Directions for use
Refraction unit cubeONE

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Contents

Safety instructions

Before the first start of the refraction unit cubeONE please read the instructions and the instructions of the system equipment manufacturers. For further information please contact our service or authorized dealers.

General advises

The refraction unit cubeONE is an ophthalmologic examination unit and serves to receive testing and measuring instruments of eyewear. The modular design of the unit could be individually designed and can be ordered in different types. The refraction cubeONE is manufactured in accordance with the current state of the art and according to accepted safety requirements. Each unit is subject to stringent quality control and production control.

Intended use (use as directed)

The examination unit cubeONE is an ophthalmologic examination unit and used exclusively to accommodate testing and measuring instruments of eyewear. Another use than the specified is not allowed.

Classification/ declaration of manufacturer

According to the directive of medical devices 93/ 42/ EEC, the ophthalmologic examination unit cubeONE a non-invasive, active medical device in category I.

CE

Device class according to medical directive:	I
EMC:	electromagnetic compatibility – page 20.
UMDNS- No:	18-014

Meaning of used symbols and icons:

ATTENTION, WARNING

If you do not take into account the information given under CAUTION, may lead to moderate injuries and / or property damage or changes in the product.

DANGER OF VOLTAGE; ELECTRICITY

If you do not take into account the information given under Electricity, it can lead to exposure to electricity.

MAIN VOLTAGE

If you open the housing please separate the unit from the mains voltage.

Risk of clamping

Please have a look of moveable parts or eletromotoric movement. These parts are an risk of clamping!

GROUNDING

Points for security on the ground (protective earth).

CE- marking

The ophthalmic examination unit CUBEONE complies with medical product directive 93/42/EEC.

WEEE- marking: DE 67707987

Regard to the proper disposal of a waste disposal service

Safety instruction of assembly and operating

- Observe the legal regulations for the prevention of accidents
- Don't install or use the examination unit in moist rooms.
  Avoid dribbling or splashing water.
- Don't operate the examination unit in hazardous location.

  Environmental conditions for transport and installation:

  a) Ambient temperature: +10°C... +40°C

  b) Relative humidity: 30%... 75%, no condensation

  c) Air pressure: 700hPa... 1060hPa

- Only specialist staff, which is thoroughly acquainted with in stallation, implementing and operation of the product, is allowed to install the examination unit and put it into operation.
  Specialist staff in the sense of this operating manual is every person, who can assess the assigned works and perceive possible dangers on account of their professional education, their skills and experiences as well as their knowledge of the relevant norms. Only our service staff or authorized dealers are allowed to do Modifications and repairs on the examination unit. The fabricator is not legally liable for possible damages which are caused by non- authorized treatments.
  In this case all warranty claims do expire.
- Before first start-up, please pay attention that stability of the unit is ensured. Therefore the matching additional weights are to be assembled in the rear corpus of the unit.
- The examination unit has been levelled in the process of in stallation. If you want to move the unit, please pay attention that all mounting elements of the base plate do touch the ground.
  Only in this case the static safety of the unit and the stability of the examination devices are ensured
  (see also transport description).
- If you want to displace the basic unit, please pay attention that the table has completely been retracted and the examination devices have been fixed or removed. If you do not follow the safety advise, on an inclined plane a danger of tilting of about >10°exists.

- The maximum load capacity of the device table is 50kg, while the devices may be loaded position 1 with a maximum of 25kg.
- The maximum loading capacity of the patient chair is 135kg.
- The column of the patient chair is not designed for continuous operation. After an operating period of more than 60 seconds, the column of the patient chair required a cooling time by 9min.

Electric safety

- Medical devices are subject to special precautionary meas ures 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 cubeONE 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!

General construction cubeONE

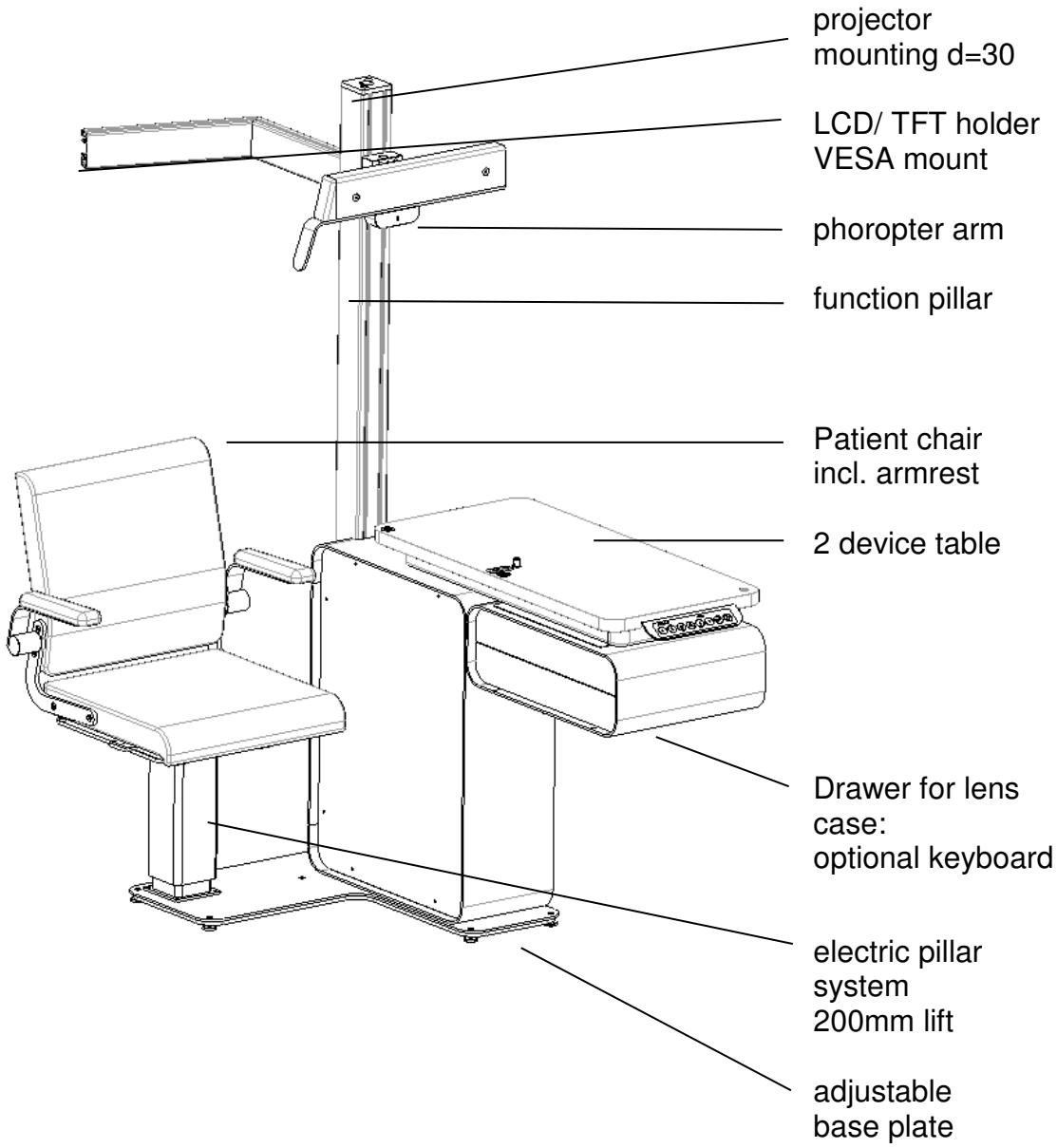


Figure 1: general structure cubeONE

Working table – two devices

The 2 device working table allows a smooth and safe pan before releasing the patient having a mechanical locking through the foot. Upon reaching the end position that will snap back automatically. When changing the survey instrument, the second hold, the table is driven by overcoming a magnetic detent in the second table position. Patient and users can maintain their seat position. Please have a look at the permissible maximum load of 50kg.

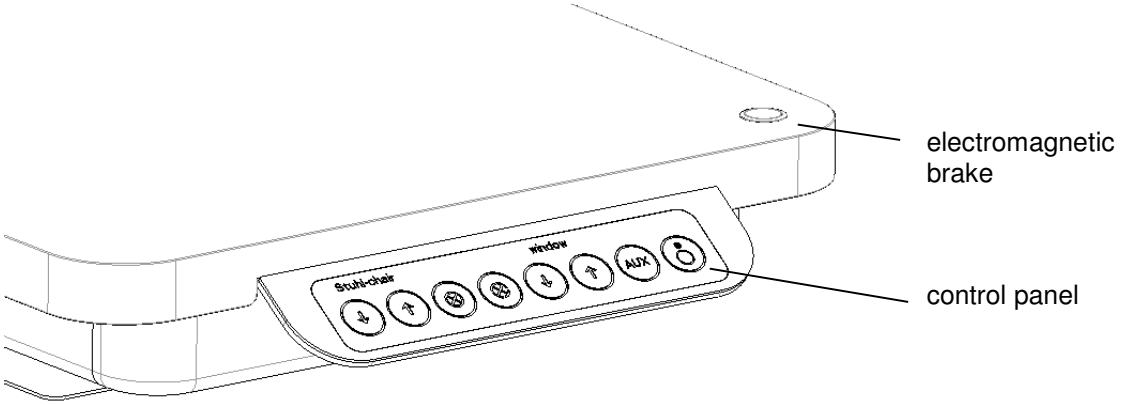


Figure 2: lose electromagnetic brake

Phoropter arm

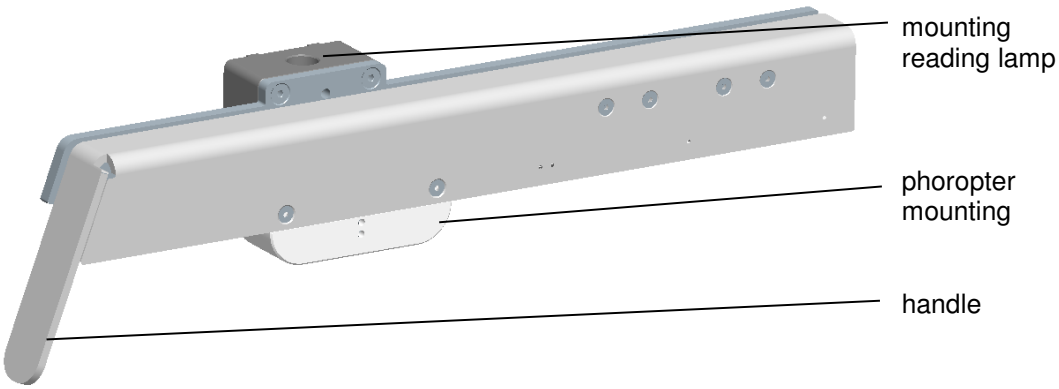


Figure 3: telescopic phoropter rail

Lens case including lens case holder

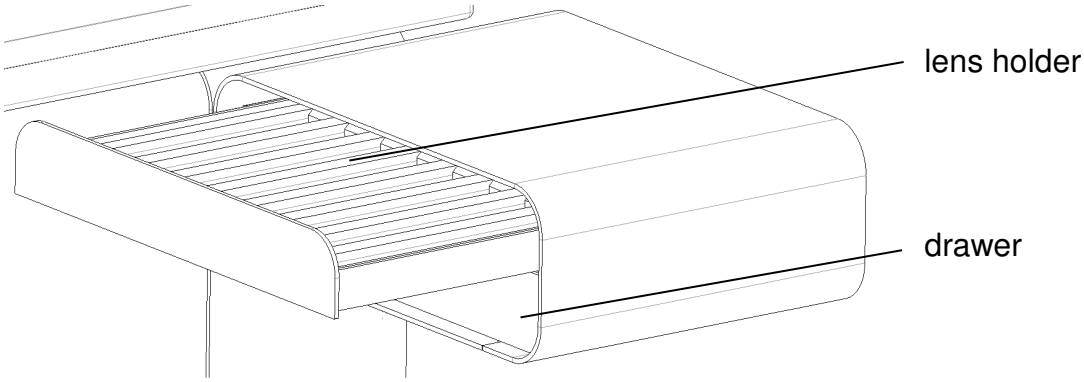


Figure 4: lens case

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.

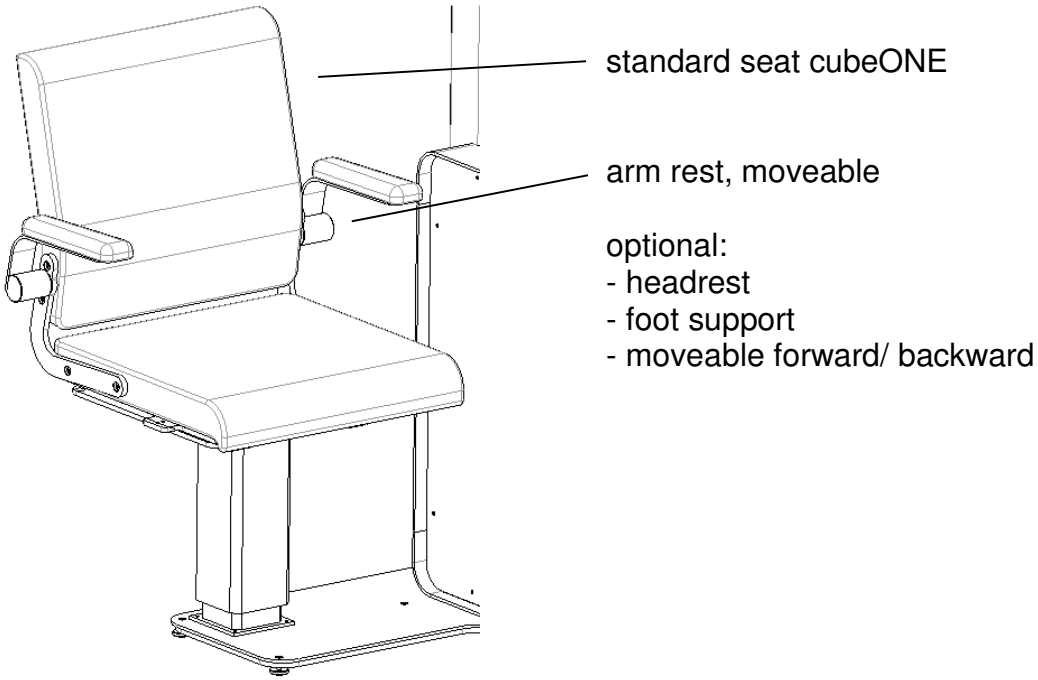
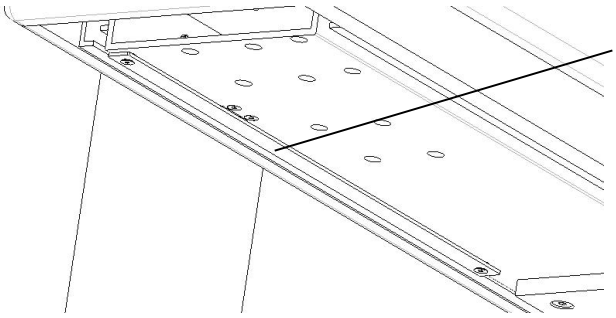


Figure 5: patient chair



Safety switch bar safety stop in the upward movement of the patient's chair

Figure 6: safety switch

Please take care of all adjustable accessories that no danger occurs to the patient. Precisely because the seat movement is a source of danger to the patient when used at actuated seat module of the patient's chair in height. The unit is staffed with a security bar for the legs, but this is by design not always engaged.

Attention!
Do not place your feet under the moveable patient chair. Risk of physical injury!

seat rotation: to place an patient on seat, moveable 4x 90°= 360°. Be careful, if you have a seat rotation and sliding system.

Please pay attention to the downward movement of the chair, that the shoes of the patient with the foot rest will not get caught!

Operation

Electrical connection

The electrical connection of the unit is on a properly installed safety socket or the included wall mounted box. Please use only the cable of mains connection, 2,5m cable length, wire size 1.0 mm2 or the cable of the wall connection box.

Initial operation

- Please connect the cable of mains connection with the power socket (1)
- Connect the cable of mains connection with a installed safety socket
- Press the power switch on „I“ (2)
- Press the power switch on the device table, the control lamp is green, figure 8 (position 8)

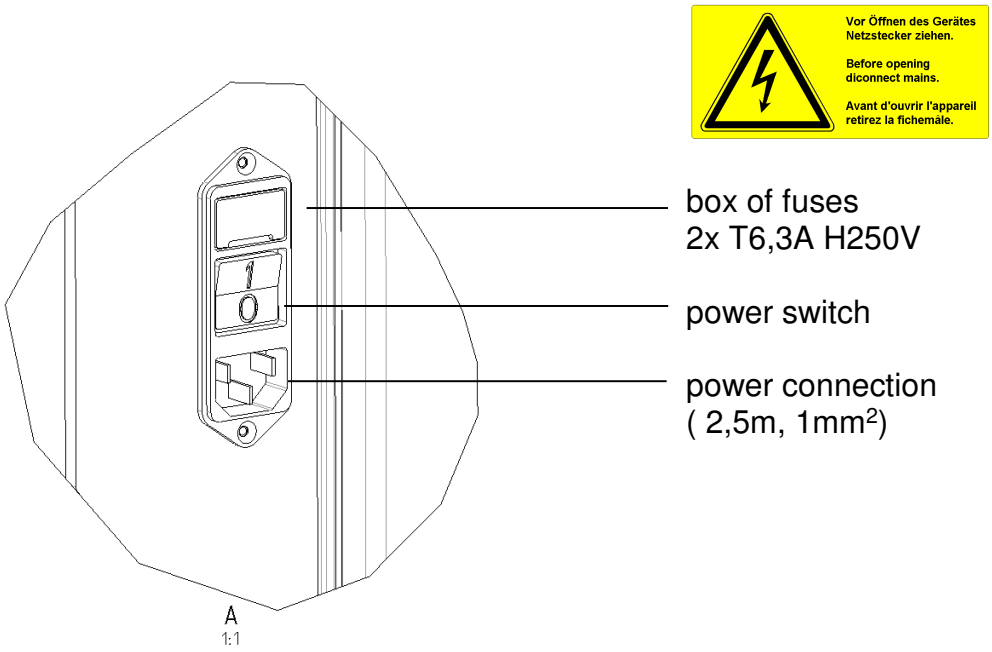


Figure 7: power connection

The engage switch with green control light is on the working device table, have a look at figure 8 (position 8). The refraction unit is from stand-by to operational as soon as the engage switch has been pressed and the lamp is green.
This also applies to already installed equipment or analysis of additional components. The survey instruments on the telescope table are automatically ready for use when the table position 1 and table position 2 are achieved. Besides the power switch located on the tabletop other switching elements.

Control panel

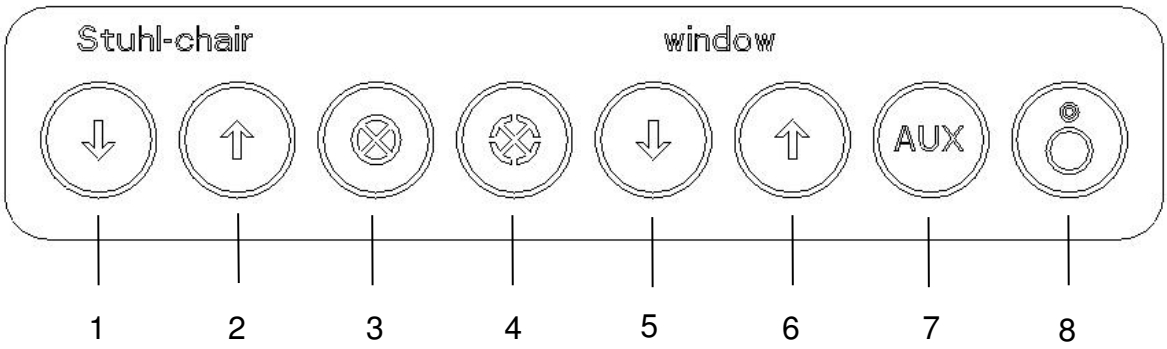


Figure 8: control panel

1 button patient chair DOWN

2 button patient chair UP

if you put on both buttons together the chair move down automatic „Automatic DOWN“, after a time delay of 10s you can move the chair UP

3 button reading lamp

4 button roomlight dimming

5 window control DOWN

6 window control UP

7 AUX, different switchable device

8 engage button with LED light green, Stand- By- Modus

Electrical connections

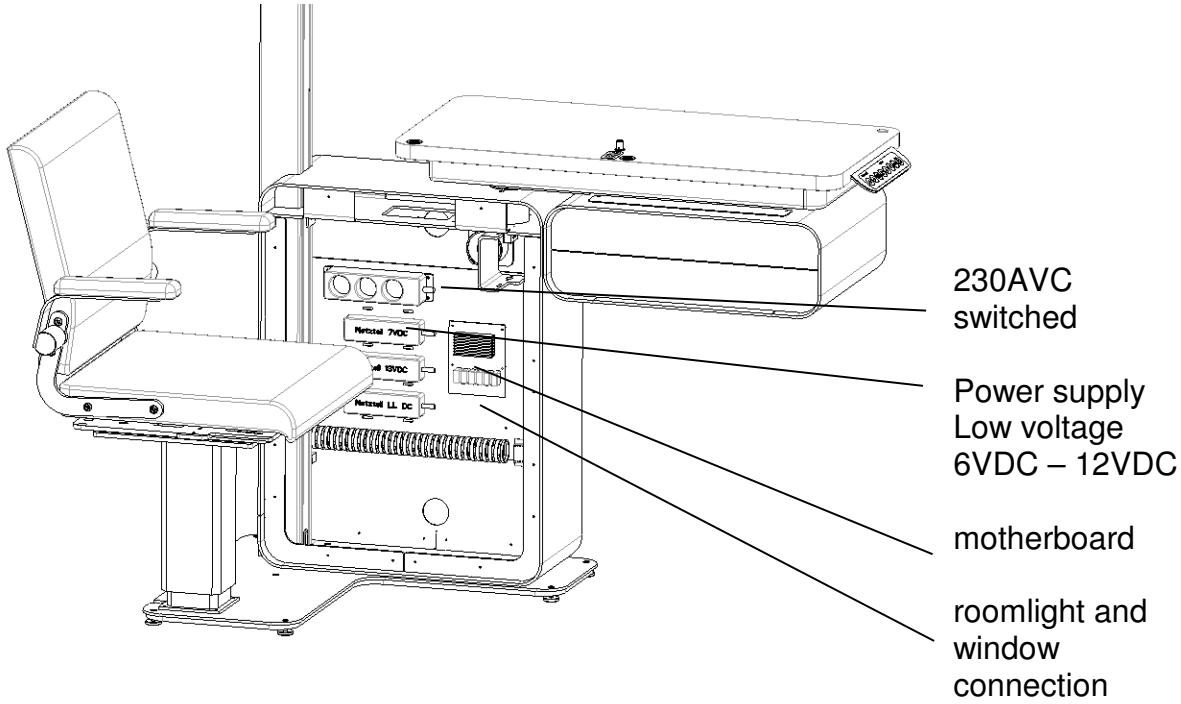


Figure 9: electrical connection

The refraction unit CUBEONE has a programmable electronic control system compatible with serial interface. The programs will be lost stored on an EEPROM. Because of external disturbing influences it may happen, that not all functions of the examination unit can be used or partial system malfunctions can arise. This malfunction can only be remedied, if you to disconnect the mains. In this case a **RESET** of the control electronics happens and the state before the malfunction will be recovered.

Attention! It is not enough to push the operation key on the control panel because in the stand-by-mode the control electronics is still 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 cubeONE 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 cubeONE and its 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 Check the proper fastening of the examination devices regularly.
2 Check the safety advices affixed at the supplied products.
3 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.
4 Check the integrity of housing an isolations
5 Check the operational reliability of safety-relevant circuits (switch-off panel and current limitations)
6 Regular measuring (annual) of substitute leakage current
7 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, every time before repairing, pull the mains plug!

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 7, position 3)
  Push the plastic tongue that is attached at the box (e.g. using a screw-driver 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.

Patients surrounding

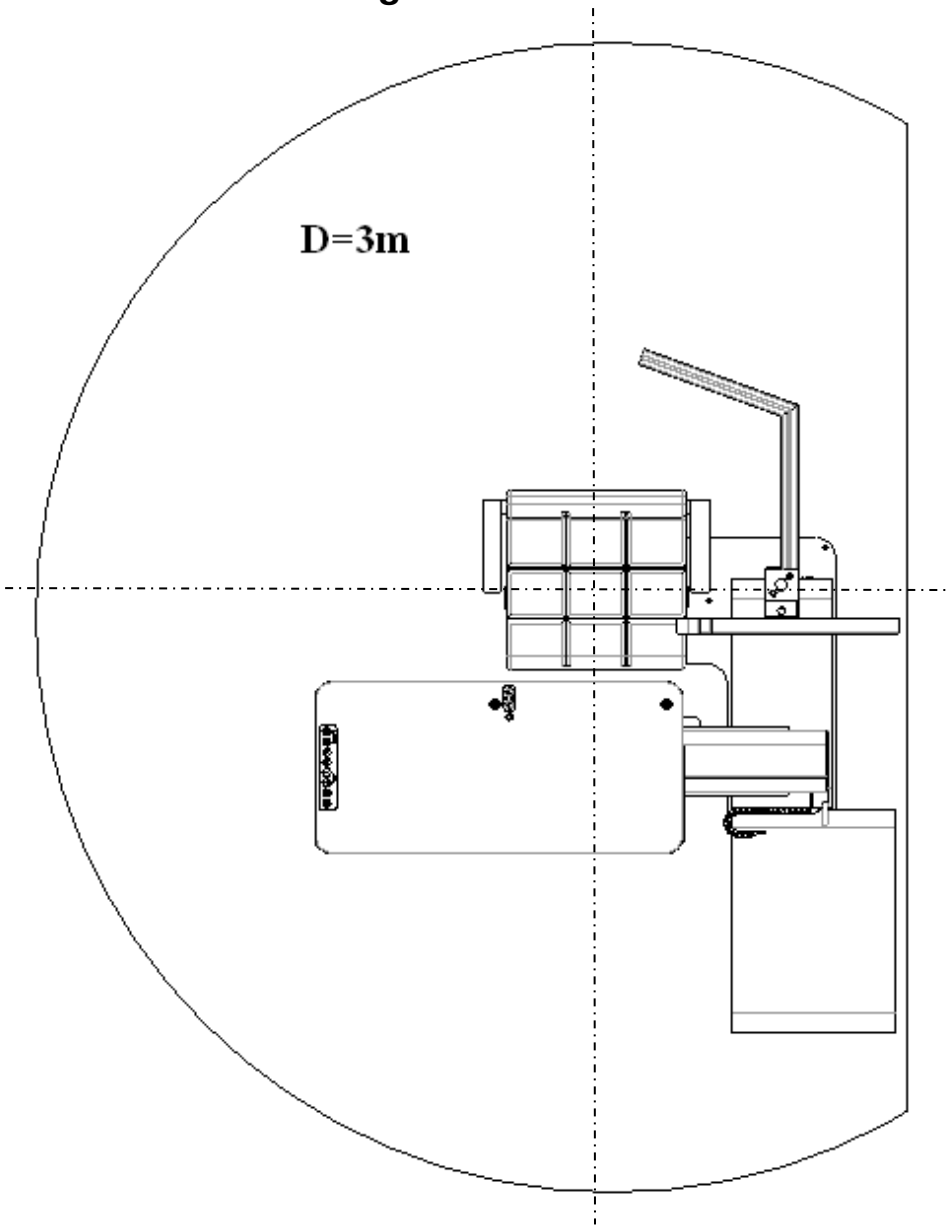


Figure 10: Patients surrounding

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.

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 defect within 12 months will be set free repair.

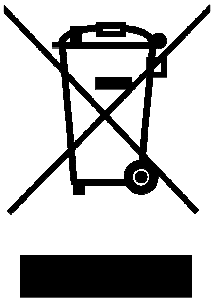
Conditions for a warranty claim:

- The invoicel 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 Conditions of the company
Wagner & Guder Medical GmbH

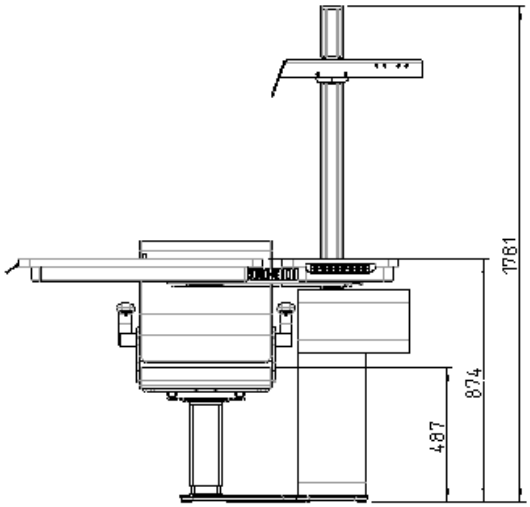
This refraction unit contains components that can not be disposed of in normal household waste. Please instruct them for the disposal of a waste management company or our services.

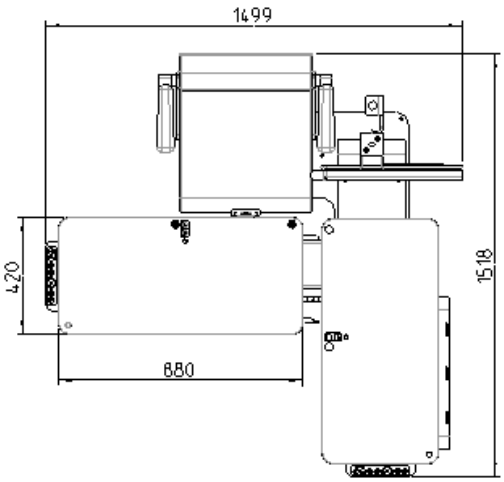


only for EU countries
WEEE-Reg.-Nr. DE 67707987

Technical data

Anschlussspannung *nominal input voltage*	230V / 50Hz
Anschlussleistung *connected load*	6A
Beleuchtung *electric lighting*	6VA LED
Schutzart Einheit *protection class unit*	IP 20
Kleinspannungs-versorgung *low voltage*	6…12VDC/ 5A
Gerätetyp *class of unit*	B
Schutzklasse *class of protection*	I
Arbeitshöhe *working height*	870mm (34,3in)
Gesamthöhe *maximum height*	1750mm (69in)
Maximalgewicht Einheit *maximum weight of unit*	170kg (398,4b)
Belastbarkeit Patientenstuhl *loading capacity chair*	135kg (297lb)
Belastbarkeit Zweigerätetisch *loading capacity table*	50kg (110lb)
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

Manufacturer's Declaration - Electromagnetic Emissions (Tab. 201 according to DIN EN 60601-1-2)

The refraction unit CubeONE is intended for use in an electromagnetic environment as described below. The customer or user of the refraction unit CubeONE 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		
The refraction unit cubeONE is intended for use in an electromagnetic environment as described below. The customer or user of the refraction unit cubeONE should ensure that the device is used in such an environment.		
Emission Measurements	**Accordance**	**Electromagnetic Environment - Guidelines**
HF emissions acc. to CISPR11	Group 1	The unit cubeONE 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	Class A	
Emission of voltage fluctuation/flicker acc. to IEC61000-3-3	agreed	

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 cubeONE 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 $d=1{,}2\sqrt{P}$	80MHz - 800MHz $d=1{,}2\sqrt{P}$	800MHz - 2,5GHz $d=2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

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 cubeONE should ensure that the device is used in such an environment.			
Interference Resistance Test	**IEC 60601- Testing Level**	**Accordance Level**	**Electromagnetic Environment - Guidelines**
			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.
Conducted HF-disturbances Acc. To IEC 61000-4-6	3 Vrms 150kHz bis 80MHz	3 Vrms	Recommended safety distance: $d=1,2\sqrt{P}$
Radiated HF-disturbances Acc. To IEC 61000-4-3	3 V/m 80MHz bis 2,5GHz	3V/m	$d=1,2\sqrt{P}$ 80MHz – 800MHz $d=2,3\sqrt{P}$ 800MHz – 2,5GHz 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: 

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.

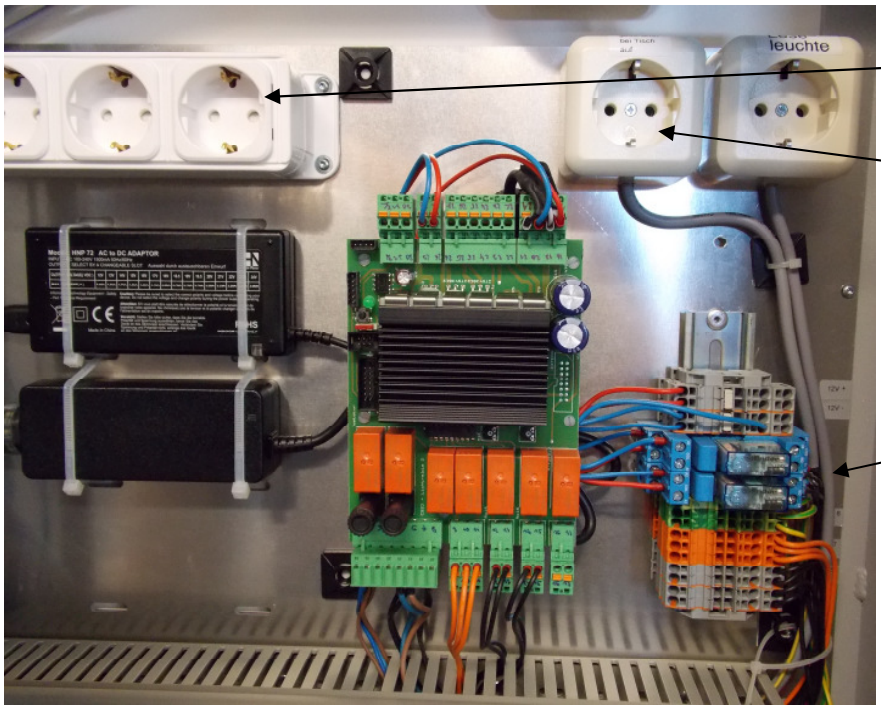
Manufacturer's Declaration - Electromagnetic Emissions (Tab. 202 according to DIN EN 60601-1-2)

The refraction unit cubeONE is intended for use in an electromagnetic environment as described below. The customer or user of cubeONE 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	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV 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	< 5% UT für 1/2 period (> 95% Break) 40% UT für 5 Period (60% Break) 70% UT für 25 Period (30% Break) < 5% UT für 5 s (> 95% Break)	< 5% UT für 1/2 Periode (> 95% Break) 40% UT für 5 Period (60% Break) 70% UT für 25 Period (30% Break) < 5% UT für 5 s (> 95% Break)	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	3 A/m	3 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		

Electrical connection cubeONE

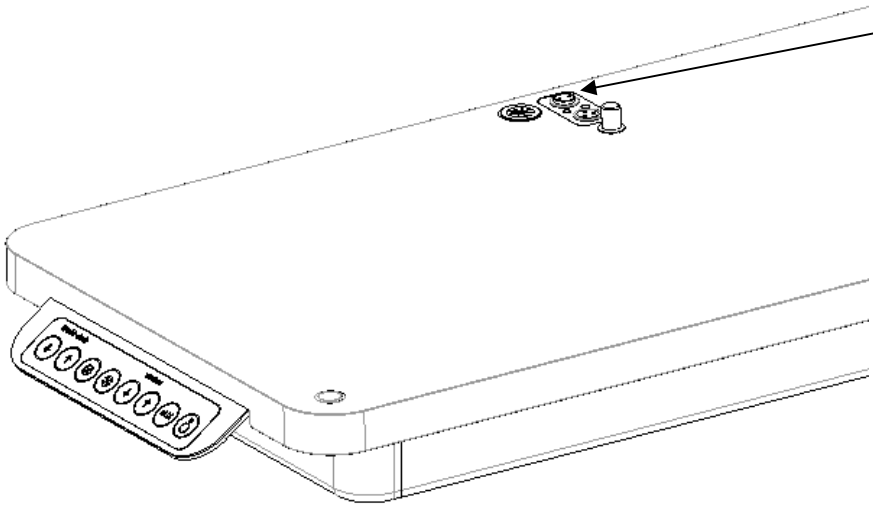


3x 230VAC/ 4A switched with unit ON/ OFF

switched 230VAC for Power supply (slit lamp) with table PIN 28/ 29 page 27

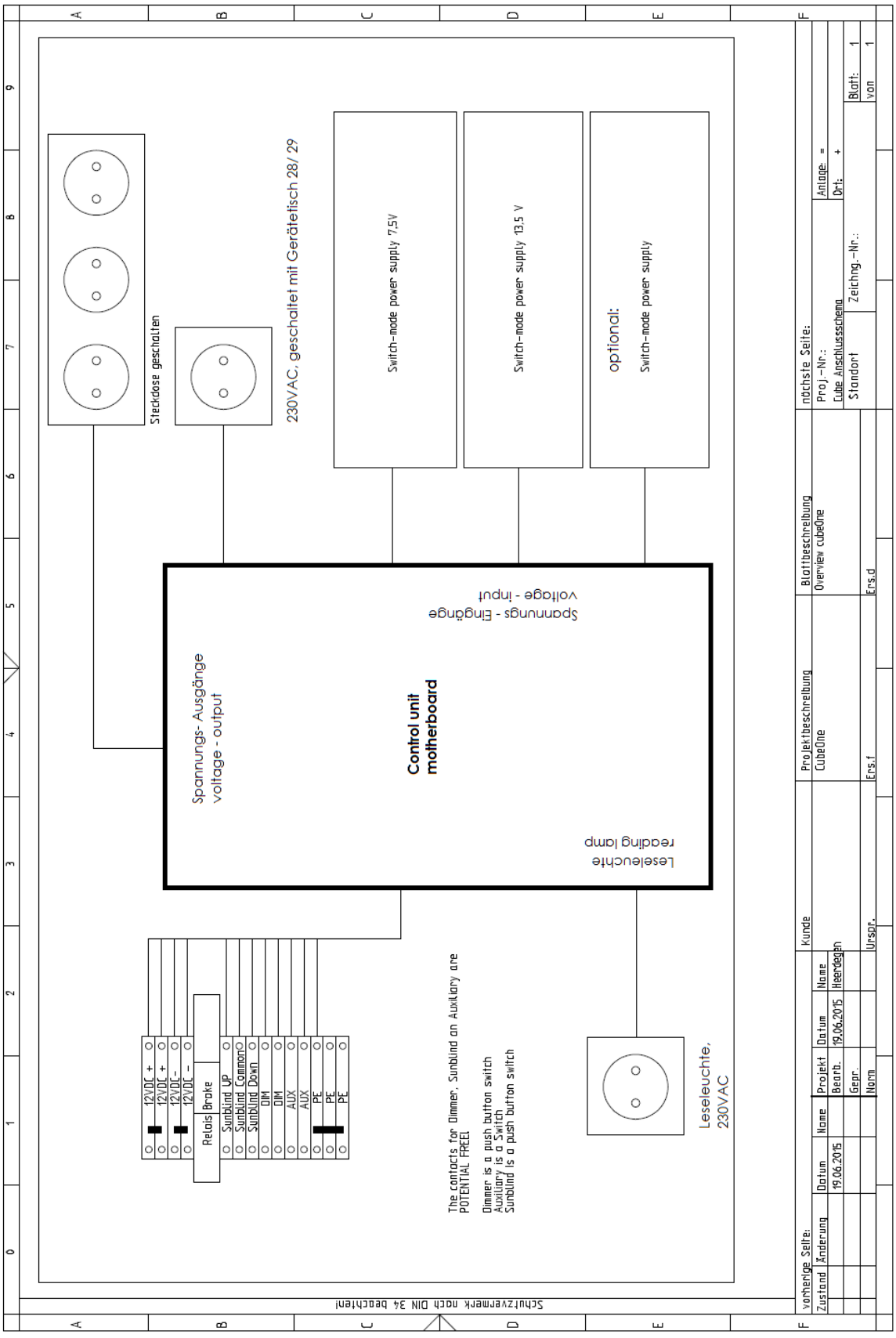
roomlight and windows connection

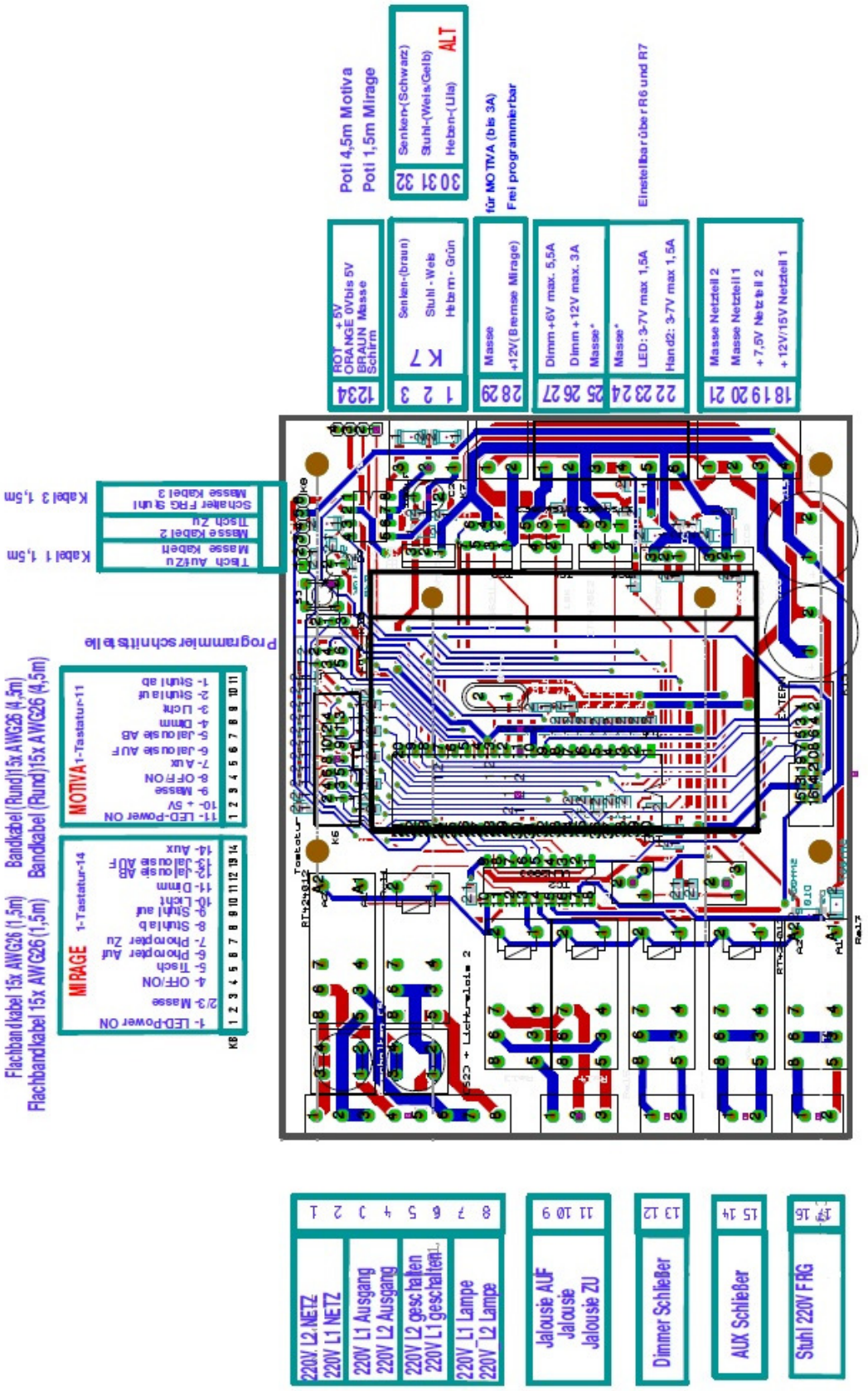
connection instrument table



Slit lamp connection from external power supply

cubeONE, motherboard




Poti 4,5m Motiva
Poti 1,5m Mirage
ALT
Senken-(Schwarz)
Stuhl-(Weis/Gelb)
Heben-(Ula)
30 31 32
für MOTIVA (bis 3A)
Frei programmierbar
Einstellbar über R6 und R7
ROT +5V
ORANGE 0Vbis 5V
BRAUN Masse
Schirm
1234
K 7
Senken-(braun)
Stuhl - Web
Heben - Grün
1 2 3
Masse
+12V(Bremse Mirage)
28 29
Dimm+6V max. 5,5A
Dimm+12V max. 3A
Masse*
25 26 27
Masse*
LED: 3-7V max 1,5A
Hand2: 3-7V max 1,5A
22 23 24
Masse Netzteil 2
Masse Netzteil 1
+7,5V Netzteil 2
+12V/15V Netzteil 1
18 19 20 21
Tisch Auf/Zu
Masse Kabel1
Kabel 1 1,5m
Masse Kabel 2
Tisch Zu
Schalter FRG Stuhl
Masse Kabel 3
Kabel 3 1,5m
Programmierschnittstelle
Bandkabel (Rund)15x AWG26 (4,5m)
Bandkabel (Rund)15x AWG26 (4,5m)
MOTIVA 1-Tastatur-11
1- Stuhl ab
2- Stuhl auf
3- Licht
4- Dimm
5- Jalousie AB
6- Jalousie AUF
7- Aux
8- OFF/ON
9- Masse
10- + 5V
11- LED-Power ON
Flachbandkabel 15x AWG26 (1,5m)
Flachbandkabel 15x AWG26 (1,5m)
MIRAGE 1-Tastatur-14
1- LED-Power ON
2/3- Masse
4- OFF/ON
5- Tisch
6- Phomopler Auf
7- Phomopler Zu
8- Stuhl ab
9- Stuhl auf
10- Licht
11- Dimm
12- Jalousie AB
13- Jalousie AUF
14- Aux
K8
220V L2 NETZ
220V L1 NETZ
220V L1 Ausgang
220V L2 Ausgang
220V L2 geschalten
220V L1 geschalten
220V L1 Lampe
220V L2 Lampe
Jalousie AUF
Jalousie
Jalousie ZU
Dimmer Schließer
AUX Schließer
Stuhl 220V FRG

EG- Konformitätserklärung
Declaration of conformity

Gerätebezeichnung *product*	Refraktionseinheit cubeONE *refraction unit cubeONE*
Typ/ UMDNS-CODE: *type/ UMDNS-CODE:*	ophth. Untersuchungs-/ Behandlungsplatz (18-014)
Klassifizierung: *classification*	**I** (Richtlinie 93/42/EWG) **I** *(directive 93/42/EEC)*

Hiermit erklären wir, dass das bezeichnete Gerät aufgrund seiner Konzeption und Bauart sowie in der von uns in Verkehr gebrachten Ausführung den Anforderungen der Medizinproduktrichtlinie 93/42/EWG entspricht.
The refraction unit is on the basis of design in all type of construction in correlation with directive 93/42/EEC.

Angewandte Normen: *Applied standards:*	EN 60601-1:2006 + A1:2013 (Edition 3.1) IEC 60601-1:2005 + A1:2012 (Edition 3.1)

Die Refractionseinheit cubeONE gilt nach der Medizingeräterichtlinie 93/ 42/ EWG als nicht invasives, aktives Medizinprodukte der Klasse I und entsprecht den aktuellen Sicherheits- und Gesundheitsanforderungen zur Aufnahme von Prüf- und Messuntersuchungsgeräten der Augenoptik.
The refraction unit cubeONE applies to the Medical Device Directive 93/ 42/ EEC as a non-invasive, active medical device in class I and in terms of safety and health requirements for inclusion of ophthalmics test and measurement equipment.

Diese Erklärung wird verantwortlich abgegeben durch:
This declaration is submitted by:

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Kennzeichnung/
marked with

CE

Stefan Guder, Dipl.-Ing.(FH)
(Geschäftsführung)

Hermstedt, 01.01.2018