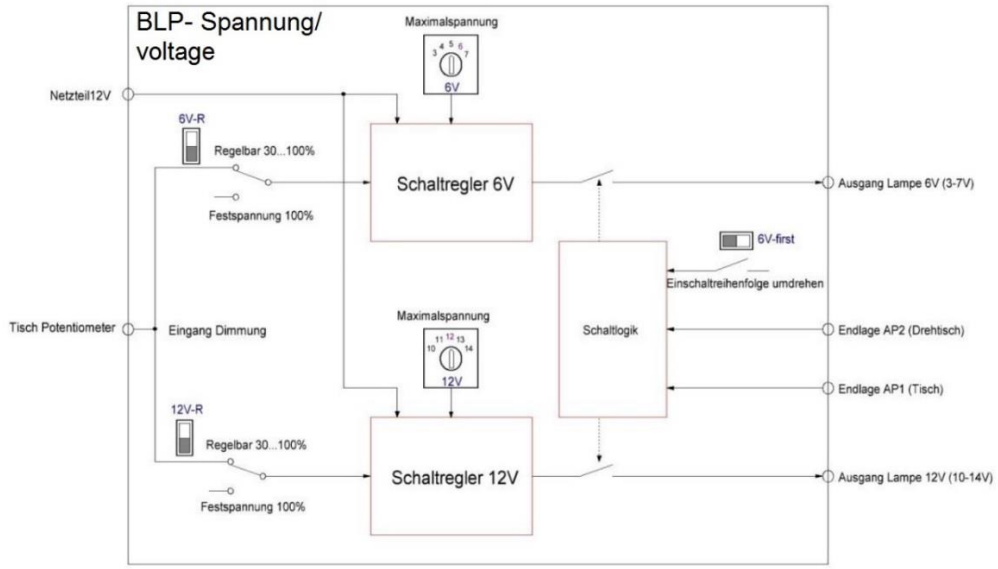
Attention! An actuation of the operating switch is not sufficient, since the control electronics is still active in stand-by mode.



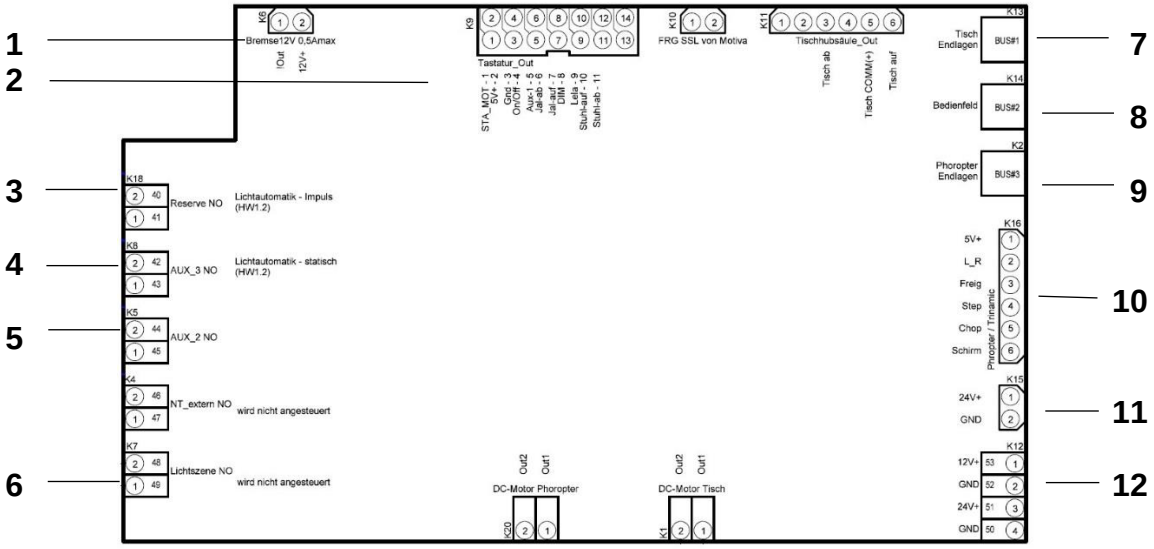
Basic board – lower board



1 fuse Si2 (230V T 4 A / H)
2 change between working position 1 and 2
3 fuse Si3 (230V T 4 A / H)
4 RESET - board
5 6V output (max.5,5A), position 1,2,3,4,5 equal to: 3V, 4V, 5V, 6V, 7V
6 12V output (max. 3A), position 1,2,3,4,5 equal to: 10V, 11V, 12V, 13V, 14V
7 LED- 6V (Fixation light), position 1,2,3,4,5 equal to: 3V, 4V, 5V, 6V, 7V
8 switching 6V-R dimmable/ 6V fixed voltage
9 switching 12V-R dimmable/ 12V fixed voltage



Upper board



1	Electric magnet (brake) 12V+ first table position
2	Connection control panel
3	Automatic room light - impuls signal
4	Automatic room light - static signal
5	AUX – free port
6	DIM – connection to roomlight
7	Data bus end switch table
8	Data bus control panel
9	Data bus end switch phoropter
10	Phoropter connection
11	Power output phoropter
12	Power output instrument table
13	power output DC motor instrument table

Instrument table – motoric drive

Table movement in working and basic position:

With the help of the potentiometers R7, R8, R9 deceleration, acceleration and final speed of the table can be adjusted. The settings have 3 steps per potentiometer.

The following table shows the settings of braking time, acceleration time and speed according to the potentiometer positions

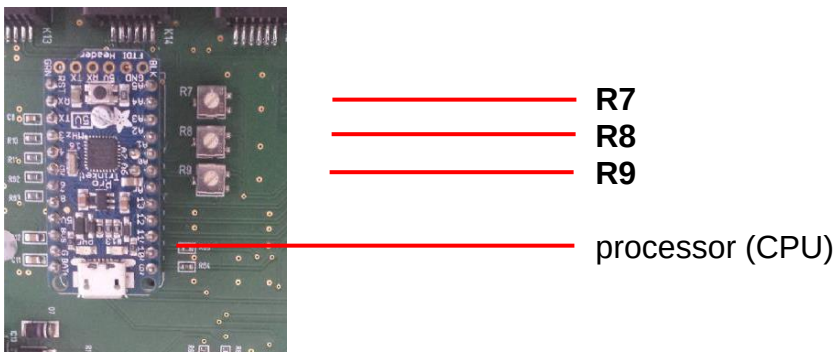
position	R7	R8	R9
1	Maximum time to brake	Maximum time to accelerate	Minimum final speed
2	Average time to brake	Average time to accelerate	Average final speed
3	Minimum time to brake	Minimum time to accelerate	Maximum final speed

Position 1 corresponds to the right stop. This means that position 1 is reached when turning clockwise to the stop.

Position 3 corresponds to the left stop. This means position 3 is reached when turning counterclockwise until the stop.

Position 2 corresponds to the middle position between position 1 and 3.

The following figure shows all three potentiometers in position 1.

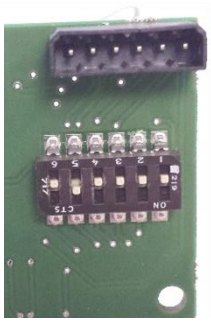
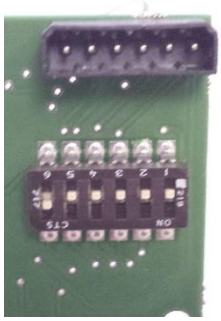
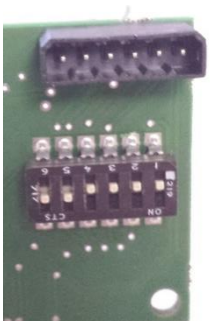


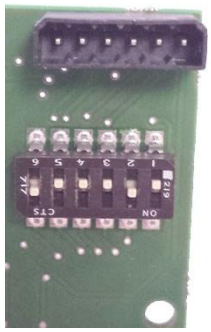
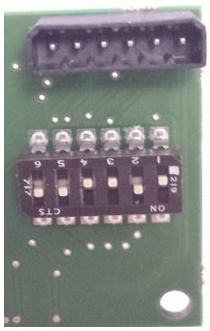
The set positions become active only when the system is started by pressing the power key on the keyboard. This means that if changes are made while the system is active, it must first be deactivated and reactivated by control panel.

Setting of the bus coupler

Settings for phoropter and instrument table:

adress table → DIP- Switch 3=OFF, 2=ON, 1=OFF
adress phoropter → DIP- Switch 3=OFF, 2=OFF, 1=OFF
motoric → DIP- Switch 6 = OFF
manuell → DIP- Switch 6 = ON
automatic light active → DIP- Switch 5 = OFF
automatic light non active → DIP- Switch 5 = ON

phoropter motoric drive automatic light active	phoropter motoric drive automatic light non active	phoropter manuell automatic light active	phoropter manuell automatic light non active
			

Instrument table motoric drive automatic light active	Instrument table motoric drive automatic light non active	Instrument table manuell automatic light active	Instrument table manuell automatic light non active
			

Instruction for maintenance and repair

Switch off the examination unit with the power button and disconnect the mains! Please avoid in case of cleaning, that cleansing agent or other fluids can get into the examination unit or on installed examination devices.

Cleaning

For cleaning the varnished parts and the seat upholstery of cubeEVO please use a wet cloth. Into the water you can add a mild cleaning agent (if necessary „scouring milk“). Obstinate dirt at varnished surfaces can be removed with the help of cleaning solvent or rectified spirits.
In case of cleaning the installed examination devices, please follow the hints and comments of each device producers or ask authorized specialist staff.

Maintenance/ Technical service

The examination unit cubeEVO and it’s accessories are low-maintenance when proper used. Nevertheless periodic maintenance works, which serve the units safety, have to be carried out either self- supporting or by our service partners:.

1	**Saferty test according to §6 MP operator ordinance to EN/IEC 62353 is recommended every 2 years**
2	Check the proper fastening of the examination devices regularly.
3	Check the safety advices affixed at the supplied products.
4	Check the safety inscriptions at your examination unit. When inscription elements are missing or damaged contrary to the user manual please contact our service technician.
5	Check the integrity of housing an isolations
6	Check the operational reliability of safety-relevant circuits (switch-off panel and current limitations)
7	Regular measuring (annual) of substitute leakage current
8	Complete check of examination unit’s and accessory's operational Reliability

In case of technical problems or decline of handling please consult your dealer or our service center.

Repairs by yourself

Please pull the mains plug before every repair!

Exchange of main fuses

An exchange of the main fuses must not be done while the mains plug is not disconnected. You should consider an exchange only when the control lamp does not shine even though the power button and the operating key are switched on.

- You can find the mains fuses in the fuse box on the side face of the examination unit (figure 8)
  Push the plastic tongue that is attached at the box (e.g. using a screwdriver or the like) upwards. That loosens the lock of the fuse box.
- Pull the box out of the hatch by hand.
- Replace the defect fuses with new once
  (identification: T6,3A/ H 250V).
- Push the fuse box back into the therefore intended hatch until the plastic tongue clicks into place.

In the electronic pocket further four protected fuse carriers are situated on the master module. These contain the fuses for the chair, the projector, the reading lamp, the 6V-devices fuse, the 12V-devices fuse etc.
An exchange of these fuses may only be carried out by authorized specialist staff or our service technicians!

Combination with medical devices or devices from other manufactures

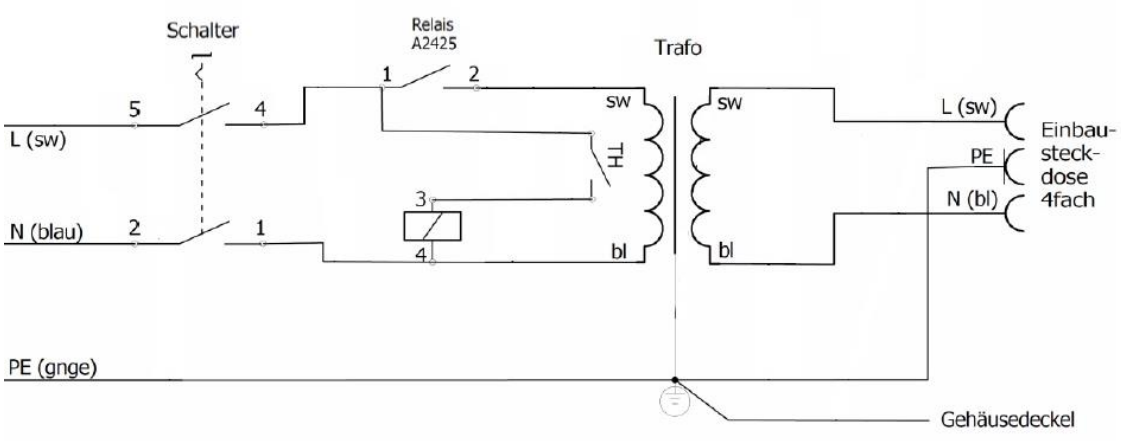
Please assemble on the refraction unit only medical devices produced against medical directive EN 60601-1. A different application than that provided by the manufacturers is not allowed. A control for roomlight and window control is potential free and is made possible through a wall connection box. There are different lighting systems and also different boxes. For security reasons, the installation must be made by an electrician.

In order to ensure 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 measures may be necessary for this purpose.

1. Isolating transformer (optional)

To ensure 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 used is supplied with mains voltage, must comply with the DIN EN 60601-1 standard and have protection class I.



Mains input: 1x 230 VAC
Output: 1x 230 VAC

2. Network isolator (optional)

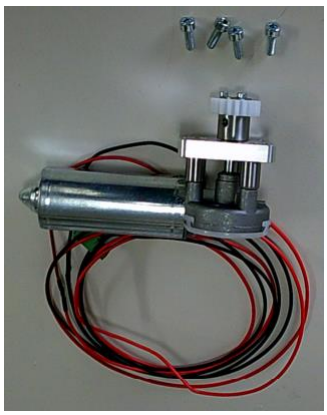
The network isolators prevent galvanic connection between MED and non-MED devices in the signal line (e.g. network feed-through) and the transmission of unwanted voltages and currents. The network isolator is connected directly into the network connection and must meet the specifications according to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

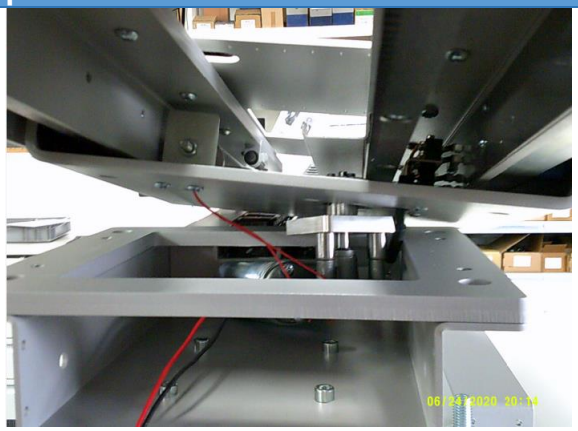
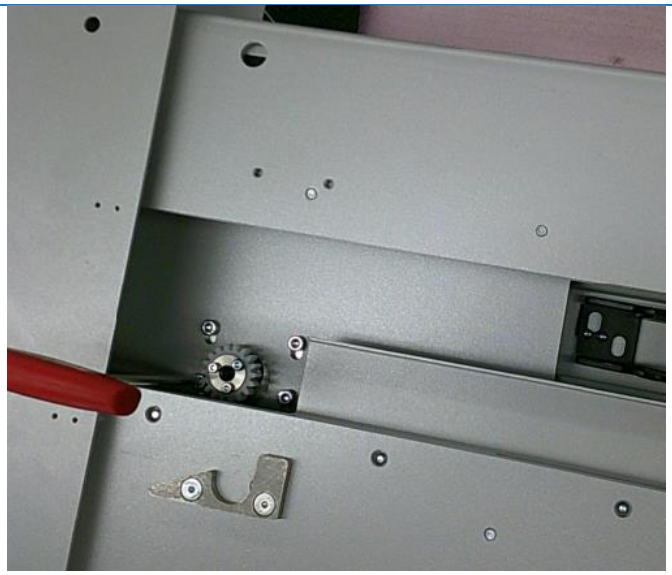
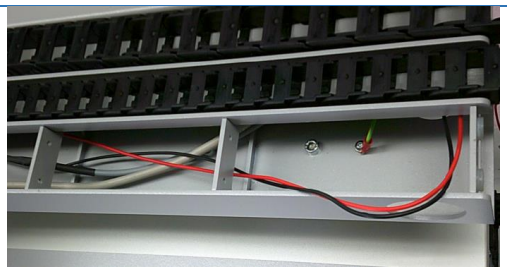
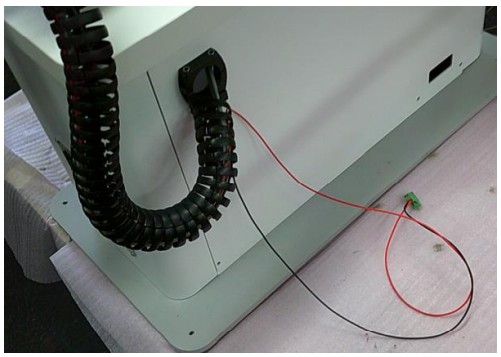
NOTE: A decoupling between the Ethernet connection and the medical device is a legal requirement according to DIN 60601-1.

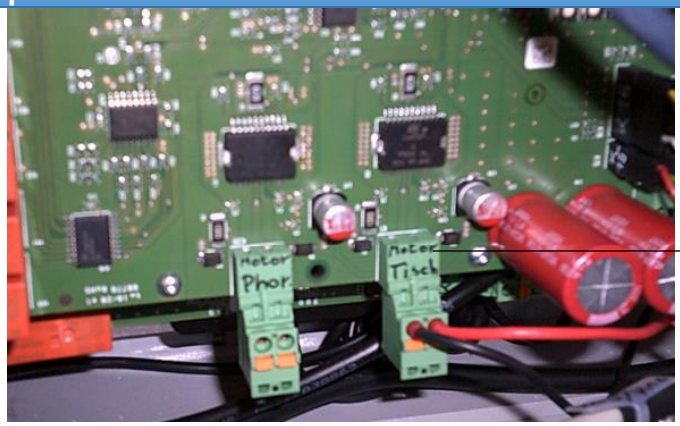
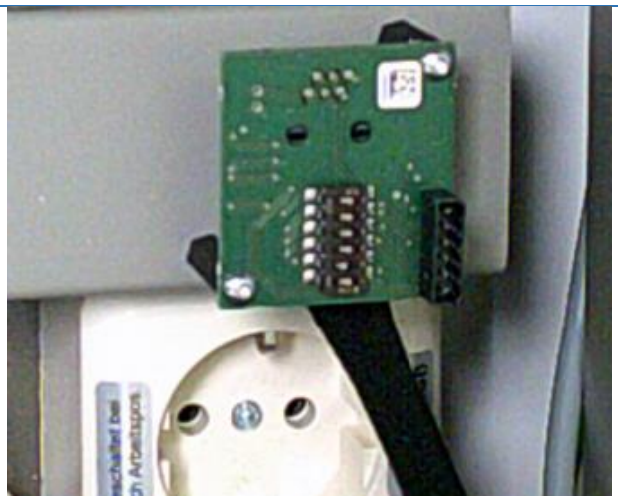
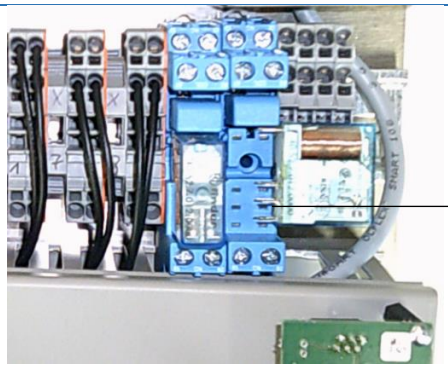
Installation from manual to motoric versions

The cubeEVO examination unit can be extended to a servo-motorized phoropter arm and servo-motorized table extension (first table position). The following steps have to be performed (this work may only be performed by qualified specialists)

Instrument table motoric drive

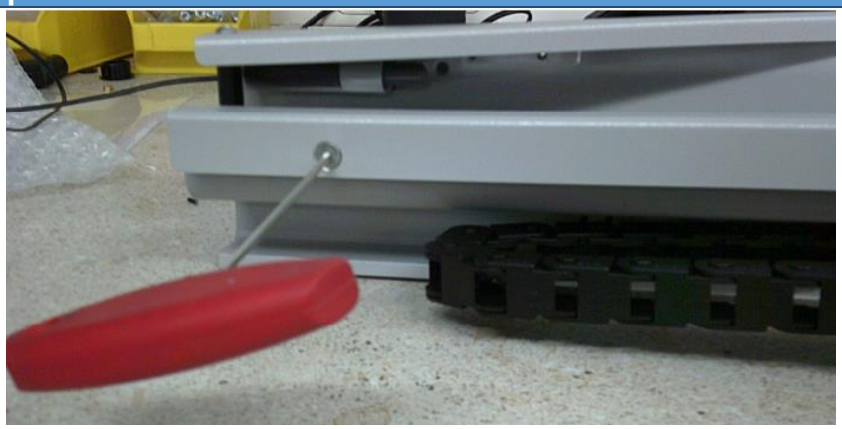
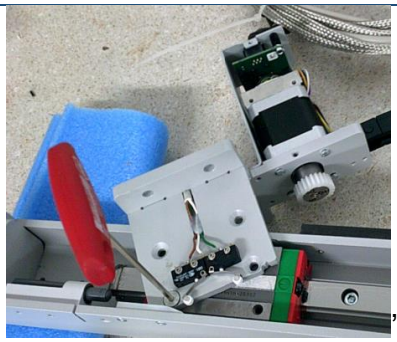
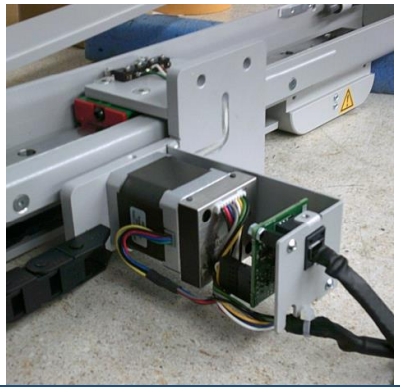
	picture	description
1	 	Required components Gear rack Drive system
2		Assembly of gear rack

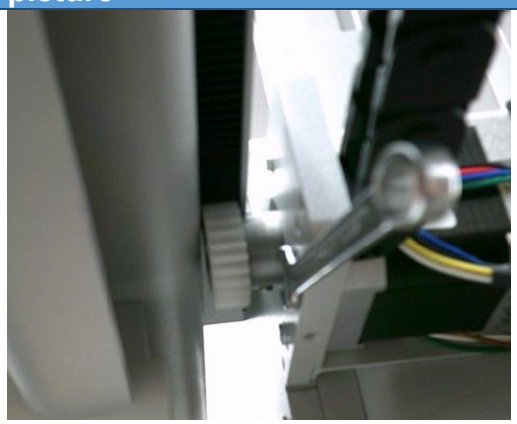
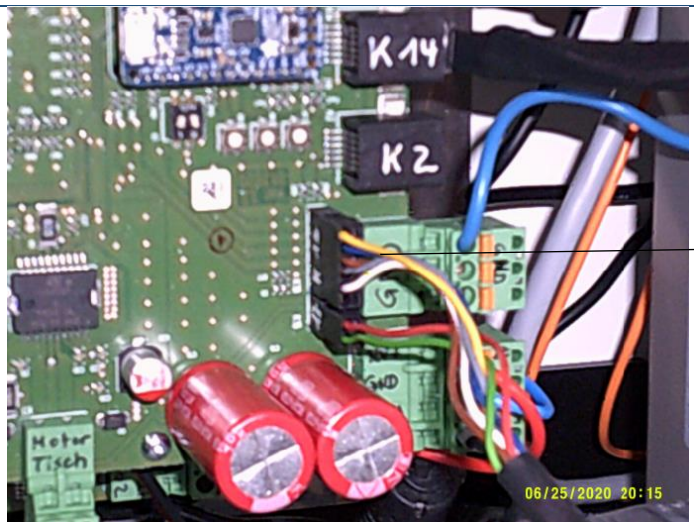
	picture	description
3		Assembly drive system between table system and base mounting
4		Adjust drive system to gear rack with minimum slackness
5	 	Cabling through base frame

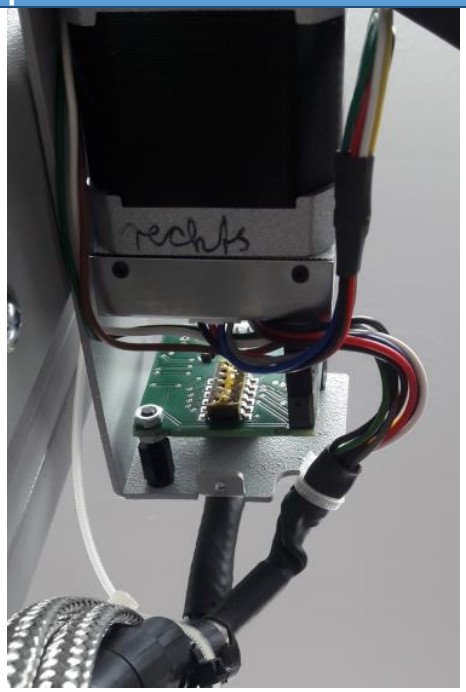
	picture	description
6		connection to upper board
7		Change settings of the bus coupler page 24
8		Disconnect relais from socket

Phoropter rail to motoric drive

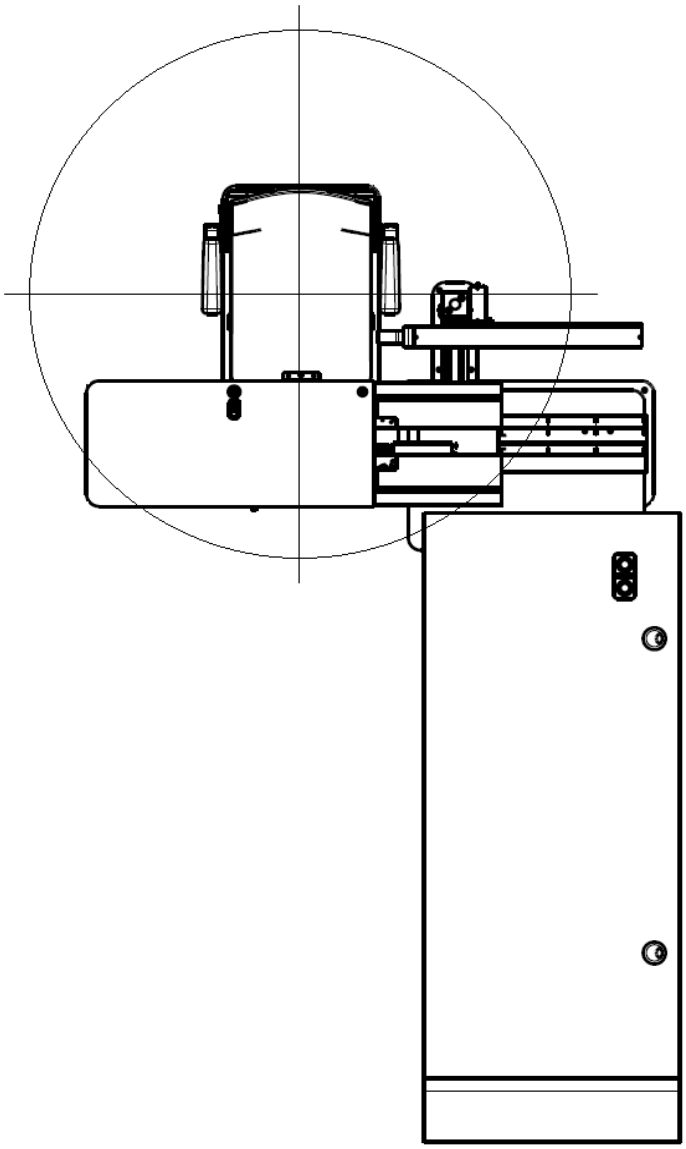
	Picture	description
1	 	Required components Gear rack Stepper drive system
2	  	Disassembly phoropter cover Disassemble phoropter rail

	picture	description
3	 	Remove cover from gear rack
4	 	Remove base plate from slide carriage Mount stepper drive on base plate 4x M3 screw

	picture	description
5	 	Adjust stepper drive to gear rack with minimum slackness
6		Connection to upper board phoropter

	picture	description
7		Correct settings of bus coupler
8		Cabling through pillar

Patients surrounding

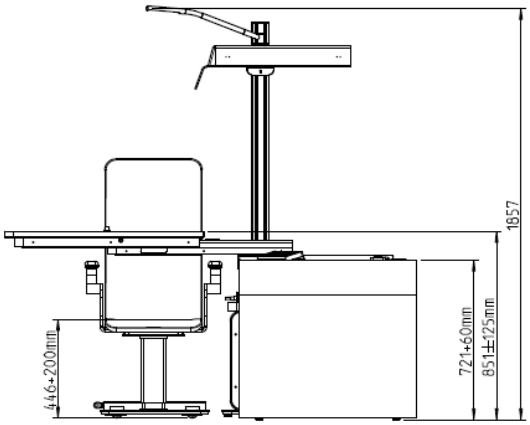


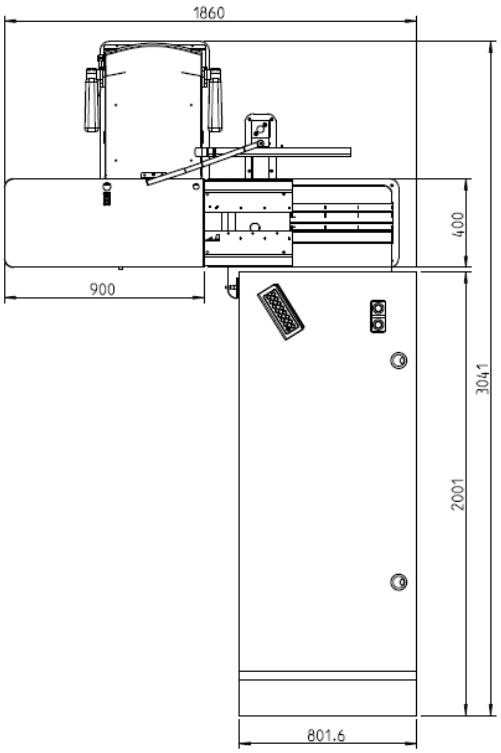
As patients surrounding the above areas is highlighted. In this area will ensure for the patient, the maximum possible protection. In the area surrounding the patient may experience dangerous areas. Here is a special duty of care of the doctor or optician is precisely in connection with the installed equipment.

Outside of this region must share the doctor or optician to patients accordingly, does not reside in a different area.

Technical data

Anschlussspannung *nominal input voltage*	230V / 50Hz
Anschlussleistung *connected load*	6,3A
Beleuchtung *electric lighting*	6VA LED
Kleinspannungs-versorgung *low voltage*	6…12VDC/ 5A
Gerätetyp *class of unit*	B
Schutzklasse *class of protection*	I
Arbeitshöhe *working height*	850±125mm
Gesamthöhe *maximum height*	1857mm
Maximalgewicht Einheit *maximum weight of unit*	292kg
Belastbarkeit Patientenstuhl *loading capacity chair*	135kg
Belastbarkeit Zweigerätetisch *loading capacity table*	40kg
Raumlichtanschluss *roomlight connection*	potentialfrei *potential free*





Gerätesicherheit/ *realiability of devices*

DIN EN 60601-1
DIN EN 60601-1-1

EMV/ *electromagnetic compatibility*

DIN EN 60601-1-2

Environmental conditions

1. For operation in the intended use

Feature	Permitted value range
Temperature	+5°C … +40°C
Relative air humidity	30% … 75% (no condensation)
Insert High	till 2000m use above sea level

2. For transport and storage (in transport packaging)

Feature	Permitted value range
Temperature	-40°C … +70°C
Relative air humidity	10% … 95%
Insert High	500hPa … 1060hPa

3. Storage conditions

Feature	Permitted value range
Temperature	-10°C … +55°C
Relative air humidity	10% … 95% (no condensation)
Insert High	700hPa … 1060hPa

Warranty and waste disposal

If there are defects from installation, assembly or materials within 24 months after purchase, we guarantee the fastest and free repair of the refraction unit, or after our decision, a free exchange. For electronic components such as power supply or motherboard, lifting column defect within 12 months will be set free repair.

Conditions for a warranty claim:

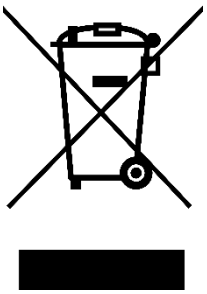
- The invoice with the date of purchase is available
- The refraction unit was used properly and as intended
- Repairs were carried out exclusively by the customer or by authorized persons

Warranties cause any extension of the warranty periods, nor does it set a new warranty period. Consumable or normal signs of use are not covered under warranty.

Please have a look at the general terms and conditions of the company Wagner & Guder Medical GmbH

Disposal

This refraction unit contains components that can not be disposed of in normal household waste. Please instruct them for the disposal of a waste management company or our services.



only for EU countries
WEEE-Reg.-Nr. DE 67707987

Eliminating electromagnetic interference

according to: Radiated RF IEC 61000-4-3

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

Caution!

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

Manufacturer's Declaration - Electromagnetic Emissions

(Tab. 201 according to DIN EN 60601-1-2)

The refraction unit cubeEVO is intended for use in an electromagnetic environment as described below. The customer or user of the refraction unit cubeEVO should ensure that the device is used in such an environment.

Warning! The use of longer cable length may cause an increased emission or a reduced interference resistance. The use of other sensors or cables except the ones mentioned above is not allowed.

- Cable length incomming voltage (2,5m)
- Wall mounted box incomming cable (3m)

Manufacturer's Declaration - Electromagnetic Emissions (Tab. 201 – Guidance and manufacture's declaration)		
The refraction unit cubeEVO is intended for use in an electromagnetic environment as described below. The customer or user of the refraction unit cubeEVO should ensure that the device is used in such an environment.		
Emission Measurements	**Accordance**	**Electromagnetic Environment - Guidance**
HF emissions acc. to CISPR11	Group 1	The unit cubeEVO uses HF energy exclusively for its internal function. Thus the HF emission is very low and it is unlikely that nearby electronic devices would be disturbed.
HF emissions acc. to CISPR11	Class B	The device is intended for use in all facilities including living quarters and such ones which are connected directly to a public power supply that supplies also buildings used for living purposes.
Emission of overtones acc. to IEC61000-3-2	complies	
Emission of voltage fluctuation/flicker acc. to IEC61000-3-3	complies	

Recommended Safety Distances between portable and mobile HF Telecommunication Devices and the refraction unit (Tab. 206 according to DIN EN 60601-1-2)

The refraction unit cubeEVO is intended for use in an electromagnetic environment with controlled HF disturbances. The user of the device can help to avoid electromagnetic disturbances by keeping the minimum distance between portable and mobile telecommunication devices (transmitters) and the device - depending on the output power of the telecommunication devices as described below.

Nominal power of transmitter (W)	Safety Distance Depending on the Frequency in 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	0,1	0,2	0,44
1	0,35	0,7	1,4
10	1,1	2,2	4,4
100	3,5	7	14

For transmitters with a maximum nominal power not mentioned above: To detect the recommended safety distance use the equitation in the corresponding column. P is the maximum nominal power of the transmitter in watt (W) according to the specifications of the transmitter manufacturer.

NOTE 1: For 80 Hz and 800 MHz the higher frequency range is valid.

NOTE 2: These guidelines may not be applicable for all cases. The propagation of electromagnetic values is influenced by absorptions and reflections of buildings, objects and people.

Manufacturer's Declaration - Electromagnetic Interference Resistance (Tab. 204 according to DIN EN 60601-1-2)			
The refraction unit is intended for use in an electromagnetic environment as described below. The customer or user of the cubeEVO should ensure that the device is used in such an environment.			
Interference Resistance Test	**IEC 60601-Testing Level**	**Compliance Level**	**Electromagnetic Environment - Guidelines**
Conducted HF-disturbances Acc. To IEC 61000-4-6	3 Vrms 150kHz to 80MHz 6 Vrms 150kHz to 80MHz In ISM bands	3 Vrms 6 Vrms In ISM bands	Portable and mobile radio sets should be used in a no less distances to the device including the cables than it is recommended by the equation for the frequency. Recommended safety distance: $d=0{,}35\sqrt{P}$ $d=0{,}7\sqrt{P}$ 80MHz – 800MHz $d=1{,}4\sqrt{P}$ 800MHz – 2,7GHz P is the nominal power of the transmitter in watt (W) according to the specifications of the transmitter manufacturer; d is the recommended safety distance in meters (m).(a) The field strength of stationary transmitters should be lower than the accordance level for all frequencies according to a testing on location.(b) Disturbances are possible near devices with the following symbol: 
Radiated HF-disturbances Acc. To IEC 61000-4-3	3 V/m 80MHz to 2,7GHz 10 V/m 80MHz bis 2,7GHz	3V/m 10 V/m 80Mhz- 1 Ghz 80%@ 1 kHz AM Modulation	
NOTE 1: For 80 Hz and 800 MHz the higher frequency range is valid. NOTE 2: These guidelines may not be applicable for all cases. The propagation of electromagnetic values is influenced by absorptions and reflections of buildings, objects and people.			

a	The field strength of stationary transmitters such as fixed parts of cellular phones and mobile radio sets, amateur radio stations, AM and FM radio and television cannot be determined exactly in theory. To detect the electromagnetic environment in regard to stationary transmitters a study of the location should be considered. If the measured field strength at the location where the device is being used exceeds the accordance level above the device should be watched to verify the proper functions. If unusual features are watched additional actions might be necessary such as a modified orientation or another location of the device.
b	For the frequency range of 150 kHz to 80 MHz the field strength should be lower than 3 V/m.

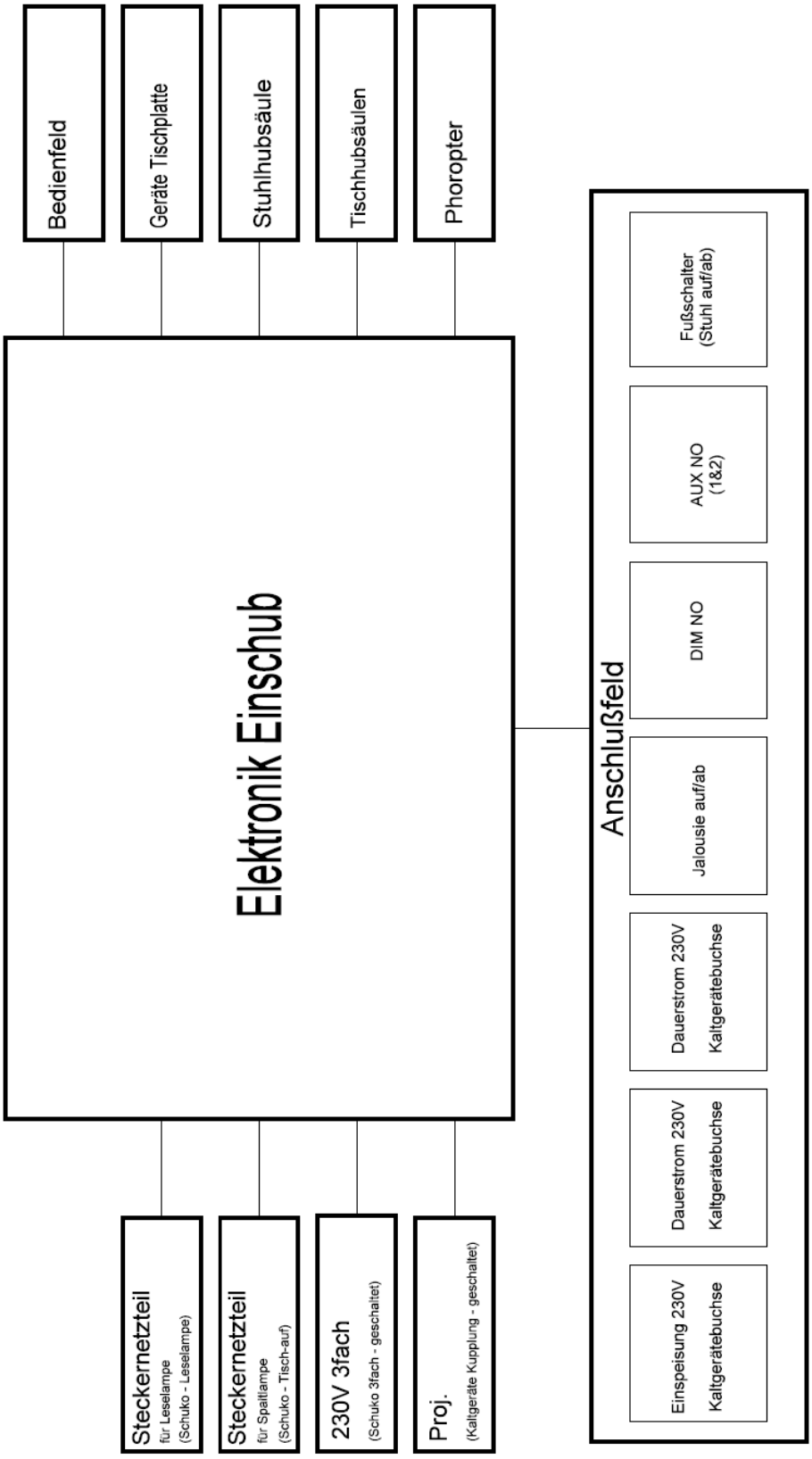
Manufacturer's Declaration - Electromagnetic Emissions (Tab. 202 according to DIN EN 60601-1-2)

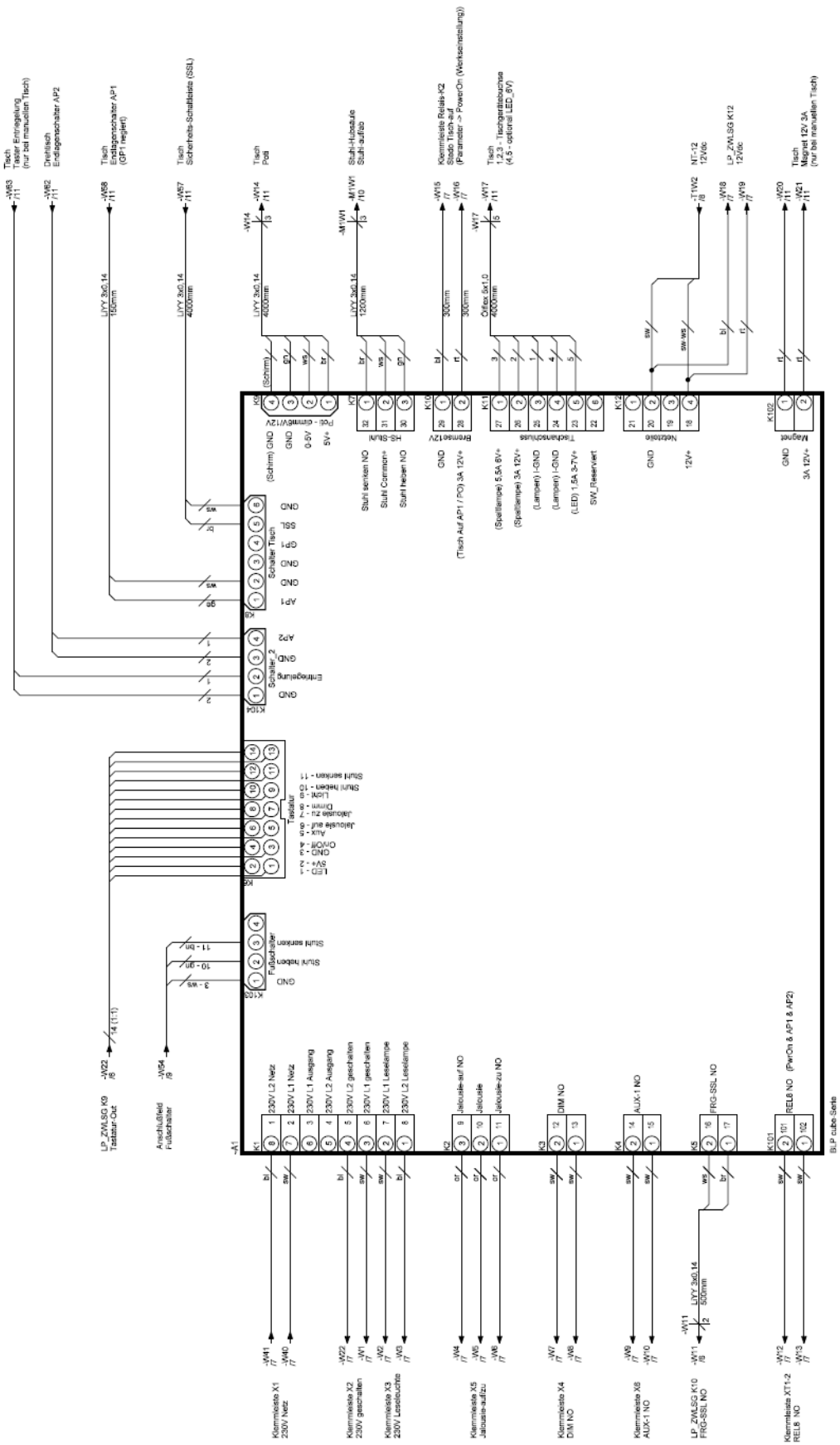
The refraction unit cubeEVO is intended for use in an electromagnetic environment as described below. The customer or user of the cubeEVO should ensure that the device is used in such an environment.

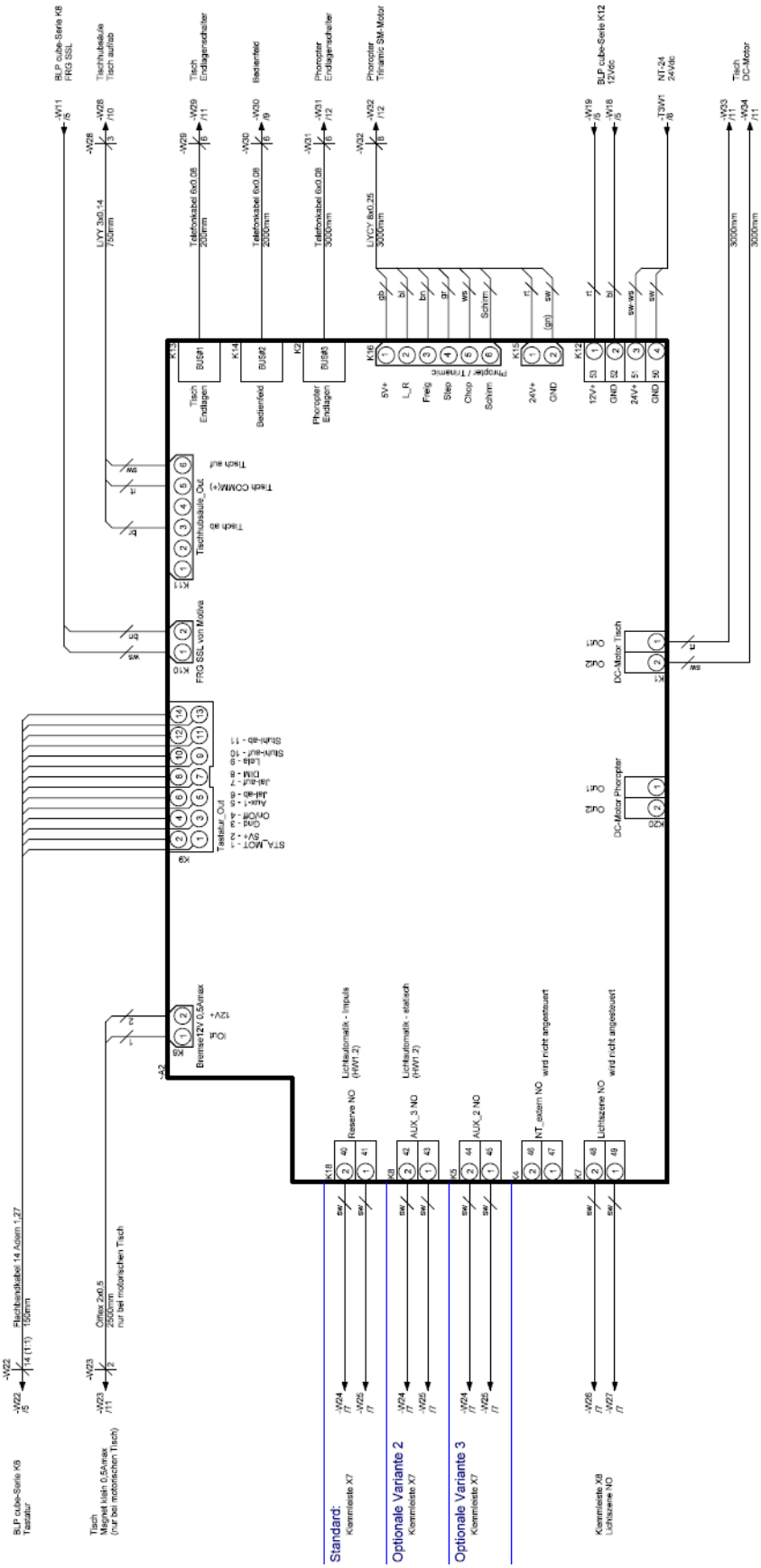
Interference Resistance Test	IEC 60601-Testing level	Accordance Level	Electromagnetic Environment - Guidelines
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	± 8 kV contact discharge ± 15 kV Air air discharge	± 8 kV contact discharge ± 15 kV Air air discharge	Floors should be of wood, concrete or ceramic tiles. If the floor is tiled with synthetic material the relative air humidity must have 30 % at least.
Fast transient electric disturbances / bursts acc. to IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input and output lines	± 2 kV for power lines ± 1 kV for input and output lines	The quality of the supply voltage should conform to a typical business or clinic environment.
Surge voltage acc. to IEC 6100-4-5	± 1 kV normal mode voltage ± 2 kV common mode voltage	± 1 kV normal mode voltage ± 2 kV common mode voltage	The quality of the supply voltage should conform to a typical business or clinic environment.

Interference Resistance Test	IEC 60601-Testing level	Accordance Level	Electromagnetic Environment - Guidelines
Voltage drops, short interruptions and variations in supply voltage acc. to IEC 61000-4-11	0% U_T 10ms 0% U_T 20ms 70% U_T 0,5s	0% U_T 10ms 0% U_T 20ms 70% U_T 0,5s	Floors should be of wood, concrete or ceramic tiles. If the floor is tiled with synthetic material the relative air humidity must have 30 % at least. The quality of the supply voltage should conform to a typical business or clinic environment.
Magnetic field at the supply frequency (50/60 Hz) acc. to IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields at the supply frequency should conform to the typical values as they occur in the business or clinic environment.
NOTE:	U_T is the AC mains voltage before the use of testing levels		

Electric connection cubeEVO






Standard:
Optionale Variante 2
Optionale Variante 3
Reserve NO
AUX_3 NO
AUX_2 NO
NT_ostern NO
Lichtszene NO
wird nicht angesteuert
Lichtautomatik - Impuls
Lichtautomatik - statisch
Bremse12V 0,5Amax
DC-Motor Tisch
DC-Motor Phoropter
FRG SSL von Motive
Tischhubsäule_Out
Tastatur_Out
Tisch Endlagen
Bedienfeld
Phoropter Endlagen
Phoropter / Trianetic
Tischhubsäule Tisch auflab
Phoropter Trianetic SM-Motor
BLP cube-Serie K8 FRG SSL
BLP cube-Serie K12 12Vdc
NT-24 24Vdc
Tisch DC-Motor
BLP cube-Serie K9 Tastatur
Tisch Magnet klein 0,5Amax (nur bei motorischen Tisch)
Flachbandkabel 14 Adern 1,27
Litze 2x0,5 2500mm nur bei motorischen Tisch