# Instrument tables OT series

## Instructions for use

**GA2025_06_EN**

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WAGNER & GUDER
MEDICAL GMBH

Please familiarise yourself with the operating instructions and safety regulations before using the appliance. Read the instructions carefully and follow the information regarding the safe use of the appliance.

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

**NOTE**

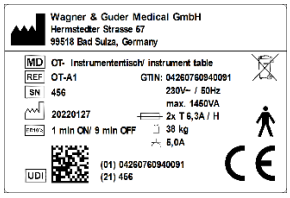
## Contents

## Security measures

## Explanation of the symbols

**"Follow instructions for use" sign**
In particular, read the safety instructions and follow the accompanying documents

**Device identification plate "Type plate"**




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

**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.

**WEEE labelling "Observe disposal regulations"**
Electrical or electronic devices or assemblies must not be disposed of as normal household waste.

# Field of application

## Intended use

The instrument table is used exclusively for holding testing and measuring devices used in ophthalmic optics.

Any use other than that specified is not permitted.

## Intended use application

The instrument table is a versatile device for positioning a seated patient or client in front of ophthalmic examination equipment. At least one electromotive lifting system is 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.

## Classification/ manufacturer's declaration

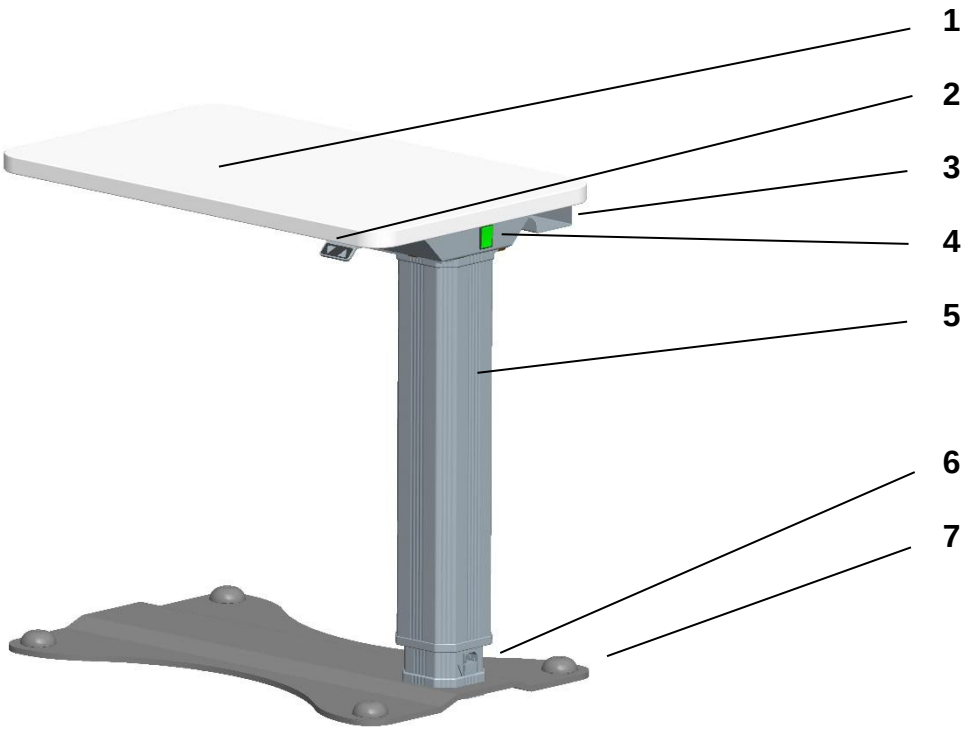
In accordance with EU Regulation 2017/745 (MDR) on medical devices, the instrument table is a Class I active device - non-invasive.

| | |
|---|---|
| Device class according to MDR | I |
| Basis UDI-DI | 426073094TABLE8E |
| EMC | Electromagnetic compatibility Page 23ff. |

## Authorisations and requirements

| Description of the | Labelling |
|---|---|
| Electrical version | DIN EN 60601-1:2022-11<br>Protection class I |
| EMC requirements | The device fulfils the EMC requirements of DIN EN 60601-1-2:2022-01, 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 CE |

## General structure




**1** tabletop, application part (HPL plastic coating)

**2** Control panel **UP/ DOWN**

**3** Cable duct

**4** Operating switch for table-top units **I-** ON/ **0-** OFF

**5** Hub column with network feed-through CAT.5 E

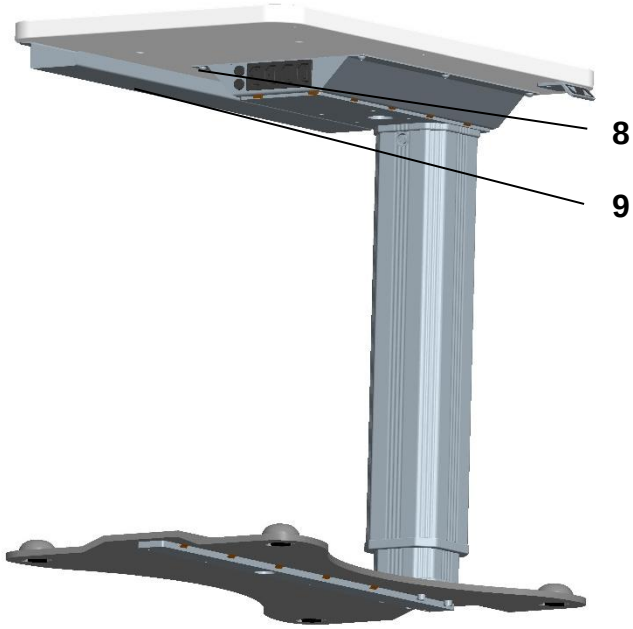
**6** **Mains input** with fuse holder 2x T 6.3 A / H - 250V

Detachable mains cable
2.5m x 1mm$^2$and
3-pin IEC plug

**NOTE**

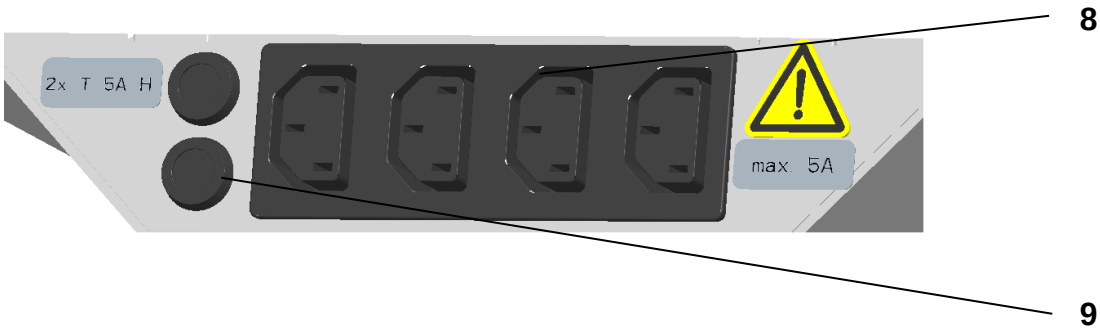
**Disconnect here in the event of a fault!**

**7** Base plate with adjustable feet




**8** 4x IEC connection Multiple socket outlet

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

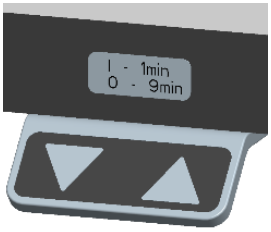


## Commissioning and operation

Ensure that the instrument table is stable.
Connect the power supply using the mains connection cable provided.
The electromotive lifting columns guarantee height adjustment over a very wide range. Adjust the height to the patient's height using the installed examination equipment.

Duty cycle 10%
1 min ON / 9 min OFF

**AB**




**UP**

Operating button for table-top devices


**0** - OFF
**I** - ON

**Caution!**

Ensure that there are no objects or body parts in the lifting range of the table top. Be aware of the possible risk 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!

## Variants

Asymmetrical variant

Order no: OT-A1, OT-A2, OT-A3, OT-A4, OT-A5
Mass: 35 kg

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Symmetrical variant

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

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Symmetrical variant

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

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Asymmetrical variant

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

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Asymmetrical variant R2
with isolating transformer

Order no: OT-R2-TT
Mass: 45 kg

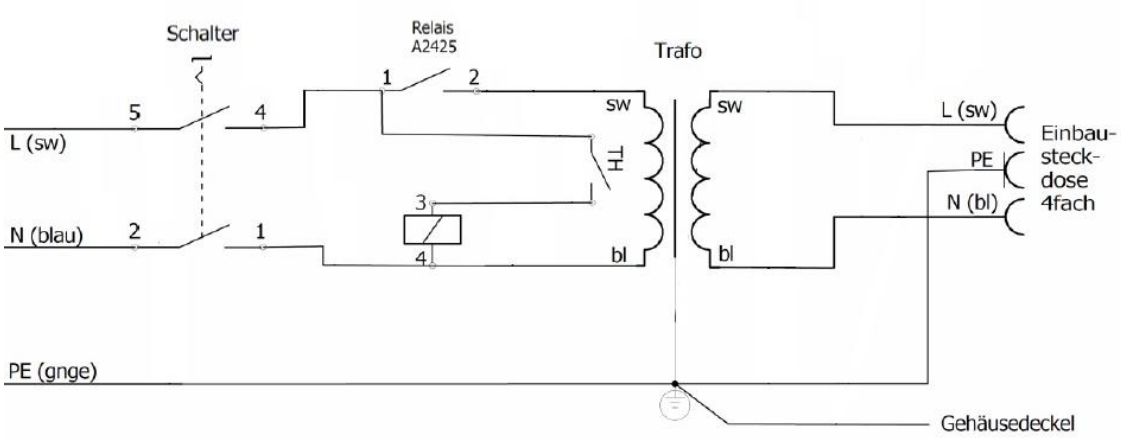
## System combination with non-ME devices

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)

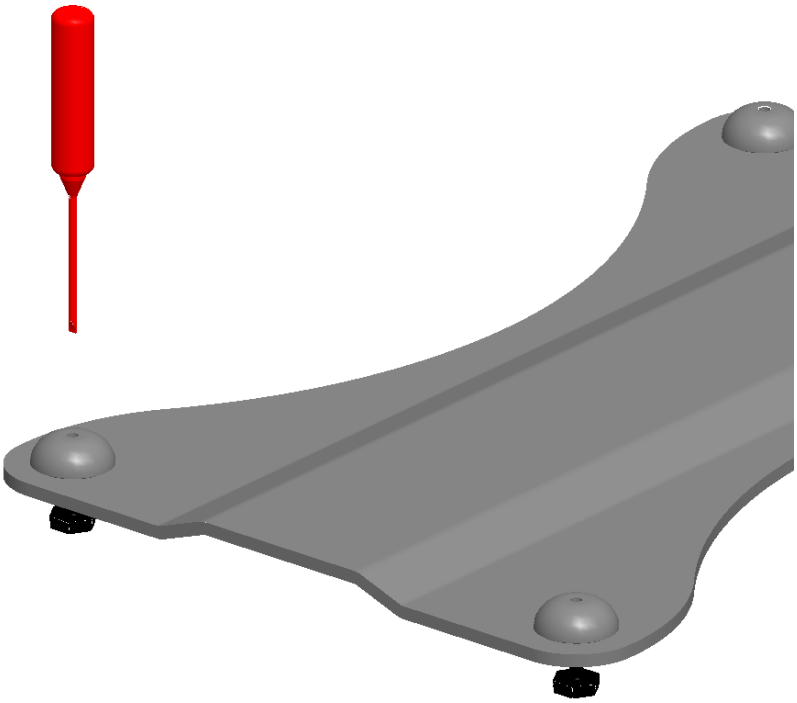
## Instructions for installation and use

- **Warning:** To avoid the risk of electric shock, this appliance may only be connected to a supply network with a protective earth conductor.
- Comply with the statutory accident prevention regulations.
- Compare the information on the rating plate and the existing mains voltage
- The mains plug may only be connected to a socket outlet with an earthing contact.
- Never pull on the mains cable.
- 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 use.
- The instrument tables must not be operated in potentially explosive atmospheres.
- The instrument tables must be set up in such a way that they can be easily disconnected from the power supply.

- The instrument tables may only be installed and commissioned by persons who are familiar with the installation and commissioning. Please check any necessary regulations and qualification certificates in your country.
- Before commissioning, check the attachment points of the lifting units, tighten the screws if necessary and ensure the stability of the table
  Modifications and repairs to the instrument tables 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.
- Please observe the device manufacturer's operating instructions and notes during installation and commissioning
- In the event 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, non-slip floor. They are positioned and fixed in place using 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 illustration to ensure optimum stability of the product.
Risks relating to positioning and the nature of the installation site can be found in the risk management report and the product FMEA.



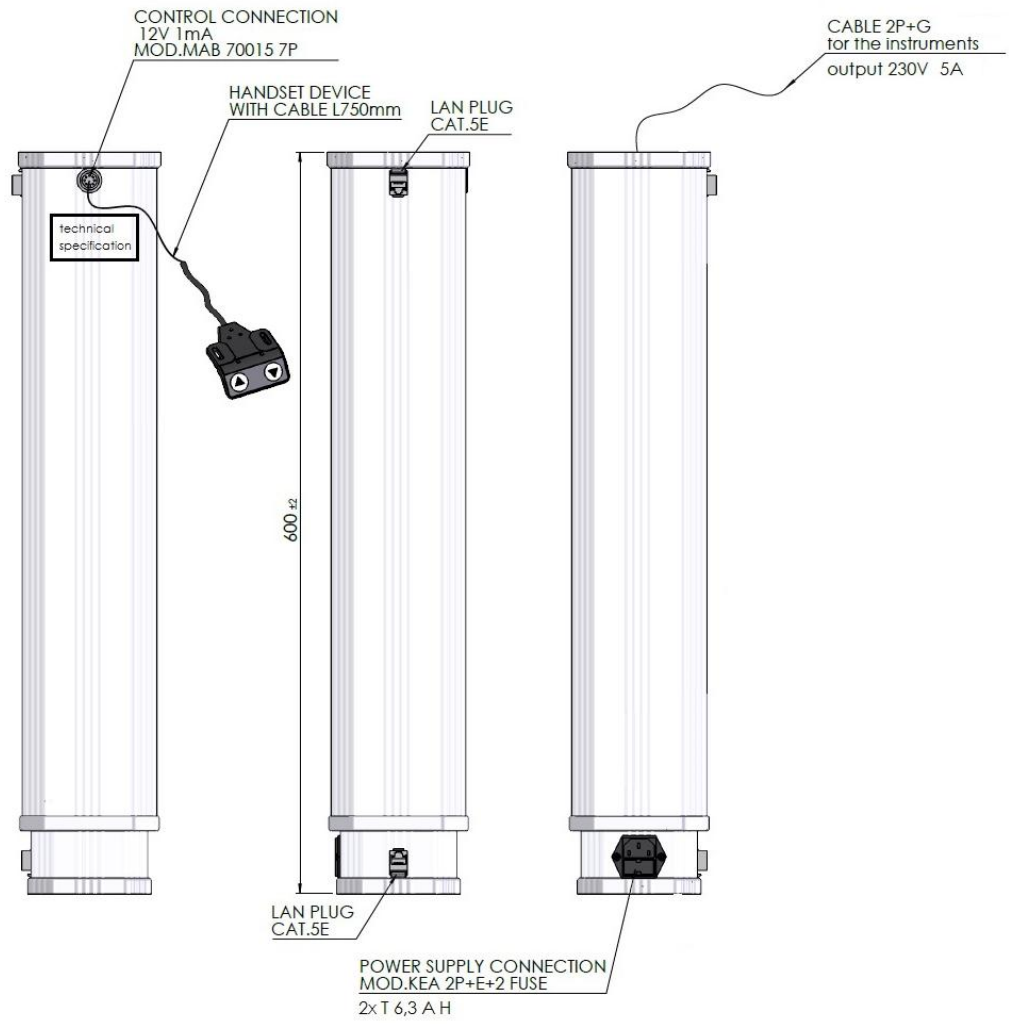
## Recommendation

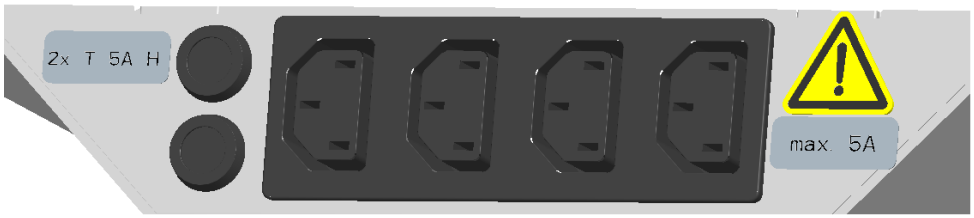
Only use CE-certified products as examination chairs or stools; lockable castors are recommended!

## Devices and accessories

| | |
|---|---|
| Ophthalmological examination equipment | 60 kg symmetrical (centric load)<br>40 kg * asymmetrical |

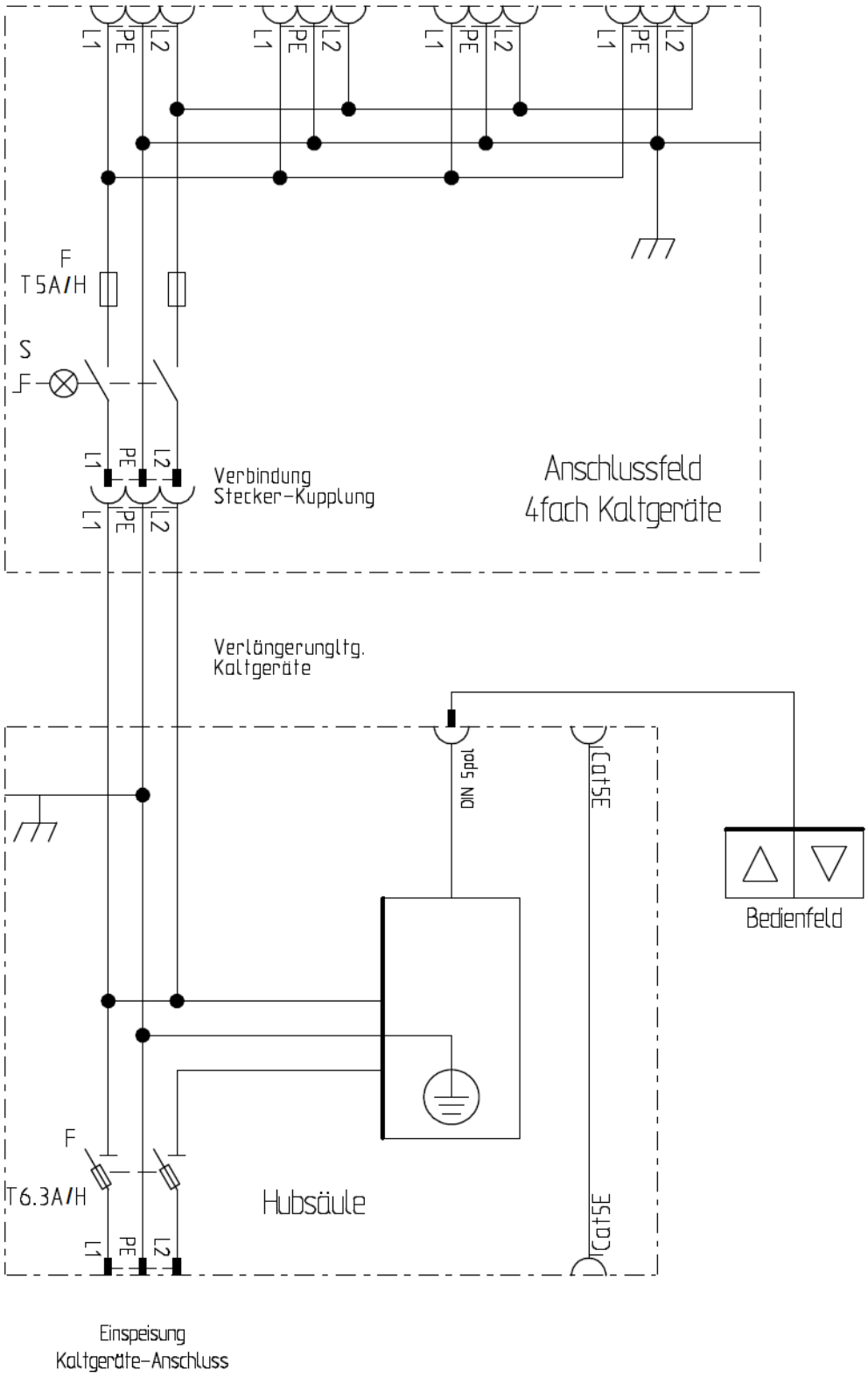
## Electrical Structure




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 ophthalmological devices and measuring and testing accessories, which do not exceed an additional load of 5 A on the multiple sockets.

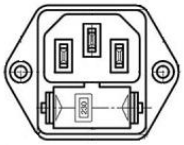
## Circuit diagram




## Fuse replacement

The system fuses are contained in the mains input socket for the mains cable. They may only be changed when the device is de-energised and by trained or qualified personnel. Please only use the specified fuse sizes!

### 1. Mains input (6)



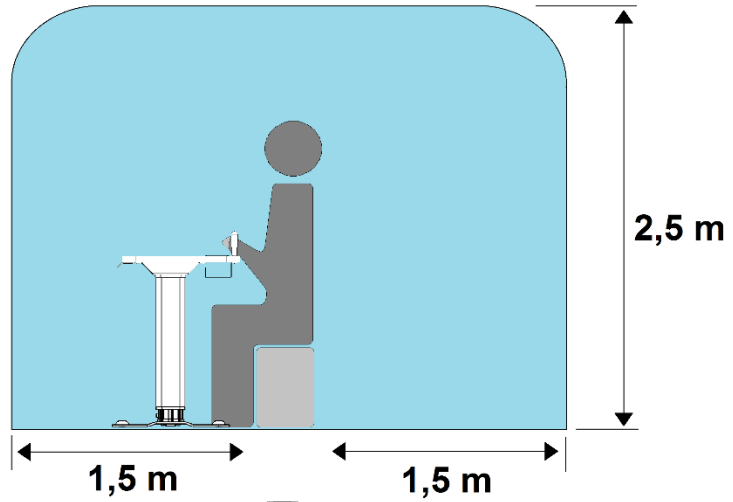
Fuse holder with clamping lugs
Fuse 2x T 6.3 A / H 250 VAC

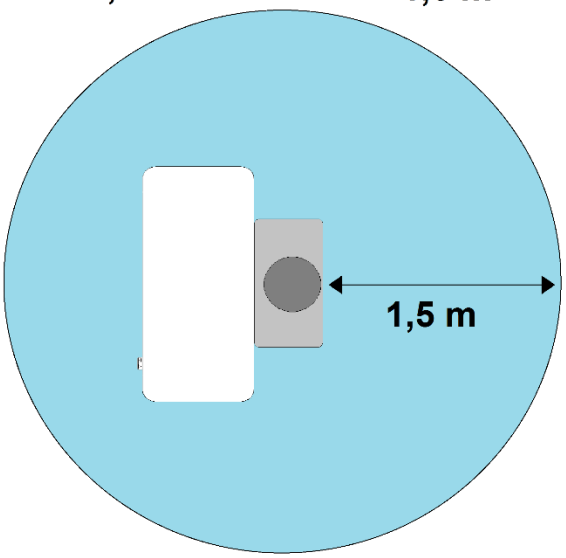
Remove the fuse holder and replace the
replace the defective fuse inserts

### 2. Device fuse (9)

Turn the fuse holder to the left to
to the left to open it and you will reach the
appliance fuse 2x T 5 A / H 250 VAC.
After replacing the fuse
and close by turning clockwise
close

## Patient environment




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.
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 measures

### Maintenance

The instrument tables are designed for an expected service life of 8 years and are maintenance-free, provided that the device is handled as described in these instructions for use. In order to ensure safe and proper operation at all times, all 2 years an inspection by the manufacturer or service partner.

As a minimum, the following safety checks should be carried out on the appliance by the manufacturer or a qualified service partner.

- Check that the instructions for use are present
- Visual inspection of the device and accessories for damage
- Legibility and presence of labelling (p.3)
- Function test of the operating functions (p.7)
- Check electrical safety (see below)
- Documentation of the test results

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

Check electrical safety (IEC 62353 VDE 0751-1)

Please note that the electrical safety of the appliance may deteriorate due to ageing and wear.

- Find out about the regulations applicable in your country regarding the inspection of electrical systems. These must be complied with
- Unless otherwise stipulated by local legislation, the operator is recommended to have a qualified service partner carry out a biennial electrical safety test in accordance with IEC 62353 VDE 0751-1.
- See measuring points on the device (page 17)

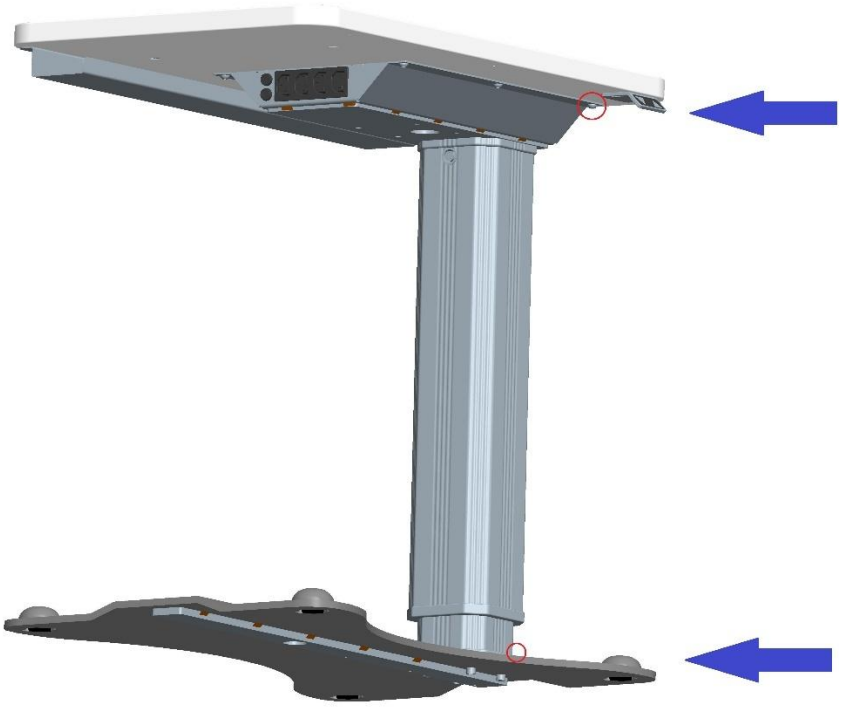
Accessories and additional devices

Additional devices or systems that are operated with the refraction unit and are electrically connected must demonstrably comply with IEC or ISO standards.

Furthermore, all configurations must comply with the normative requirements for medical systems (see IEC60601-1-1 or section 16 of IEC 60601-1, respectively).

Anyone who connects additional devices to medical electrical systems is responsible for ensuring that the system complies with the legal and standardised requirements for systems!

In this case, safety checks must always be carried out and documented for the system network.



*Measuring points on the device*

**Procedure**

1. Carry out a visual inspection of all components and cables to ensure that they are in good condition

2. If there is any doubt about the effectiveness of the insulation (e.g. tripping of the RCD or other protective devices in the doctor's surgery or liquids in the appliance), measure the insulation resistance with a test voltage of 500V.
   → The measured value must not fall below 1MΩ .

3. Measure the protective conductor resistance
   → the measured value must not exceed 0.2Ω .

4. Measure the device leakage current
   → the measured value must not exceed 1mA.

5. Complete the check with a functional test and document the results.

6. If the safety test is not passed, appropriate measures must be taken. Contact your service partner or the manufacturer!

## Care of the appliance

Disconnect the instrument table from the mains and pull out the mains plug! During cleaning work, prevent cleaning agents or other liquids from getting into the lifting unit or onto live parts.

### Cleaning and disinfection

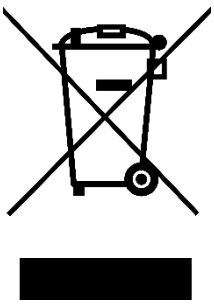
#### Equipment table

The worktop is provided with a plastic surface. It has a plastic-coated surface in accordance with EN 14322, is biocompatible in accordance with ISO 10993-1 and is correspondingly resistant. Disinfectants may also be used for cleaning.
Clean the table surface before each examination with the authorised disinfectants.

Only clean the painted parts 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!

### Waste disposal

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



**WEEE-Reg.-No. DE 67707987**

## Key performance feature of the instrument tables

The instrument tables do 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 reassess the presence of essential performance features 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, label the device as non-functional and contact the provider of your overall system.

**For your safety**

## Technical fault in the system

| Malfunction | Possible cause | Remedy | Reference |
|---|---|---|---|
| No function at all | Mains plug not plugged in | Check mains connection between system table and socket outlet | - |
| | Power failure | Notify the in-house electrician | - |
| | Mains input fuse defective | Fuse replacement | Page 14 |
| Desktop appliances without Function | Desktop devices not switched on | Switch on the desktop device or additional power supply units | GA of the device manufacturer |
| | Fuse of the table-top appliance defective | Check fuse and replace if necessary | GA of the device manufacturer |
| | Cable connection between the examination device and multiple socket outlet disconnected | Check the cable connection between the analyser and the multiple socket outlet | Page 12 |
| | Device fuse<br><br>Defective | Check the fuse of the multiple socket outlet and replace if necessary | Page 12/14 |
| Lifting system without function | See no function | | |
| | Operation button UP/DOWN defective | Check the plug connection to the lifting column | Page 7 |

## Eliminate electromagnetic interference

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<br>Wireless<br>Communication equipment | Transmission frequency (MHz) | Test frequency (MHz) | max. power P (W) | Distance d (m) |
|---|---|---|---|---|
| Various radio services<br>(TETRA 400) | 380-390 | 385 | 1,8 | 0,3 |
| Walkie-talkie (FRS)<br>Rescue service, police, fire brigade<br>Maintenance (GMRS) | 430-470 | 450 | 2 | 0,3 |
| LTE Band 13/17 | 704-707 | 710/745/<br>780 | 0,2 | 0,3 |
| GSM 800/900<br>LTE Band 5<br>CT1+, CT2, CT3 radio telephone | 800-960 | 810/870/<br>930 | 2 | 0,3 |
| GSM 1800/1900<br>DECT (radio telephone)<br>LTE Band 1/3/4/25<br>UMTS | 1700-1990 | 1720/1845/<br>1970 | 2 | 0,3 |
| Bluetooth, WLAN 802.11b/g/n<br>LTE Band 7<br>RFID 2450 (active & passive<br>Transponders & readers) | 2044-2570 | 2450 | 2 | 0,3 |
| WLAN 802.11a/n | 5100-5800 | 5240/5500/<br>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

## Environmental conditions

### 1. For operation

| Feature | Permissible value range |
|---|---|
| Temperature | +5°C ... +40°C |
| Rel. humidity | 30% ... 75% no condensation |
| Insert height | up to 2000m above sea level |

### 2. For transport and storage

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

## Technical data

| Feature | Permissible values |
|---|---|
| Nominal voltage | 230 V AC ±10% |
| Nominal frequency | 50 Hz |
| Protection class | I |
| Device type | B |
| Power consumption | 6,3 A |
| Power consumption Stroke | 1,8 A |
| Power output<br>Appliance sockets | <br>5 A |
| Operating mode - ED10%: | 1 min ON/ 9 min OFF |
| Table height min: | 650mm |
| Table height max: | 900mm |
| $v_{stroke}$: | 250mm |
| Lifting speed | 10mm/s |
| Tare mass | 35 kg - 37 kg |
| Table load | 60 kg symmetrical (centric load)<br>40 kg *asymmetrical |

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## 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)

| Guidelines and manufacturer's declaration - Electromagnetic emissions | | |
|---|---|---|
| The instrument tables are 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 instrument tables use HF energy exclusively for their internal function. Therefore, its HF 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 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 IEC 61000-3-2 | Matches | |
| Voltage fluctuations/ Flicker according to IEC 61000-3-3 | Matches | |

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

The device 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 device as recommended below, according to the maximum output power of the communications equipment.

| Rated 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 whose rated power is not specified in the table above, the distance can be determined using the equation associated with the relevant column, where P is the rated power of the transmitter in watts (W), as specified by the transmitter manufacturer.

Note 1 An additional factor of 10/3 was used to calculate the recommended safety distance from transmitters in the frequency range from 80 MHz to 2.7 GHz in order to reduce the probability that a mobile/portable communication device that a mobile/portable communication device unintentionally brought into the patient area will cause interference.

Note 2 These guidelines will not apply in all situations. The propagation of electromagnetic waves is influenced by absorption and reflections 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 assure that it is used in such an environment. | | | |
| **Interference immunity tests** | **IEC 60601-Test level** | **Matching level** | **Electromagnetic environment - Guidelines** |
| managed HF disturbance variables to IEC 61000-4-6 | 3 Vrms 150kHz to 80MHz<br><br>6 Vrms 150kHz to 80MHz | 3 Vrms<br><br>6 Vrms | Portable and mobile radios are in no less Distance to the test unit including the cables as the recommended safety distance which is used according to the Transmission frequency suitable equation is calculated. Recommended safety distance:<br>$d=0{,}35\sqrt{P}$<br>$d=0.7\sqrt{P}$ 80MHz - 800MHz<br>$d=1.4\sqrt{P}$ 800MHz - 2.7GHz<br>with P as the rated power of the 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 [a] lower than the compliance level. [b] In the neighbourhood of Devices that display the following symbol are possible. possible. |
| blasted HF disturbance variables to IEC 61000-4-3 | 3 V/m 80MHz to 2.7GHz<br><br>10 V/m 80MHz - 2.7GHz 80%@ 1 kHz AM modulation | 3V/m<br><br>10 V/m | |
| Note 1 At 80MHz and 800MHz the higher value applies<br><br>Note 2 These guidelines may not apply in all situations. The propagation of electromagnetic waves is affected by the absorption and reflection and reflections from buildings, objects and people. | | | |

[a] 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 instrument table is used exceeds the 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 instrument table.

[b] The field strength should be less than 3 V/m over the frequency range from 150 kHz to 80 MHz.

| 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 assure that it is used in such an environment. | | | |
| **Interference immunity examinations** | **IEC 60601- Test level** | **Agreement Mood 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 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 IEC 61000-4-4 | ± 2 kV Mains cables ± 1 kV for input and Output lines | ± 2 kV Mains cables ± 1 kV for input and Output lines | 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 level | Electromagnetic Environment guidelines |
|---|---|---|---|
| Surge voltages (Surges) according to IEC 61000-4-5 | ± 1 kV Manager-Manager<br>± 2 kV Ladder earth | ± 1 kV Manager-Manager<br>± 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 in the Supply voltage according to IEC 61000-4-11 | 0% $U_T$ 10ms<br>0% $U_T$ 20ms<br>70% $U_{(T)\ 0.}$5s | 0% $U_T$ 10ms<br>0% $U_T$ 20ms<br>70% $U_{(T)\ 0.}$5s | The quality of the supply voltage should be that of a typical commercial or hospital environment. If the user of the instrument tables requires continued operation 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 IEC 61000-4-8 | 30 A/m | 30 A/m | 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. | | | |

# Order data

### Spare parts

| Description of the | 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 |
| Lifting column 230VAC | TU401551 |
| Lifting column 115VAC | at request |
| System table control panel | DPA-K-06 |
| Handles | GN798 |
| Instructions for use OT instrument tables | WG-OTGA |