Instrument tables OT series

Instruction manual

GA2023_05_EN

Edition May 2023

WAGNER & GUDER MEDICAL GMBH

NOTE

Please familiarize yourself with the instructions for use and the safety regulations before using the equipment. Read the instructions carefully and follow the notes concerning the safe handling of the device.

We reserve the right to make changes to the design and scope of delivery within the scope of further technical developments.

Content

Regulations

- The OT series instrument tables have been designed in compliance with the DIN EN 60601-1 and ISO 14971 standards.
  Manufacturing, testing, installation, maintenance and repair are carried out in compliance with German and European requirements.
- It is expressly pointed out not to use the equipment tables as a means of transport.

- **Please observe the assembly instructions for the equipment tables**

- All electrical components connected to the mains voltage comply with VDE
- The accident prevention measures in accordance with the legal regulations must be observed by the user.
- The instrument table is suitable for use in all establishments, including domestic establishments and those directly connected to the public mains supply which also supplies buildings used for domestic purposes. The quality of the supply voltage should be that of a typical commercial or hospital environment. Operation from a multiple socket outlet is expressly not permitted.

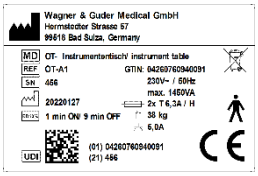
Medical devicelaw

The instrument tables comply with the EU Regulation 2017/745 (MDR).

The ST Series instrument tables are Class I active devices - non-invasive according to the EU Medical Device Regulation 2017/745 (MDR).

Medical device according to MDR:	I
Base UDI-DI.:	426073094TABLE8E
EMC:	electromagnetic Compatibility - Page 22 ff.

Warning and information signs



Device identification

Nameplate - description see page 8

MAINS VOLTAGE

If you do not follow the information given under POWER VOLTAGE, you may be exposed to an electrical hazard.

MAINS VOLTAGE/INPUT

Please disconnect the equipment table from the mains when setting up or carrying out maintenance work.

CAUTION, ATTENTION

Failure to observe the information given in CAUTION may result in moderate injury and/or damage to or alteration of the product.

CE marking

The instrument table complies with the requirements of Regulation (EU) 2017/745 and Medical Devices Act.

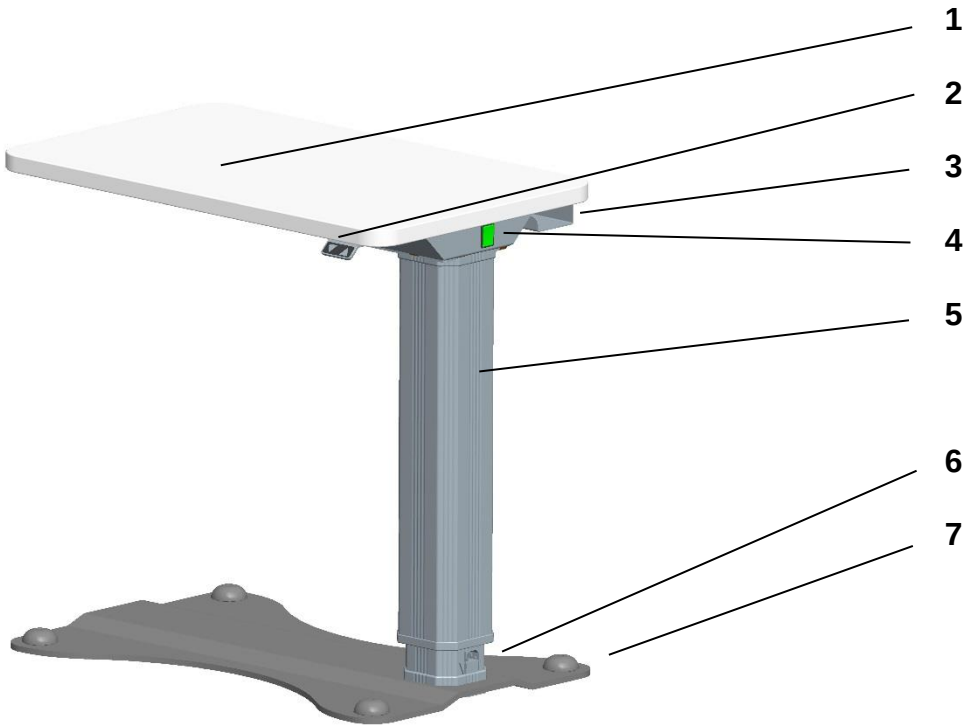
Medical device according to MDR: I
Base UDI-DI: 426073094TABLE8E

In the event of modifications to the product which have not been authorised by the manufacturer, this declaration shall lose its validity.

WEEE markingNote

on proper disposal

General structure



1 Device table top, application part (HPL plastic coating)

2 Control panel **UP/ DOWN**

3 Cable duct

4 Operating switch table devices **I-** ON/ **0-** OFF

5 Hub column with network bushing CAT.5 E

6 **Mains input** with fuse holder 2x T 6.3 A / H - 250V

detachable mains cable 2,5m x 1mm2 and 3pin IEC plug

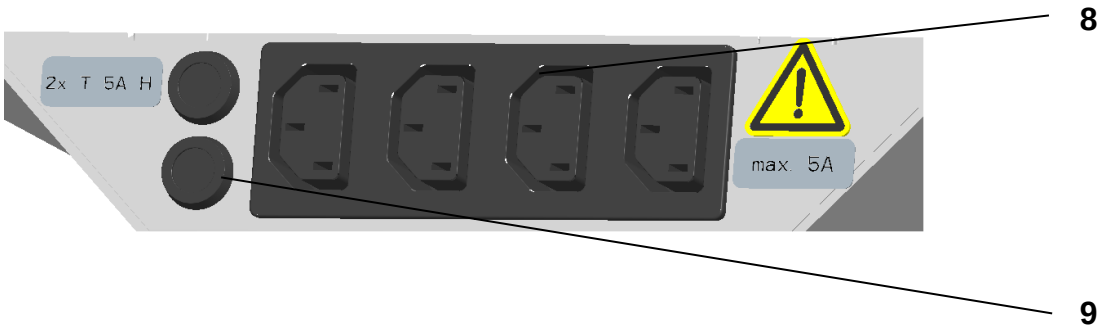
NOTE

In case of error, disconnect here!

7 **Foot plate** with adjustable feet

8 4x cold appliance connection Multiple socket

9 **Device fuse** 2x T 5 A / H



Variants

Asymmetric variant

Order no: OT-A1, OT-A2, OT-A3, OT-A4
Mass: 35 kg

Symmetrical variant

Order no: OT-S1, OT-S2
Mass: 35 kg

Symmetrical variant

Order no: OT-V1, OT-V2
Mass: 37 kg

Asymmetric variant

Order no: OT-R1, OT-R2
Mass: 37 kg

Asymmetrische Variante R2
mit Trenntransformator

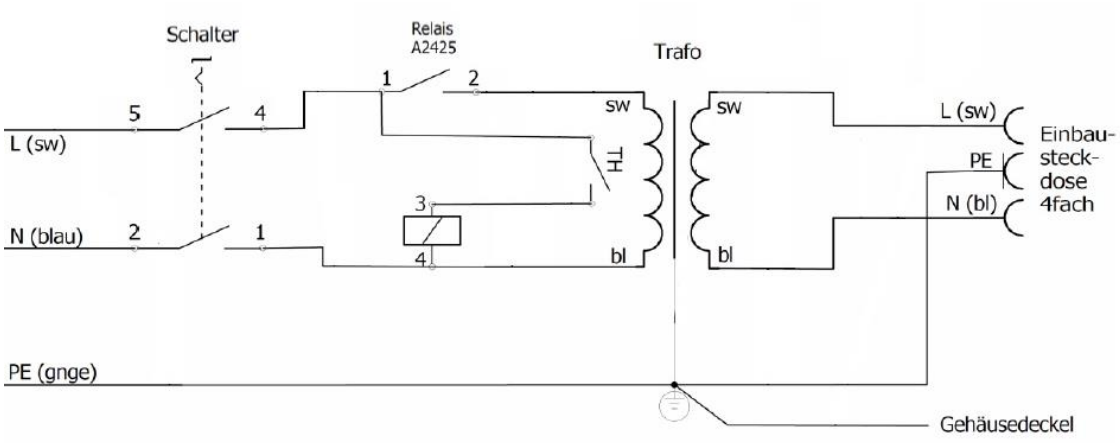
Best.-Nr.: OT-R2-TT
Masse: 45 kg

System combination with non-ME devices

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

1. **Isolating transformer (optional)**

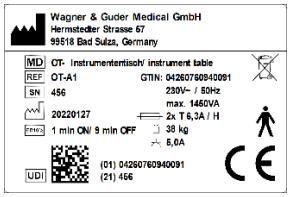
   To ensure the electrical safety of medical devices and non-medical devices (e.g. printers), operation in medical protection areas is provided with an isolating transformer (accessory).
   The isolating
   transformer used is supplied with mains voltage from the instrument table, complies with the IEC 60601-1 standard and has protection class I.



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

Nameplate

Gerätekennzeichnungsschild „Typenschild“



	Manufacturer		
	Date of manufacture	**GTIN**	**Global trade item number**
ED10%	**Opterating cycle** **lifting unit**	UDI	**Unique device identifier**
CE	**EU conformity**		**Device type B**
	Fuse	SN	**Serial number**
MD	**Medical device**	~	**AC**
REF	**Series**		**Disposal note**
	Data Matrix Code according to GS1		**Weigth ot the product**
	Max. power connection		

Intended use

The height-adjustable instrument tables are used to hold ophthalmic devices as well as measuring and testing accessories.
Medical devices do not serve as means of transport!
Any use other than that specified is not permitted.

Reporting obligations of operators and users

Operators and users are obliged to report serious incidents to the manufacturer or distributor immediately and without culpable hesitation. Reportable incidents are malfunctions that affect the characteristics and performance of the product in its entirety. The following table shows the possible effects of the device on the suitability for use and the risk to the patient and/or operator. In countries of the European Union, observe the reporting obligations to the competent authority as well as your national legislation.

Devices and accessories

Ophthalmological examination equipment	60 kg symmetrical (centric load) 40 kg * asymmetrical

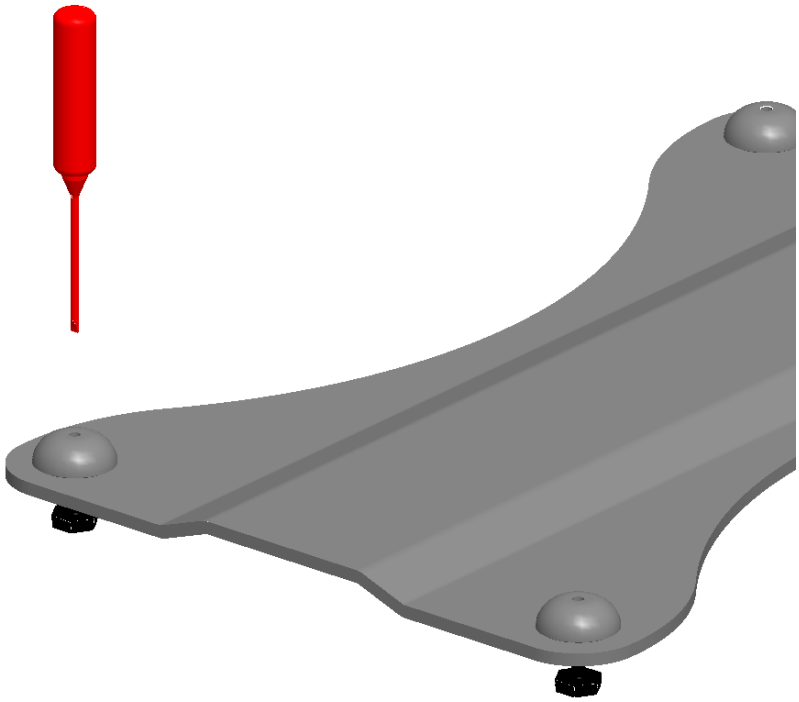
Instructions for installation and use

- **Warning:** To avoid the risk of electric shock, this appliance must only be connected to a supply mains with a protective earth conductor.
- Comply with the statutory accident prevention regulations.
- Compare the information on the type plate and the existing mains voltage
- The mains plug may only be connected to a socket outlet with a protective contact.
- Never pull on the power cord.
- The instrument tables must not be set up and operated in damp rooms. Avoid dripping and splashing water. The instrument tables may only be operated on floors that are typical for indoor areas.
- The instrument tables must not be operated in potentially explosive atmospheres.
- The instrument tables must be positioned in such a way that disconnection from the mains can be easily achieved.

- The instrument tables may only be mounted and started up by persons familiar with the mounting and start-up procedures. Please check any necessary regulations and qualification certificates for your country.
- Before commissioning, the fastening points of the lifting units must be checked and, if necessary, the screws must be tightened and the stability of the table
  must be ensured.
  The manufacturer is not liable for possible damage caused by unauthorized tampering with the unit. In this case, all warranty claims become void.
- Please observe the operating instructions and notes of the device manufacturers during installation and commissioning.
- In case of system problems, always disconnect the mains plug at the mains input **(6)** - page 5.

Instructions for installation site and accident prevention

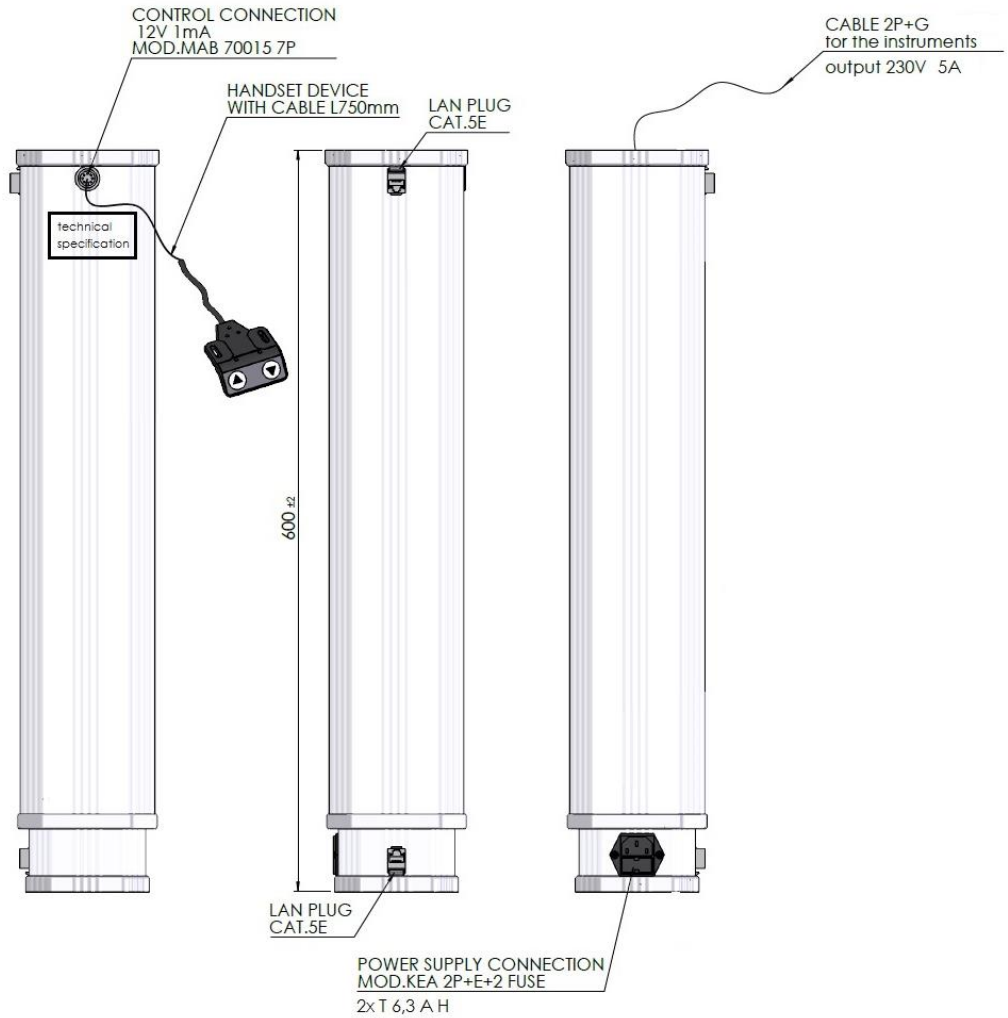
The instrument tables may only be moved and set up on a level, tread-resistant floor. The positioning and fixing at the place of destination is carried out by means of the adjustable feet or fixable fixed castors in the base plate of the instrument table. These must be adjusted and secured as shown in the following figure to ensure optimum stability of the product.
Risks related to positioning and the nature of the installation site can be found in the risk management report and the product FMEA.

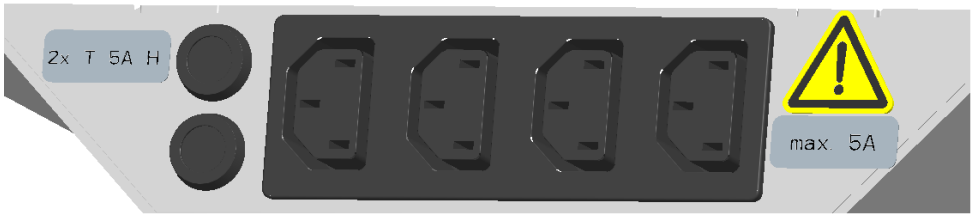


Recommendation

Only use CE-certified products as examination chairs or stools; fixable castors are recommended!

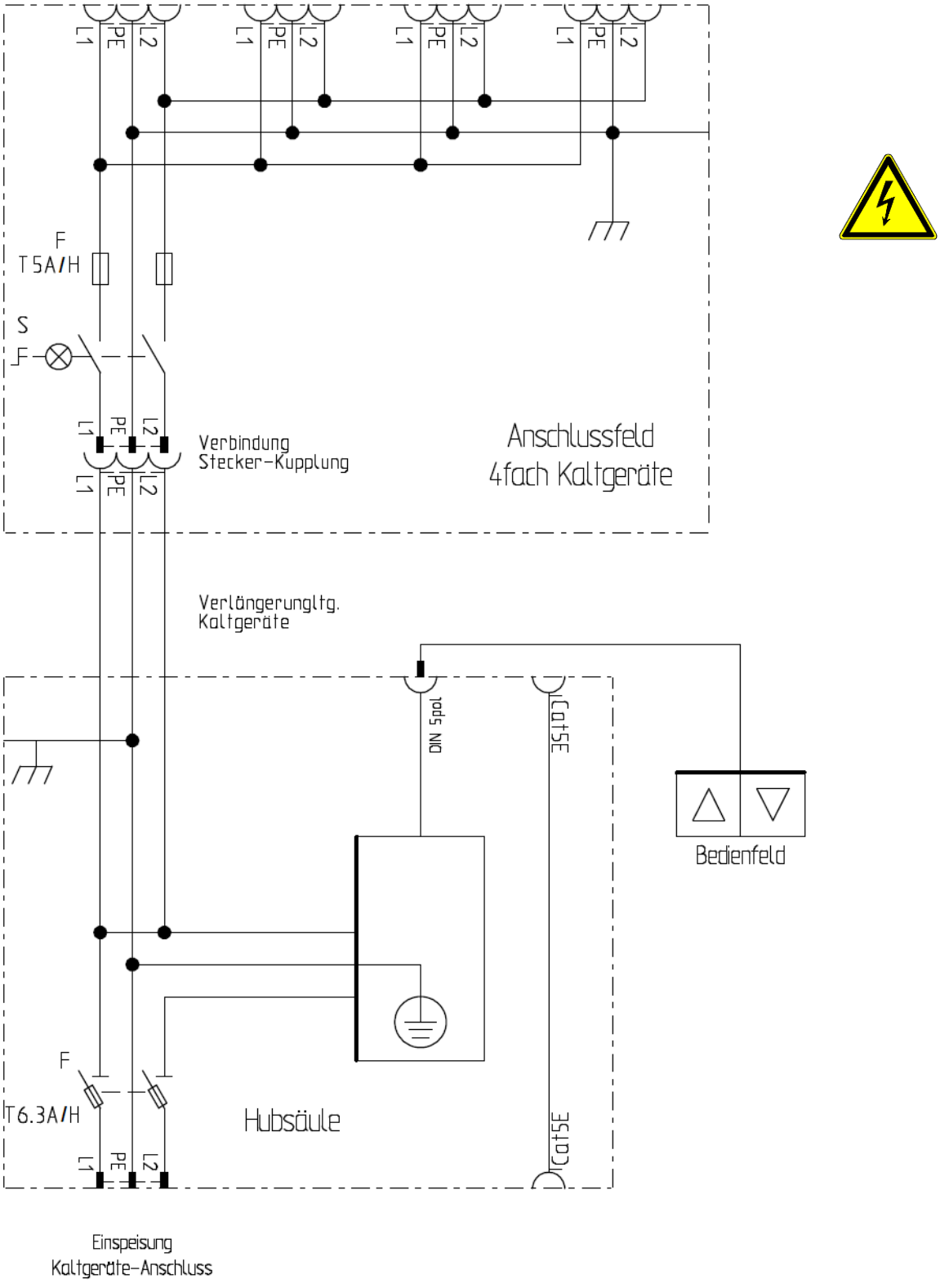
Electrical construction





Additional multiple sockets or extension cables must not be connected to the instrument table.
The multiple sockets on the instrument table may only be used for the intended ophthalmic devices as well as measuring and test accessories, which do not exceed an additional additional load of 5 A on the multiple sockets.

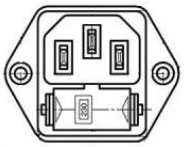
Circuit diagram



Fuse replacement

The system fuses are contained in the mains input socket for the mains cable. A change may only be carried out in voltage-free operation and by instructed or technically suitable personnel. Please use only the specified fuse sizes!

1. **Mains input (6)**



Fuse holder with clamping lugs
Fuse 2x T 6.3 A / H 250 VAC

2. **Device fuse (9)**

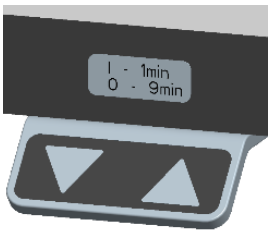
Turn the fuse holder to the
left to open it
and you will reach the
device fuse 2x T 5 A / H 250 VAC.
After changing the fuse again
insert and
close with clockwise rotation

Commissioning and operation

Ensure that the instrument table is stable.
Establish the power supply with the mains connection cable provided for this purpose. The electromotive lifting columns guarantee height adjustment over a very wide range. Adjust the height to the patient's body size with the installed examination devices.

Duty cycle 10%
1 min ON / 9 min OFF

AB



AT

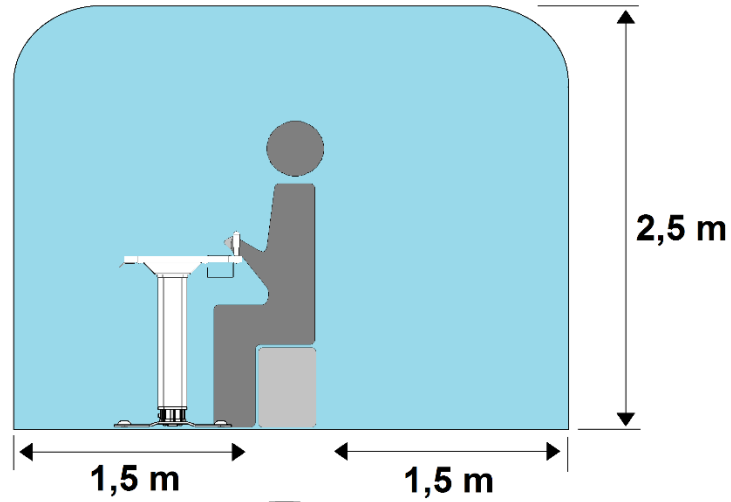
Operating pushbuttons for table-top units

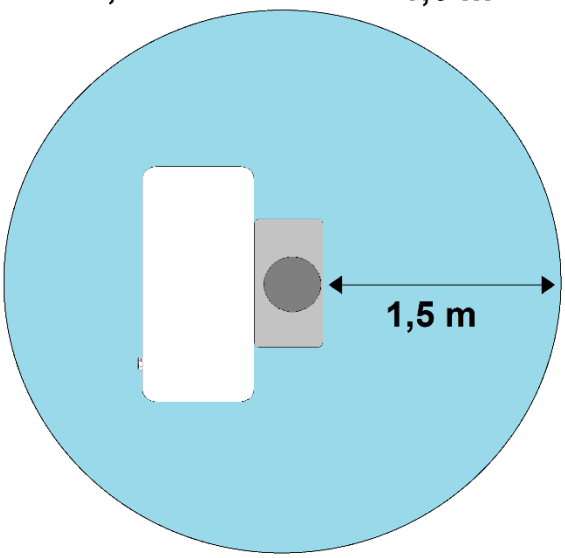
0 - OFF
I - ON

Heads up!

Make sure that there are no objects or body parts in the lifting range of the tabletop. Observe the possible danger of trapping and crushing in the patient environment!
As the operator, please ensure that you do not touch application parts and the patient at the same time!

Patient environment





The patient environment is considered to be the area marked above. In this area, the maximum possible protection is ensured for the patient. Danger points can occur in the patient environment area. The attending physician or optician must exercise particular care here, especially in connection with the installed devices.
Under certain circumstances, a patient may intentionally or unintentionally create an electrically conductive connection in this area.
This must be prevented by suitable protective measures!

Maintenance and care

The instrument tables of the OT series are maintenance-free. The instrument tables are designed for a service life of 10 years.
To ensure safe and proper operation and a long service life on a continuous basis, regular preventive maintenance must be carried out. The electrical safety of the device may deteriorate due to ageing and wear.

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

- Checking for the presence of the instructions for use
- Visual inspection of the device and accessories for damage
- Legibility of the inscription
- Leakage current test
- Protective conductor test
- Function and wear test
- Function test of the control element
- Documentation of the results

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

Attention duty cycle!

The lifting system of the instrument tables is not designed for continuous operation.

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

Maintenance of the instrument tables

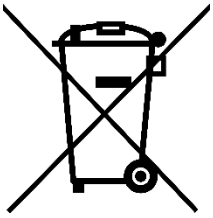
All table tops (application part) have a plastic-coated surface according to EN 14322 are biocompatible according to ISO 10993-1 and correspondingly resistant. Only the outer surfaces of the instrument tables may be cleaned. A non-dripping cloth with a mild cleaning solution (e.g. soap) is recommended for cleaning. The instrument table surface and the handles (optional) may be cleaned with alcohol and rapid disinfection!

Attention!

The use of solvents (ether, acetone), acids or abrasive cleaning agents may cause discoloration or damage.

Disposal

This symbol only applies to EU member states.
To avoid possible negative effects on the environment and possibly on human health, this device must be disposed of (i) in accordance with the EU Directive on Waste Electrical and Electronic Equipment WEEE in EU member states and (ii) in accordance with local regulations for the disposal and recycling of hazardous waste in all other countries.



WEEE-Reg. No. DE 67707987

Essential performance characteristic of the instrument tables

The OT instrument tables do not have an essential performance characteristic as defined in 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, an essential performance characteristic may be the unconditional holding of the stroke position during an ophthalmic procedure.

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

Behaviour in the event of a fault

If a fault occurs that you cannot rectify using the following fault list, mark the device as non-functional and notify the supplier of your overall system.

For their safety

Technical malfunction of the system

Malfunction	Possible cause	Remedy	Reference
No function	Mains plug not plugged in	Check mains connection between system table and socket outlet	-
	Power failure	Notify house electrician	-
	Power input fuse failure	Fuse replacement	Page 13
Table devices without Function	Table devices not switched on	Switch on table-top unit or additional power supply units	GA of the device manufacturer
	Fuse of the tabletop unit defective	Check fuse and replace if necessary	GA of the device manufacturer
	Cable connection between the under-examination device and multiple socket disconnected	Check the cable connection between the under-examination device and the multiple socket outlet	Page 6
	Device fuse defective	Check fuse of multiple socket, replace if necessary	Page 6
Lifting system without function	See no function		
	Operation button UP/DOWN defective	Check plug connection to lifting column	Page 14

Eliminate electromagnetic disturbance

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 observed depends on the output power of the respective telecommunications device, see the following table.

HF source Wireless Communication facilities	Transmit 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 Radio telephone CT1+, CT2,CT3	800-960	810/870/ 930	2	0,3
GSM 1800/1900 DECT (wireless 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

To correct electromagnetic interference, the user can take the following measures

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

Environmental conditions

1. For the operation

Property	Permissible value range
Temperature	+5°C ... +40°C
Rel. humidity	30% ... 75% no condensation
Insert height	up to 2000m a.s.l.

2. For transport and storage

Property	Permissible value range
Temperature	-20°C ... +70°C
Rel. humidity	10% ... 90% no condensation
Air pressure	500hPa ... 1060hPa

Technical data

Property	Permissible values
Rated voltage	230 V AC ±10%
Nominal frequency	50 Hz
Protection class	I
Device type	B
Power consumption	6,3 A
Power consumptionHub	1,8 A
Power output Device sockets	 5 A
Operating mode - ED10%:	1 min ON/ 9 min OFF
Table height min:	650mm
Table height max:	900mm
vHub:	250mm
Hoist speed	10mm/s
Net weight	35 kg - 37 kg
Table load	60 kg symmetrical (centric load) 40 kg *asymmetrical

Wagner & Guder Medical GmbH
Hermstedter Street 57
99518 Bad Sulza, Germany

Electromagnetic compatibility

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

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

- Mains connection cable (2.5m)

Guidelines and manufacturer's declaration - Electromagnetic emission		
The instrument tables are intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.		
Emission measurements	**Consistency**	**Electromagnetic Environment - Guidelines**
HF emissions according to CISPR 11	Group 1	The instrument tables use RF energy exclusively for its internal function. Therefore, its RF emission very low and it is unlikely that neighbouring electronic devices will be disturbed.
HF emissions according to CISPR 11	Class B	The instrument tables are intended for use in all establishments, including living quarters and those directly connected to a public supply network, that also supplies buildings that are used for residential purposes.
Harmonics according to IEC 61000-3-2	Agrees	
Voltage fluctuations/ Flicker according to IEC 61000-3-3	Agrees	

Recommended protective distances between portable and mobile RF communications equipment and the device.

The device is intended for operation 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 minimum distances between portable and mobile RF communications equipment (transmitters) and the equipment as recommended below according to the maximum output power of the communications equipment.

Nominal power of the transmitter W	Protective distance according to transmission frequency m		
	150kHz - 80MHz d=0,35 $\sqrt{P}$	80MHz - 800MHz d=0,7 $\sqrt{P}$	800MHz - 2.7GHz d=1,4 $\sqrt{P}$
0,01	0,04	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 not rated in the above table, the distance can be determined using the equation associated with each column, where P is the transmitter's rated power in watts (W), as specified by the transmitter manufacturer.

Note 1 An additional factor of 10/3 was used to calculate the recommended separation distance of transmitters in the frequency range from 80 MHz to 2.7 GHz to reduce the likelihood that a mobile/portable communication device inadvertently introduced into the patient area would cause interference.

Note 2 These guidelines will not apply in all situations. The propagation of electromagnetic waves is affected by absorption and reflection from buildings, objects and people.

Guidelines and manufacturer's declaration - Electromagnetic immunity			
The instrument tables are intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.			
Immunity tests	**IEC 60601-Test level**	**Sync and corrections by Rafael UPD level**	**Electromagnetic environment - Guidelines**
guided HF disturbance variables to IEC 61000-4-6	3 Vrms 150kHz to 80MHz 6 Vrms 150kHz to 80MHz	3 Vrms 6 Vrms	Portable and mobile radios will be in no less Distance to the examination unit including the lines as the recommended safety distance is used, which is determined according to the Transmit frequency suitable equation is calculated. Recommended protective distance: d=0,35 $\sqrt{P}$
beamed HF disturbance variables to IEC 61000-4-3	3 V/m 80MHz to 2.7GHz 10 V/m 80MHz - 2.7GHz 80%@ 1 kHz AM modulation	3V/m 10 V/m	d=0.7 $\sqrt{P}$ 80MHz - 800MHz d=1.4 $\sqrt{P}$ 800MHz - 2.7GHz with P as the nominal power of the transmitter in watts (W) as specified by the transmitter manufacturer and d as the recommended separation distance in meters (m). The field strength of stationary radio transmitters at all frequencies is in accordance with a On-site examination [a] lower than the compliance level. [b] In the vicinity of devices which bear the following symbol are wearing, there is a possibility of... 
Note 1	For 80MHz and 800MHz, the higher value applies.		
Note 2	These guidelines may not apply in all situations. The propagation of electromagnetic waves is influenced by the absorptions and reflections from buildings, objects and people.		

a	The field strength of stationary transmitters, such as base stations of radiotelephones and land mobile services, amateur stations, AM and FM radio and television transmitters, cannot be predicted theoretically with accuracy. To determine the electromagnetic environment following stationary RF transmitters, a site survey is recommended. If the determined field strength at the instrument table location exceeds the compliance level specified above, the instrument table must be observed for normal operation at each application location. If unusual performance characteristics are observed, it may be necessary to take additional measures, such as reorienting or relocating the instrument table.
b	Over the frequency range from 150 kHz to 80 MHz, the field strength should be less than 3 V/m.

Guidelines and manufacturer's declaration - Electromagnetic immunity			
The instrument tables are intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.			
Immunity-exams	**IEC 60601-Test level**	**Sync and corrected by dr.jackson for Sync and corrections by n17t01 level**	**Electromagnetic Environment - Guidelines**
Discharge of static Electricity (ESD) according to IEC 61000-4-2	± 8 kV Contact discharge ± 15 kV Air Discharge	± 8 kV Contact discharge ± 15 kV Air Discharge	Floors should be made of wood or concrete or finished with ceramic tiles must be provided. If the floor with synthetic material, the relative humidity must be at least 30%.
fast transient electrical Disturbance/ Bursts according to IEC 61000-4-4	± 2 kV Power lines ± 1 kV for input and Output lines	± 2 kV Power lines ± 1 kV for input and Output lines	The quality of the Supply voltage should be that of a typical commercial or hospital environment.

Immunity-exams	IEC 60601-Test level	Sync and corrected by dr.jackson for Sync and corrections by n17t01 level	Electromagnetic Environment - Guidelines
Surge voltages (Surges) according to IEC 61000-4-5	± 1 kV Manager-Leader ± 2 kV Ladder Earth	± 1 kV Manager-Leader ± 2 kV Ladder Earth	The quality of the Supply voltage should be that of a typical commercial or hospital environment.
Voltage dips Short-term interruptions and fluctuations of the Supply voltage according to IEC 61000-4-11	0% $_{UT}$ 10ms 0% $_{UT}$ 20ms 70% $_{UT}$ 0.5s	0% $_{UT}$ 10ms 0% $_{UT}$ 20ms 70% $_{UT}$ 0.5s	The quality of the power supply should be that of a typical commercial or hospital environment. If the user of the instrument tables requires continued operation even when power interruptions occur, it is recommended that the system be powered from an uninterruptible power supply. power supply or a battery.
Magnetic field during Supply frequency (50/60Hz) according to IEC 61000-4-8	30 A/m	30 A/m	The line-frequency magnetic fields should match the characteristics at a typical installation site in a commercial or clinical environment.
Note :UT is the AC line voltage before the test level is applied.			

Ordering data

Spare parts

Description	Order number
Mains cable 2,5m	MC-B1D12500
Device connection cable 1m	MG-D1S11000
Fuse T 6.3 A / H	42G1788
Fuse T 10 A / H	42G1794
Electric pillar 230VAC	TU401551
Electric pillar 115VAC	at request
Control panel System table	DPA-K-06
Handles	GN798
Instruction manual OT instrument tables	WG-OTGA