Refraction unit cubeEVO



Directions for use

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About these instructions	<ul> <li>The instructions for use are part of the scope of delivery.</li> <li>Please read carefully before use</li> <li>Familiarise yourself with the safety regulations</li> <li>Store at the place of use of the device</li> <li>Store during the service life of the device</li> <li>Pass on to any subsequent owner or user of the device</li> <li>We reserve the right to make changes to the design and scope of delivery within the scope of further technical developments.</li> </ul>			
Orientation aids	<ul> <li>The table of contents at the beginning of the instructions for use gives you an overview of the topics covered</li> <li>Pictures and signs warn of hazards or point out special features</li> </ul>			
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## Safety instructions

#### Explanation of the symbols



#### Read the "Observe instructions for use" sign,

especially the safety instructions, and follow the accompanying documents

#### Device identification plate "Type plate"



	Manufacturer		
$\sim$	Date of manufacture	GTIN	Trade number
ED10%	Lifting unit operating cycle	UDI	Unique device identifier
CE	EU conformity	Ŕ	Device type B
Щ	Fuse	SN	Serial number
MD	Medical device	~	Alternating current
REF	Construction series		Disposal instructions
	Data Matrix Code according to GS1		Weight of the product



#### Warning notice "Risk of entrapment"

Watch out for moving or motorised parts that could pose a risk of entrapment for the patient due to their design.



# **Warnings** 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.



#### Earthing

Indicates the earthing (protective conductor) for safety reasons.



#### CE labelling

Indicates compliance with the standards for medical devices.



#### WEEE labelling "Observe disposal regulations"

Electrical or electronic devices or assemblies must not be disposed of as normal household waste.

#### **Field of application**

#### Purpose

The cubeEVO refraction unit is an ophthalmological refraction unit and is used exclusively to accommodate testing and measuring devices for ophthalmic optics.

Any use other than that specified is not permitted.

#### Intended use

The cubeEVO refraction unit is a versatile device for positioning a seated patient or customer in front of ophthalmic examination devices. Both manual and motorised adjustment options are available for positioning.

#### Reporting obligations of operators and users

Operators and users are obliged to report any serious incidents to the manufacturer or sales partner immediately and without undue delay. Reportable incidents are malfunctions that affect the characteristics and performance of the product in terms of its suitability for use and could endanger the patient and/or operator. In countries of the European Union, please observe the reporting obligations to the responsible authority as well as your national legislation.

#### **Medical Devices Act**

The cubeEVO refraction unit, in accordance with EU Regulation 2017/745 (MDR) on medical devices, is a Class I active device - non-invasive.

Device class according	I
to MDR	
Basis UDI-DI	426076094UNITET
EMC	Electromagnetic compatibility
	Page 38ff.

#### Authorisations and requirements

Description of the	Labelling	
Electrical version	DIN EN 60601-1: 2006 + Cor.:2010 + A1:2013 Protection class I	
EMC requirements	The device fulfils the EMC requirements of DIN EN 60601-1-2: 2016, class B	
CE labelling	The device fulfils the basic safety requirements in accordance with EU Regulation 2017/745 on medical devices	
	The device is labelled with	

#### Notes for the operator

- Familiarise yourself thoroughly with the contents of the operating instructions before using the appliance. Also observe the instructions for use for accessories and other system components.
- The refraction unit may only be installed and commissioned by specialised personnel who are familiar with the installation, commissioning and operation of the product. For the purposes of these instructions for use, qualified personnel are persons who are able to assess the work assigned to them and recognise potential hazards due to their specialist training, knowledge and experience as well as their knowledge of the relevant standards.
- Keep the operating instructions to hand at all times for the operating or service personnel.
- Observe the legal regulations on accident prevention and occupational safety applicable in the respective country.
- Modifications and repairs to the refraction unit may only be carried out by our service personnel or authorised dealers. The manufacturer is not liable for any damage caused by unauthorised tampering with the unit. In this case, all warranty claims are void.
- The refraction unit must not be set up and operated in damp rooms. Avoid dripping and splashing water.
- The refraction unit must not be operated in potentially explosive atmospheres.
- The refraction unit was levelled when it was installed. If the unit needs to be moved, please ensure that all adjusting elements on the base plate are in contact with the floor. This is the only way to ensure the stability of the unit and the examination devices.
- The telescopic table and the phoropter arm must be swivelled and moved to ensure that the examination devices are in the specified working position. Please ensure that the patient does not come into contact with any moving parts. There is a risk of injury here!
- The maximum load capacity of the appliance table is 40 kg, with a maximum load of 30 kg in appliance position 1.
- Observe the maximum load capacity of the patient chair of 135 kg.
- The lifting column of the patient chair is not designed for continuous operation. After an operating time of more than 1 min, the lifting column of the patient chair requires a cooling time of 9 min.

- The refraction unit may only be operated from a correctly installed 230V/AC mains voltage socket with the mains cable supplied or in conjunction with the wall connection box.
- Extension leads and portable multiple sockets must not be used for operating the refraction unit.
- Interrupting the protective conductor is not permitted, as this can endanger the user/patient and damage installed devices.
- If the protective earth conductor is impaired or electrical cables are damaged, the refraction unit must be disconnected from the electrical connection and secured against unintentional operation.
- Never open the appliance! There are live parts inside.
- The refraction unit may only be opened by authorised specialist personnel.
- Only the main mains fuses accessible from the outside may be changed.
- Please disconnect the mains plug before cleaning. Please ensure that no cleaning agent or water enters the refraction unit.
- Additional devices that you connect to the refraction unit must demonstrably comply 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-powered devices directly to the refraction unit. According to IEC/VDE, the limit values are max. 0.5mA for the touch current and max.  $0.2\Omega$  for the protective conductor resistance.
- Possible risks associated with commissioning the refraction unit and installing additional devices are taken into account in the product FMEA and risk management.

## Set-up and installation instructions

To avoid the risk of electric shock, this refraction unit may only be connected to a supply network with a protective earth conductor. Operation via a multiple socket is expressly prohibited. Ensure that the unit is disconnected from the mains supply in the event of a fault.



WARNING!

## Notes on device installation



Refraction unit in singledevice mode

> 1st table position: max. **30kg**

2nd table position: FREE

3. desk: max. **60kg** 



1st table position: max. **15kg** 

2nd table position: max. 25kg

> 3. desk: max. **60kg**

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





## Requirements for operation

#### Before initial commissioning

- Check the stability of the examination station
- Check the attachment points of the installed devices
- 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 outlet with a faultless protective earth conductor.
- Check safety-relevant circuits

#### **Before each operation**

- Check the fastening of the installed devices
- Disinfect authorised surfaces of the refraction unit and contact surfaces of the installed devices
- Point out potential hazards to patients/customers

#### During each operation

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

#### After each operation

- Switch off the appliance on the control panel if it is not going to be used for a long period of time
- Insufficient hygiene or incorrect cleaning contrary to the instructions for use can contribute to the risk of infection for the patient/client and damage the surfaces of the refraction unit or lead to discolouration

#### Liability and warranty

The warranty and liability are based on the contractually agreed conditions

#### **NOTE** Loss of warranty

The manufacturer is not liable for damage caused by unauthorised tampering with the device or improper handling. This also voids all warranty claims.

## General structure of cubeEVO



#### Two-axis table

The two-axis table enables smooth and safe movement in front of the patient. When the end position is reached, an electromagnet engages automatically. It is retracted by releasing the holding magnet by pressing the AUX button. When changing the examination device to the second holding position, the table is moved to the second table position by pressing a mechanical detent. The patient and user can maintain their sitting position. The maximum permissible load of the two-position table is 40kg.



Patient chair safety edge

## Table-top unit assembly

#### Appliance table - Electrical connection

Version 1



#### Version 2



## 5-pole cable - marking 1 to 4 and PE

1Working position 1 for device connection (cable 1+2)PIN 2:PE protective conductorPIN 1+3:6 VDC or 12 VDC (on base circuit board - p.23)

K11 Output 6V: PIN 25/27

K11 Output 12V: PIN 25/ 26

- 2 Working position 2 for device connection, (cable 3+4) PIN 2: PE protective conductor
- **3** Potentiometer brightness control

## Slit lamp installation



#### Phoropter arm

#### manually



#### Electromotive



#### Phoropter arm height adjustment



#### Desk with add-on parts

The shape of the desk can be customised. **Maximum load: 60kg!** 

It is prepared for the installation of e.g. measuring glass insert (plastic insert "Obrira") or drawer or Heine NT300 drawer holder.



#### Adjusting the working height

The height of the cubeEVO desk can be adjusted.

The height of the walking desk can be adjusted in the range of approx. 700 to 800 mm using the desk mount. Recommendations according to ISO 5970:



#### **Patient chair**

The patient chair is designed as a single chair and has an electromagnetic height adjustment with a safety edge under the equipment table. This bar is designed to prevent the patient's leg from colliding with the equipment table. The chair is available with additional adjustment functions and can be retrofitted. The permissible lifting capacity of the patient chair is 135kg.



Please ensure that patients do not place their feet under the footrest! Due to its design, the lifting column does not register as an obstacle!





Please ensure that all adjustable accessories do not pose a risk to the patient. The seat adjustment and footrest in particular are a source of danger to the patient if the patient chair is moved in height when the seat module is activated. Although the unit has a safety rail under the instrument table for the legs, this is not engaged everywhere due to the design.

Seat swivel: The seat swivel serves to make it easier for the patient to get in and out of the chair, a catch holds the chair in its rest position  $4x 90=360^{\circ}$ . When swivelling, make sure that the seat adjustment is in a forward position.

When lowering the chair, please ensure that the patient's shoes are not trapped by the footrest!

## Reading light/ reading spotlight



- 1 Reading light holder height-adjustable, rotatable
- 2 Light source, GU5.3 4.6VA 4000K

#### Commissioning

- Connect the mains cable to a properly installed earthed socket outlet
- Connect the mains cable included in the scope of delivery to the mains input socket, connection length 2.5m, cable cross-section 1mm<sup>2</sup> or the connection cable of the wall connection box
- Actuate the mains input switch switch position I
- Confirm the operating button on the control panel. The operating status is indicated by the green LED





#### **Control panel**



Control panel cubeEVO

## Keyboard symbols



 Patient chair, downwards and upwards when both buttons are pressed, the "AUTOMATIC DOWN" function is activated. This function is controlled by a time loop on the lifting columns used. (time loop 10 sec) The chair can only be raised again after this time has elapsed!

- 2 Table trip FORWARD/ BACK
- 3 Phoropter FORWARD/ BACK
- 4 Device table UP/ DOWN
- 5 Move curtain control downwards and upwards
- 6 Push-button reading light and room light dimming
- AUX 1 + 2 buttons for additional functions (no curtain control possible!)
   AUX 3 Automatic alternating movement between table and phoropter (only with E-version)

8push-button with operating LED (green), stand-by mode

#### **Control electronics**

The cubeEVO refraction unit has programmable control electronics with an interface. The programmes are permanently stored on an EEPROM. Due to external interference, not all functions of the refraction unit may be available or partial system malfunctions may occur. This malfunction can only be rectified if the unit is disconnected from the mains for at least 30 seconds. In this case, the control electronics and the data bus are **RESET** and the status prior to the fault is restored.

Caution! Pressing the operating button is not sufficient, as the control electronics are still active in stand-by mode.

## Circuit structure - data bus



Illustration: Version without electromotive phoropter arm

Illustration: Version with electromotive phoropter arm



Bus coupler 2 is located on the phoropter arm

Bus coupler 1 table

#### Internal circuit design:



Touch signalStatic signal (control of automatic room lighting)

#### 230 VAC/ 4 A

Reading lamp

Terminal strip room light Venetian blind AUX

Socket for external voltage 230 VAC (e.g. slit lamp) switched

Data bus system Keyboard BUS BUS device table Phoropter BUS

Limit switch Phoropter

Power supply Phoropter

#### Base circuit board BLP



- 1 Fuse Si2 (230V T 4 A / H)
- 2 Switching the power supply from operating position 1 and 2
- 3 Fuse Si3 (230V T 4 A / H)
- 4 RESET Control unit
- 5 6V output (max. 5.5A), switching position 1,2,3,4,5 corresponds to: 3V, 4V, 5V, 6V, 7V
- 6 12V output (max. 3A), switching position 1,2,3,4,5 corresponds to: 10V, 11V, 12V, 13V, 14V
- 8 LED- 6V (fixing light), switching position 1,2,3,4,5 corresponds to: 3V, 4V, 5V, 6V, 7V
   9 Switchover 6V-R dimmed/ 6V DC fixed voltage

Switchover 12V-R dimmed/ 12V DC fixed voltage





#### Additional printed circuit board ZLP

- 1 Electromagnet 12V+ Fixing first appliance table position
- 2 Control panel connection
- **3** Automatic light touch signal
- 4 Automatic light control continuous or static signal
- 5 AUX free ports
- 6 Room light connection
- 7 Data bus connection Table
- 8 Phoropter data bus connection
- 9 Data bus connection Control panel
- **10** End position sensor phoropter arm
- 11 Phoropter power supply Electromotive
- 12 Power supply 12VDC BLP base circuit board, power supply input 24VDC
- 13 Table motor power supply

## Speed control for appliance table

#### Table travel in working and basic position:

Potentiometers R7, R8, R9 can be used to set the deceleration, acceleration and final speed of the table.

The settings are 3-stage for each potentiometer.

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

Position	R7	R8	R9
1	Maximum time for braking	Maximum time to accelerate	Minimum final speed
2	Medium braking time	Average time to accelerate	Average final speed
3	Minimum time for braking	Minimum time to accelerate	Maximum top speed

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

Position 3 corresponds to the left stop. This means that position 3 is reached by turning anticlockwise to the stop.

Position 2 corresponds to the centre position between positions 1 and 3.

The following illustration shows all three potentiometers in position 1.



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

## Setting the bus coupler

#### Settings for phoropter and table:

Table address	$\rightarrow$ DIP switch 3=OFF, 2=ON, 1=OFF
Address phoropter	$\rightarrow$ DIP switch 3=OFF, 2=OFF, 1=OFF
motorised	$\rightarrow$ DIP switch 6 = OFF
manual	$\rightarrow$ DIP switch 6 = ON
automatic light active	$\rightarrow$ DIP switch 5 = OFF automatic light
not active	$\rightarrow$ DIP switch 5 = ON

Phoropter	Phoropter	Phoropter	Phoropter
motorised	motorised	manually	manual
Automatic light control	Automatic lighting not	Automatic light control	Automatic lighting not
active	active	active	active

Table motorised Automatic light control active	Table motorised Automatic light control not active	Table manually Automatic light control active	Manual table Automatic light control not active

## Cleaning

Only clean the painted parts and seat upholstery on the cubeEVO with a damp cloth and mild cleaning agents. Stubborn dirt on painted surfaces can be removed with petroleum ether or white spirit. Repeated use can lead to changes in the colour of the components!

The appliance worktop has a plastic surface. Disinfectants may also be used for cleaning.

For cleaning work on the installed examination devices, please follow the instructions and explanations of the respective device manufacturer or enquire with authorised specialist personnel.

## Maintenance/ inspections

The cubeEVO refraction unit and its optional accessories are maintenance-free and designed for a service life of 6 years if operated correctly. Regular preventive maintenance must be carried out to ensure safe and proper operation and a long service life. The electrical safety of the appliance may deteriorate due to ageing and wear.



Failure to observe the inspection intervals may result in a hazard.

As a minimum, the following safety checks should be carried out on the system by the manufacturer or qualified persons.

- Visual inspection of the device and accessories for damage
- Legibility of the labelling
- Leakage current test
- Protective conductor test
- Function and wear test of the guide rollers
- Function test of the operating elements
- Check that the instructions for use are present
- Documentation of the results

In the event of technical problems or deterioration in handling, please conta your dealer or our service department.

#### Self-executable repair work

Please disconnect the mains plug before carrying out any repairs!

#### Changing 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 indicator lamp does not light up despite the mains switch and operating switch being switched on.



- The mains fuses can be found in the fuse box on the side of the refraction unit. Press up the plastic tab attached to the box (e.g. using a screwdriver or similar). This releases the locking mechanism of the fuse box.
- Pull the fuse box out of the opening by hand.
- Replace the defective fuses with new fuses ( designation: T6.3A H 250V).



Push the fuse box back into the opening provided until the plastic tongue clicks into place.

There are two additional protected fuse holders in the electronics compartment. These fuses may only be replaced by authorised specialist personnel or our service technicians!

## Combinations with examination devices or supplier modules

Examination devices from suppliers may only be used if they comply with the standards for medical devices EN 60601-1. Any use other than that intended by the manufacturer is not permitted. Room light dimming and blinds can be controlled potential-free via a wall connection box. Various lighting systems can be controlled.

For safety reasons, installation may only be carried out by an electrician!

## Environment oft he patient



The area marked above is regarded as the patient environment. In this area, the maximum possible protection is ensured for the patient. Hazardous areas can occur in the patient environment. The attending physician or optician has a special duty of care here, particularly in connection with the installed devices.

Outside of this area, the attending physician or optician must inform the patient not to stay in another area.

## System combination with non- medical devices

To ensure the electrical safety of medical devices and non-medical devices (e.g. printers), safe isolation in accordance with IEC 60601-1 with 2x MOPP is required. The following measures may be required for this.

**1.** Isolating transformer (optional)

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

The isolating transformer used is supplied with mains voltage from the instrument table, fulfils the IEC 60601-1 standard and has protection class I.



Mains input: 1x 230 VAC Output: 4x 230 VAC (max. 2.5 A)

2. Network isolator (optional)

The network isolators prevent a galvanic connection between the 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 fulfil the requirements of DIN EN 60601-1!

Note:

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

## **Technical data**

Feature	Permissible values	
Supply voltage	230V / 50Hz	
Connected load	6,3A	
Reading light	6VA LED	
low voltage power	612VDC/ 53 A	
Device type	B	<u>85+60mm</u> 869±125mm
Protection class		
Working height	850± 125mm	
Total height	1754mm	
Maximum weight Unit	292kg	
Patient chair load capacity	135kg	2001
Load capacity two device table	40kg	0
Room light connection	Potential free	
-	Wagner & Guder Medical GmbH	

Hermstedter Straße 57, 99518 Bad Sulza, Germany

#### Key performance feature of the examination unit

The examination unit does not have any essential performance characteristics as defined by IEC 60601-1:2005 + Cor.:2006 + Cor.:2007 + A1:2012.

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, a key performance feature can be the unconditional maintenance of the lifting position during ophthalmological treatment.

It is therefore essential to re-evaluate the presence of essential performance features when creating medical electrical systems!

#### Warranty and warranty conditions

If defects occur due to material or manufacturing faults within 24 months of purchase, we guarantee to repair the refraction unit as quickly as possible and free of charge or, at our discretion, to exchange it free of charge. For electronic components such as power supply units or motherboards, defects will be repaired free of charge within 12 months.

Requirements for a warranty claim:

- The invoice with purchase date is available
- The device has been used properly or as intended
- Repairs were carried out exclusively by customer service or by persons authorised by us

Warranty services do not extend the warranty periods, nor do they start a new warranty period. Consumables or normal signs of use are not subject to warranty claims.

The General Terms and Conditions of Wagner & Guder Medical GmbH apply

## Technical fault in the system

If a fault occurs, take the system out of operation and use the following fault list to rectify the fault. If this does not rectify the fault, label the device as non-functional and inform the distributor of your complete system.

Malfunction	Possible cause	Remedy	Reference
No function at all	Mains plug not plugged in	Check mains connection between refraction unit and socket outlet	Page 12/ 19
	Power failure	Notify the in-house electrician	-
	Power supply unit defective	Contact the distributor	Page 22/ 50
	Mains input fuse defective	Fuse replacement	Page 12/ 19
Desktop appliances without Function	Desktop devices not switched on	Switch on the desktop device or additional power supply units	GA of the device manufacturer
	Appliance table not In working position	Move appliance table to end position	Page 13
	Limit position switch Defective	Contact the distributor	Page 13
	Cable connection to the examination device disconnected (cable break)	Contact the distributor	Page 14
	Power supply unit defective	Contact the distributor	Page 22
Patient chair without lifting function	See no function	-	-
	Cable break in the control panel	Contact the distributor	Page 20
	Lifting column defective	Contact the distributor	-
	Safety edge actuated or jammed	Check safety edge for function	Page 18

Malfunction	Possible cause	Remedy	Reference
Installed 230V devices without function	See no function	-	-
	Fuse on the circuit board defective	Contact the distributor	-
	Device fuse defective	Change fuse	GA of the device manufacturer
Desktop unit dimming without function	Potentiometer defective	Contact the distributor	Page 14
	Cable break	Contact the distributor	-
	Potable cable disconnected on circuit board	Contact the distributor	Page 23/ 51
Reading lamp without function	Light source or power supply unit defective	Replace bulbs	Page 12
	Reading light output defective	Contact the distributor	Page 23
Safety edge without function	Button defective	Contact the distributor	Page 18
	Bent moulding	Restore the switching contact	Page 18
	Cable break	Contact the distributor	Page 18
	Plug connection on circuit board disconnected	Contact the distributor	Page 23
Table movement in 1st working position not	Pushbutton retaining spring broken	Contact the distributor	Page 13
, possible	Cable blocked in the drag chain	Contact the distributor	-
	Foreign objects in the rail system	Remove foreign objects or contact the distributor	Page 13

Malfunction	Possible cause	Remedy	Reference
Table movement not in 2nd working	Table button jammed or incorrectly adjusted	Contact the distributor	Page 13
position possible	Desktop appliances too heavy	Remove desktop unit	Page 13
Device table does not stop in	Holding magnet defective	Contact the distributor	Page 13
the 1st working position	Switching relay defective	Contact the distributor	Page 24
	Limit position switch defective	Contact the distributor	Page 13
Electromagnetic	See below (Table E- Malfunction)	Increase distance Potential equalisation	Page 44

#### Remedy electromagnetic disturbance

Table according to EN 61000-4-3

The user can reduce electromagnetic interference by observing the recommended minimum distances between portable and mobile RF telecommunications equipment (transmitters) and the device. The distance to be maintained depends on the output power of the respective telecommunications device, see the following table.

HF source Wireless Communication equipment	Transmiss ion frequency (MHz)	Test frequency (MHz)	max. power P (W)	Distance d (m)
Various radio services (TETRA 400)	380-390	385	1,8	0,3
Walkie-talkie (FRS) Rescue service, police, fire brigade Maintenance (GMRS)	430-470	450	2	0,3
LTE Band 13/17	704-707	710/745/ 780	0,2	0,3
GSM 800/900 LTE Band 5 CT1+, CT2, CT3 radio telephone	800-960	810/870/ 930	2	0,3
GSM 1800/1900 DECT (radio telephone) 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 Transponders & readers)	2044-2570	2450	2	0,3
WLAN 802.11a/n	5100-5800	5240/5500/ 5785	2	0,3

The user can take the following measures to eliminate electromagnetic interference

- Increase the distance to the source of interference
- Rotate the instrument table or change the angle of the radiation
- Use instrument table with a different mains connection
- Only use original accessories (e.g. mains cable)
- Carry out potential equalisation

## **Electromagnetic compatibility**

Medical electrical equipment is subject to special precautions regarding EMC and must be installed and commissioned in accordance with the following guidelines. Portable and mobile RF equipment (e.g. mobile phones) can affect medical electrical equipment. The use of third-party accessories can lead to increased emissions or reduced immunity of the device.

The following information only applies in conjunction with the accessories supplied with the appliance.

- Mains connection cable (2.5m)
- Wall connection element with mains connection cable (3m)

#### Guidelines and manufacturer's declaration - Electromagnetic emissions

The refraction unit is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.

Emission measurements	Agreement	Electromagnetic Environment guidelines	
HF emissions according to CISPR 11	Group 1	The refraction unit uses RF energy exclusively for its internal function. Its HF emission is therefore very low and it is unlikely that neighbouring electronic devices will be disturbed.	
HF emissions according to CISPR 11	Class B	The refraction unit is intended for use in all establishments, including domestic establishments and those directly connected to the public low- voltage power supply network, that also supplies buildings used for residential purposes.	
Harmonics according to EN 61000-3-2	Matches		
Voltage fluctuations/ Flicker according to EN 61000-3-3	Matches		

## Recommended safety distances between portable and mobile HF communication devices and the instrument table.

The refraction unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the refraction units as recommended below, according to the maximum output power of the communications equipment.

Rated power of the transmitter	Protective distance according to transmission frequency m			
	150kHz - 80MHz	80MHz - 800MHz	800MHz - 2.7GHz	
W	d=0,35 $\sqrt{P}$	d=0,7 $\sqrt{P}$	d=1,4 $\sqrt{P}$	
0,01	0,04	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 whose nominal power is not given in the above table, the distance can be determined using the equation belonging to the respective column, where P is the nominal power of the transmitter in watts (W)

according to the transmitter manufacturer's specifications.

- Note 1 For the calculation of the recommended safety distance of transmitters in the frequency range from 80 MHz to 2.7 GHz, an additional factor of factor of 10/3 was used to reduce the likelihood of an to reduce the likelihood of an unintentional mobile/portable transmitter the patient area will cause interference. communication device will cause interference.
- Note 2 These guidelines will not apply in all situations. The propagation of electromagnetic waves is influenced by absorption and reflection from buildings, objects and people.

#### Guidelines and manufacturer's declaration - Electromagnetic immunity

The refraction unit is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.

Interference	IEC 60601-	Match level	Electromagnetic environment - Guidelines
immunity tests	Test level		
Line-guided HF disturbance variables to	3 Vrms 150kHz - 80MHz	Yes	Portable and mobile radios are in no less Distance to the refraction unit including the cables as
EN 61000-4-6	6 Vrms 150kHz - 80MHz	Yes	the recommended safety distance which is used according to the Transmission frequency suitable equation is calculated. Recommended safety distance:
	9 28 V/m	Yes	$d=0.35\sqrt{P}$
Dragless HF interference			
fields EN 61000-4-3	10 V/m 80MHz to	10 V/m 80Mhz- 1	d=0.7 $\sqrt{P}$ 80MHz - 800MHz d=1.4 $\sqrt{P}$ 800MHz - 2.7GHz with P as the rated power of the
Electromagnetic HF disturbance variables to ENC 61000-4-3	2.7GHz	Ghz 80%@ 1 kHz AM modulation	transmitter in watts (W) as specified by the transmitter manufacturer and d as the recommended safety distance in metres (m). The field strength of stationary radio transmitters is limited at all frequencies according to a On-site investigation <sup>a</sup> lower than the compliance level. <sup>b</sup> In the neighbourhood of Devices that display the following symbol are
			malfunctions are possib
Note 1For 80MHz and 800MHz, the higher value applies.			
The propagation of electromagnetic waves is affected by the absorptions and			
reflections of buildings and people.			

<sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, it is recommended to investigate the location. If the measured field strength in the location in which the refraction unit is used exceeds the applicable RF compliance level above, the instrument table should be observed to verify normal operation in each location. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the refraction unit.

<sup>b</sup> The field strength should be less than 10 V/m over the frequency range from 150 kHz to 80 MHz.

#### Guidelines and manufacturer's declaration - Electromagnetic immunity

The refraction unit is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.

Interference immunity examinations	IEC 60601- Test level	Agreement Mood Ievel	Electromagnetic Environment guidelines
Discharge of static Electricity (ESD) according to EN 61000-4-2	± 8kV Contact discharge ± 15 kV Air discharge	Yes	Floors should be made of wood or concrete or covered with ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Fast transient electrical Disturbance variable/ bursts according to EN 61000-4-4	± 2kV Mains cables ± 1kV for input and Output lines	Yes	The quality of the Supply voltage should be that of a typical commercial or hospital environment.

Interference immunity examinations	IEC 60601- Test level	Agreement Mood Ievel	Electromagnetic Environment guidelines	
Surge voltages (Surges) according to EN 61000-4-5	± 1kV Manager-Manager ± 2kV Ladder earth	Yes	The quality of the Supply voltage should be that of a typical commercial or hospital environment.	
Voltage dips Short-term interruptions and fluctuations in the Supply voltage according to EN 61000-4-11	0%10ms 0%20ms 70%0 ,5s	Yes	The quality of the supply voltage should be that of a typical commercial or hospital environment. If the user of the refraction unit requires continued function even in the event of interruptions to the power supply, it is recommended that the system be operated from an uninterruptible power supply. power supply or a battery.	
Magnetic field at the Supply frequency (50/60Hz) according to EN 61000-4-8	30A/m	Yes	The mains frequency magnetic fields should correspond to the characteristics at a typical installation site in a commercial or clinical environment.	
Note: UT is the AC mains voltage before the test level is applied.				

## Circuit diagram cubeEVO







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