

Instruction of use

Plaster saw AS ELEKTRO POWER



REF 48-100-00 - 48-100-01
48-105-00 - 48-105-01
48-110-45 - 48-190-99



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Table of contents

	Page		Page
1. Explanation of symbols	2	5.1.1 Device, serial number	5
2. Warnings	2	5.1.2 Device, switching OFF	5
2.1 Instruction for use	2	5.1.3 Device, switching ON	6
2.2 General	2	5.1.4 Device, speed control	6
2.3 Restrictions	2	5.1.5 Saw blades	6
2.4 Application and safety instructions	2	5.1.5.1 Service life of saw blades	6
2.5 Environmental conditions	3	5.1.6 Saw blades, visual differentiation	7
2.6 EMC (Electromagnetic Compatibility)	3	5.1.7 Saw blades, usage matrix	7
2.7 Additional information	3	5.1.8 Saw blades, assembly	7
3 Product description	3	5.1.8.1 Saw blades, tightening or loosening	7
3.1 Product scope Plaster saw	3	5.1.8.2 Assembly, saw blade only	8
3.2 Electric plaster saw	4	5.1.8.3 Assembly, with depth limiting disc	8
3.3 Saw blades	4	5.2 Decommissioning	8
3.4 Suction for plaster saw	4	5.3 Troubleshooting / malfunction, electrical	8
3.5 Purpose	4	5.4 Troubleshooting / malfunction, mechanical	9
3.5.1 Plaster saw	4	6 B2B warranty	9
3.5.2 Saw blades	4	7 Cleaning / Sterilization	9
3.5.3 Suction for plaster saw	4	7.1 Cleaning / sterilization, device	9
3.6 Indication	4	7.2 Cleaning / sterilization, saw blades	9
3.7 Contraindication	4	8 Maintenance I Repairs	9
3.8 Risks with the product	4	9 Definition, application part type BF	10
3.9 Complications	4	10 Environmental protection, disposal	10
3.9.1 Treatment-related complications	5	11 Serious incidents	10
3.9.2 Complications with the product	5	12 Technical description / data	10
4 Intended use	5	13 Explanation of symbols	11
4.1 Qualification of the user	5		
5 Device, operating instructions	5		
5.1 Device, commissioning	5		

REF 48-100-00 - 48-100-01
48-105-00 - 48-105-01
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1. Explanation of symbols

Please read these operating instructions carefully and follow all instructions exactly. Symbols see last page point 15.

2. Warnings

Patient and user safety is paramount when it comes to the correct use of medical devices. To ensure this, a number of points must be observed:

2.1 Instruction for use



The user must read these operating instructions carefully and follow and apply them exactly. By carefully reading these operating instructions, the user must familiarize himself with the range of functions and the mode of operation. These operating instructions apply only to the unit and do not apply to the suction units contained in part numbers 48-105-00 - 48-105-01. The suction units are not medical devices.

2.2 General



It is forbidden to open the device, as well as to exchange or change the power cord or the power plug. Furthermore, any modifications or changes to the device are prohibited.



Misuse of the power cord, such as to allow the device to be hung, is prohibited. Keep the power cord away from heat, oil, sharp edges or moving parts of the device. Damaged or coiled power cords must be repaired.

The user must satisfy himself of the functional safety and proper condition of the device before each use of the device.

Never touch the device power plug or power socket with wet or damp hands, as there is a risk of electric shock.

The ingress of liquids and solids must be expressly and absolutely avoided. No liquids may be placed or stored on or above the device.

The device is not protected against the effects of major mechanical forces and falling.

The device must be switched off and disconnected from the mains after each use.

2.3 Restrictions



The device is not intended or designed for operation in operating rooms or in rooms with a sterile environment.

The device is not intended for operation in potentially explosive atmospheres. Only connect the mains plug to the power supply outside of potentially explosive atmospheres.

The device may only be operated in conjunction with saw blades from the device manufacturer.

Only use sharp saw blades, observe chapter 5.1.5.1. The number of vibrations at level 5 or 6 should only be used in extreme exceptional cases. Devices that are operated almost continuously or permanently at level 5 or 6 are subject to higher wear and therefore have a shorter service life.

2.4 Application and safety instructions



Wear personal protective equipment such as safety goggles, dust mask and hearing protection. Observe and follow the guidelines of the employers' liability insurance association and equivalent organizations.

Wear (user) and persons in the vicinity (patient and other persons present) at least a dust mask and protective goggles while cutting open a dressing to prevent inhalation of the dusts and wait before removing the personal protective equipment until the dusts have settled (and the work environment has been cleaned, if necessary).



Caution Risk of injury, saw blades have sharp cutting edges. This warning must always be observed during use on the patient and when changing the saw blades.

Before changing the saw blades, be sure to wait a few minutes so that the saw blade can cool down to room temperature.

For noise-sensitive or anxious patients, such as children, adolescents or elderly persons, we recommend that you set the unit to a low vibration level (level 1 or 2).

Persons wearing hearing aids (e.g. hearing aids, hearing amplifiers, etc.) must remove, discard and switch off these devices.

REF 48-100-00 - 48-100-01
48-105-00 - 48-105-01
48-110-45 - 48-190-99



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We recommend that you use the device only on a low vibration level (level 1 or 2).

Persons who have partially or fully implantable hearing systems (implantable hearing aids or similar) must switch them off or mute them if possible. The device may only be operated at a low vibration level (level 1 or 2) for such patients.

2.5 Environmental conditions



The device may only be deployed or used in rooms intended for this purpose (clinics, private practices). The electrical installations and its electrical equipment must be installed at least in accordance with the applicable IEC standards and must comply with the nationally applicable laws, regulations and requirements.

The device, the mains plug and the mains socket must not be used, switched on, operated, plugged in or used in an environment under any circumstances,

- a.) those containing oxygen,
 - b.) in which flammable or ignitable mixtures of anesthetics with air or oxygen or nitrous oxide or other anesthetic gases,
 - c.) in which flammable or ignitable mixtures,
 - d.) in which readily flammable or ignitable or explosive chemicals, such as skin or surface disinfectants,
- regardless of its aggregate state (solid, liquid or gaseous), is enriched, can be enriched, could be enriched or is enriched.

For safety reasons, the device must never, at any time, be stored, temporarily stored or discarded in such an environment. This warning must be strictly observed and applied at all times, without exception. Failure to do so may result in fire and/or explosion.

2.6 EMC (Electromagnetic Compatibility)



Medical electrical equipment is subject to special precautions regarding electromagnetic compatibility and must therefore be installed and commissioned in accordance with the EMC instructions contained in the accompanying documents.

Portable and mobile RF communications equipment can affect medical electrical equipment.

The use of other mains cables and / or mains cable lengths may result in increased emission or reduced immunity of the device.

The device must not be placed directly next to or on top of other devices. If operation of the device close to or on other devices is required, the device must be observed in order to be able to monitor its intended use / operation, in this arrangement used.

2.7 Additional information



The following additional information must be observed and complied with for the device: MPBetriebV

3 Product description

3.1 Product scope plaster saw

1 pcs.	Plaster saw AS ELEKTRO POWER	
1 pcs	Saw blade Ø 50 mm	- Item no: 48-110-50
1 pcs	Saw blade Ø 65 mm	- Item no: 48-110-65
1 pair	Disposable key 11 mm	- Item no: 48-110-50

Depending on the scope of the order, the basic equipment may vary.



Please check the consignment for damage and completeness immediately upon receipt. Later complaints can not be considered.

3.2 Electric plaster saw

The device is an oscillating saw, i.e. the saw blade does not rotate a full 360 degrees, as for example with a circular saw, but it oscillates a few degrees clockwise and then back again. This ensures, among other things, that the sawdust is not distributed throughout the room or the entire environment.

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3.3 Saw blades item no: 48-110-45 - 48-180-20

The medical device (saw blade) usually consists of a circular or semicircular geometry in different diameters and blade widths. Depending on the design, the saw blades are equipped with sharp teeth at a specific angle. The teeth serve as cutting teeth and ensure the appropriate removal of the materials to be sawn (gypsum material). The saw blades can be fixed on the plaster saws by a mechanical fastening by means of a screw. The saw blades are reusable medical devices, see point 7.2.

3.4 Suction plaster saw

This product (not a medical device) is a suction system (electrical) which ensures the removal of plaster material / plaster chips by means of a vacuum suction process with appropriate power. The product thus serves the user as an aid in the separation of plaster bandages.

3.5 Purpose

The term „purpose“ is to be equated with the term „intended use“

3.5.1 Plaster saw

The device is used exclusively for separating natural plaster dressings and synthetic hard dressings.

3.5.2 Saw blades

The saw blades are designed exclusively for cutting plaster dressings in order to be able to remove them.

3.5.3 Suction for plaster saw

Removal of plaster material.

3.6 Indication

Below are examples describing the use of oscillating plaster saws with accessories:

- Removal of a cast for re-evaluation
- Removal of a cast or if the history suggests an underlying foreign body
- Removal of a cast to rule out an underlying infection associated with sepsis
- Removal of a cast for air travel (often required by airlines before boarding)
- Removal of a cast for suspected compartment syndrome
- Removal or trimming of a cast that has been incorrectly placed

3.7 Contraindication



The device must not be used on patients who have, possess or complain of skin irritations and/or skin injuries. The device must also not be used on patients with burns or chemical burns.

The device is contraindicated for all applications other than the technique specified in the intended use.

3.8 Risks with the product



Cutting injuries due to user error when touching the skin.

Risk of burns due to blunt saw blades.

3.9 Complications

3.9.1 Treatment-related complications



- Too long wearing time (demineralization, reduced blood circulation).
- Atrophy of muscles, tendons and the capsular apparatus.
- Irreversible movement restrictions.
- Thrombosis (especially in the case of immobilization of the lower extremity - thrombosis prophylaxis).
- Pressure sores with skin necrosis (especially in prominent places, such as wrist, head of fibula, elbow, ...)
- Constrictions
- Compartment syndrome
- Malpositions.

REF 48-100-00 - 48-100-01
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3.9.2 Complications with the product



- Nerve damage.
- Injury during dressing removal.
- Skin irritation.

4 Intended use



Carry out cutting tests! For this purpose, apply a bandage to a log with a diameter of approx. 7 to 10 cm, properly applied according to the bandage manufacturer's instructions. Practice ripping until you cannot see any cut marks from the saw blade on the log.

The effectiveness of a safety strip during plaster treatment protects the patient from contact with the saw blade during plaster separation. Only plaster casts with safety strips should be applied.

4.1 Qualification of the user



The unit may only be used by medically qualified personnel (specialists, doctors and technical staff) with sufficient experience in the respective field of application „plaster treatment“.

5 Device, operating instructions

5.1 Device, commissioning

Make sure that the device is switched off as shown in Figure 2. Then connect the mains plug to the mains socket.

5.1.1 Device, serial number

The serial number (SN) of the device can be found at the position as shown in Figure 1.



Figure 1

5.1.2 Device, switching OFF

When the digit „0“ (zero) is visible, as shown in Figure 2, the device is in OFF state (the device is switched off).



Figure 2

When the unit is ON, pressing the switch rocker as shown in Figure 3 will release the lock and the unit will turn OFF (the unit is OFF). Device, switching ON



Figure 3

REF 48-100-00 - 48-100-01
48-105-00 - 48-105-01
48-110-45 - 48-190-99



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5.1.3 Device, switching ON

When the digit „I“ (one) is visible, as shown in Figure 4, the device is in the ON state (the device is switched on). The device is switched on by pushing the switch rocker forwards. The rocker switch must engage perceptibly.

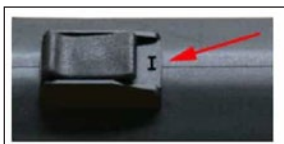


Figure 4

5.1.4 Device, speed control

With the help of the speed control, the optimum number of oscillations of the saw blades can be set in relation to the saw blade diameter, saw blade coating and dressing material. The adjustment of the number of oscillations can be made continuously by turning the control wheel, as shown in Figure 5.



Figure 5

Level	Vibration rate
1	3500 / min
2	7000 / min
3	12000 / min
4	17000 / min
5	21000 / min
6	24000 / min

5.1.5 Saw blades

5.1.5.1 Saw blades life



Due to the oscillating movement of the saw blade, the cutting edges of the saw blade only ever wear in an approx. 90 degree range. Due to this circumstance, it is possible that you can remove the saw blade and put it back on rotated by 90 degrees. Now you can continue working with a sharp saw blade area. You can repeat this process until all four 90 degree saw blade areas are worn out. Failure to do so may result in irreparable damage to the unit and endanger patients.

Approximately 3 to 5 dressings can be cut per 90 degree segment range, after which the saw blade must be set up rotated by 90 degrees or replaced.

Figure 6 shows a saw blade with sharp saw teeth.

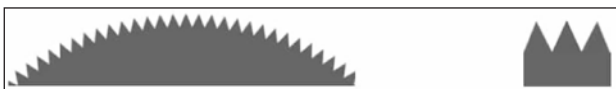


Figure 6

Figure 7 shows a saw blade with saw teeth that are at the end of their service life (approx. 35% wear at the maximum position). The saw blade must be replaced or set up rotated by 90 degrees.



Figure 7

5.1.6 Saw blades, optical differentiation

a.) Saw blades with a shiny metallic surface are intended exclusively for ripping natural plaster dressings.

Item numbers: 48-110-45 - 48-110-65 / 48-130-65 / 48-150-65 / 48-170-08 - 48-170-20
Recommended vibration level: Level 2 to 4.

b.) Saw blades with a matt light gray surface are intended for ripping natural plaster dressings and synthetic hard dressings.

Item numbers: 48-120-45 - 48-120-65 / 48-134-65 / 48-160-65 / 48-180-08 - 48-180-20
Recommended vibration level: Level 3 to 4.

REF 48-100-00 - 48-100-01
48-105-00 - 48-105-01
48-110-45 - 48-190-99



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5.1.7 Saw blades, use matrix

NGV	SHV	Artikel Nr.			
+	-	48-110-50	NGV	=	Natural plaster dressing
+++	++	48-120-50	SHV	=	Synthetic hard dressing
+	-	48-110-65	-	=	Not usable
+++	++	48-120-65	+	=	Good usability
+	-	48-130-65	++	=	Very good usability
+++	++	48-140-65	+++	=	Best usability
+	-	48-150-65			
+++	++	48-160-65			
+	-	48-170-08			
+++	++	48-180-08			
+	-	48-170-20			
+++	++	48-180-20			
+	-	48-110-45			
+++	++	48-120-45			

5.1.8 Saw blades, structure

5.1.8.1 Saw blades, tighten or loosen

Figure 8 shows how to mount the saw blade properly to avoid damage to mechanical parts.



Please use only the supplied wrenches (Art. No. 48-110-01) to tighten or loosen the saw blade.

Never use other tools such as pliers or a vice to tighten or loosen the saw blade, as this will destroy mechanical parts.

Tightening torque of the screw:

Minimum tightening torque	=	10 Nm
Maximum tightening torque	=	14 Nm

The specifications refer to smooth, clean and grease-free / oil-free surfaces. If the surfaces do not correspond to the specifications, this will result in undefinable tightening ratios.

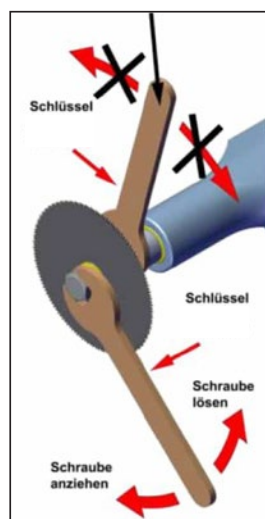


Figure 8

5.1.8.2 Structure, saw blade only

Figure 9 and Figure 10 show the correct structure of the saw blade.

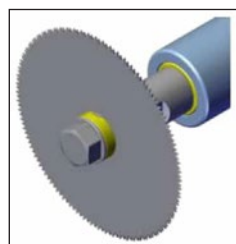


Figure 9

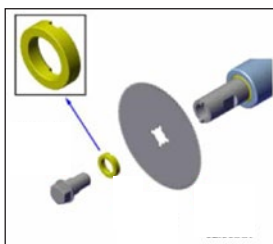


Figure 10

REF 48-100-00 - 48-100-01
48-105-00 - 48-105-01
48-110-45 - 48-190-99



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5.1.8.3 Structure, with depth limiting disc

Figure 11, Figure 12 and Figure 13 show the correct setup of the saw blade when using the eccentric depth limiting disc.

Use the optionally available eccentric depth limiting disk (can only be used in conjunction with saw blades Ø 65 mm). With the aid of this depth limiting disk, constant cutting depths of 4 to 11 mm can be performed, shown in Figure 11. This allows the cutting depth to be adjusted very well and prevents injury to the patient if the depth limiting disk is used correctly.

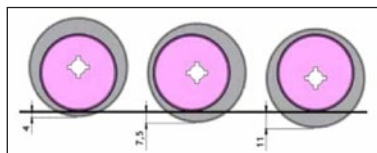


Figure 11

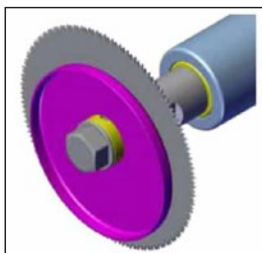


Figure 12

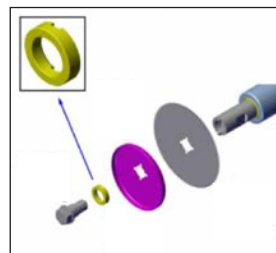


Figure 13



The eccentric depth limiting disc can only be used in conjunction with saw blades that have a diameter of 65 mm.

5.2 Decommissioning

Make sure that the device is switched off as shown in Figure 2. Then hold the power plug and carefully pull the power plug out of the power socket.



Never pull on the power cord to remove the power plug from the power socket. Only the mains plug may be held without exception.



Never touch the device power plug or power socket with wet or damp hands, as there is a risk of electric shock.

5.3 Troubleshooting / malfunction, electrical

1. The unit goes off during use for no apparent reason: Since the unit has temperature monitoring of the motor winding, the temperature limit may be exceeded under certain circumstances, such as by keeping the ventilation slot closed. Remedy: Carry out the instructions as under point 5.2 „Decommissioning“ and wait 10 minutes until the device has cooled down and can be put back into operation.
2. The device cannot be started up again as described under „I.“ Remedy: It could be that the device fuse is defective. The device must be repaired.
3. The device runs out of round: If the device has already been in operation for more than one hundred hours, this behavior indicates worn carbon brushes. Remedy: The carbon brushes must be replaced, the device must be repaired by the manufacturer.
4. The device no longer allows speed control or only rotates at maximum speed. Remedy: Carry out the instructions as described under point 5.2 „Decommissioning“. This error indicates a defect in the control electronics. The device must no longer be used and must be repaired by the manufacturer.
5. The device cannot be started up after a power failure. The device is equipped with undervoltage protection, i.e. the device will not start up by itself after the correct voltage supply has been restored. Remedy: Switch off the device at the ON-OFF switch as described. Remove the mains plug from the mains socket. **CAUTION Observe the risk of electric shock.** Wait approx. 5 minutes, then you can start up the device again as described.

5.4 Troubleshooting / malfunction, mechanical

1. The device suddenly makes unknown and loud noises. Remedy: Immediately carry out the instructions as described under point 5.2 „Decommissioning“. There is a mechanical defect. The device may no longer be used and must be repaired by the manufacturer.
2. The unit loses oil drops in the transition area from the shaft to the neck section (handle section). Remedy: Remove the oil drops with an absorbent disposable cloth. This behavior does not constitute a defect. In the case of new devices and/or long periods of individual use, any excess oil becomes thinner due to the heat generated at the lubrication point and may leak out. This process will disappear after a short time, so that no more oil will escape at the lubrication point.
3. The device loses oil or grease in the transition area between the neck section (handle section) and the motor. Remedy: Remove the oil or grease with an absorbent disposable cloth. This behavior does not constitute a defect. In the case of new devices and/or long periods of use, any excess oil or grease will become thinner due to the heat generated at the lubrication points and may leak out. This process will disappear after a short time, so that no more oil or grease will escape at the transition points.

REF 48-100-00 - 48-100-01
48-105-00 - 48-105-01
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6 B2B warranty

We grant a B2B warranty of one year from the date of purchase (proof by invoice required) for demonstrably defective parts or defective workmanship. Wear parts such as carbon brushes, ball bearings, saw blades, etc. are excluded. Defective mains cables or mains plugs, broken cables, loose contacts and the resulting defects in other components are also excluded. Transport and packaging costs as well as shipping risk cannot be assumed. Further claims are excluded.

Non-compliance with the instructions for use releases us from any liability for user, patient, environmental and operational safety. Furthermore, any warranty expires during the B2B warranty period.

Damage / losses / consequential damage resulting from incorrect operation or non-observance of these operating instructions are not covered by the warranty or guarantee claims.

7 Cleaning / Sterilization

7.1 Cleaning / Sterilization, Device



If necessary, the outer surfaces of the device must be cleaned with the surface disinfectant „schülke mikrocid® universal wipes premium maxi“ by means of wipe disinfection.

Mechanical cleaning / disinfection / sterilization is prohibited.

Before carrying out any cleaning work, disconnect the device from the mains (pull the mains plug out of the mains socket).

7.2 Cleaning / Sterilization, Saw Blades



If necessary, clean the saw blades with the disinfectant and cleaning agent „Schülke gigasept® instru AF“ by means of wipe disinfection.

Mechanical cleaning / disinfection / sterilization is prohibited.

8 Maintenance / Repair / Overhaul

All maintenance / repairs / overhauls may only be carried out by the manufacturer.



A return form and proof of decontamination is required to return the device.

9 Definition, application part type BF

The saw blades are defined as BF type applied parts, see Figure 14.

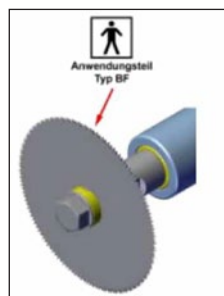


Figure 14

10 Environmental protection, disposal

The device must be disposed of properly in accordance with the European WEEE Directive 2012/19/EU. The device must not be disposed of with household waste. The saw blades should be disposed of adequately in accordance with nationally applicable regulations and laws. Protect against cutting injuries!

REF 48-100-00 - 48-100-01
48-105-00 - 48-105-01
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11 Serious incidents

Any serious incident that occurs in relation to the medical device must be reported to the manufacturer and the competent authority in the Member State where the user and / or the patient is located.

12 Technical description / data

Model	Plaster saw AS ELEKTRO POWER	
Part number	48-100-00 / 48-105-00	48-100-01 / 48-105-01
Mains voltage	230 V, AC	120 V, AC
Mains frequency	50 Hz	60 Hz
Mains cable length	approx. 5 meter (unshielded)	approx. 3 meter (unshielded)
Mains cable cross-section	2 x 0,75 mm ²	2 x 1,31 mm ²
Mains plug	Euro plug, 2-pole	US plug, NEMA-1 (Typ A), 2-pole
Primary fuse	T 10 A / 250 V	T 10 A / 250 V
Oscillations, vibrations	Typically 1.3 to 6.0 grms, under unfavorable conditions up to 12.5 grms (m / s ²). Dependent on the set vibration number, the saw blade shape, the saw blade condition (sharp / blunt) and the applied cutting force.	
Audible sound energy	approx. 65 - 85 dB (A) ± 5 dB (A) (stage 1 to 3), depending on the set vibration, under unfavorable operating conditions approx. 95 dB (A) ± 5 dB (A) (stage 4 to 6).	
Power consumption	500 W (Watt)	
Vibration	3500 to 24000 per minute, continuously variable	
Vibration angle	6°	
Protection against electric shock	Protection class II	
Medical application part	Typ BF	
Protection against harmful ingress of water	IP 20	
Sterilization device / Saw blades	Not allowed	
Suitability for use in oxygen-enriched environment	Not allowed	
Operating mode	Continuous operation	
Ambient conditions during operation	Temperature in °C + 5 to + 30 / °F +41 to +86 Relative humidity in % 10 to 70, non-condensing Air pressure in mbar 600 to 1040	
Ambient conditions during transport or storage	Temperature in °C + 5 to + 50 / °F +41 to +122 Relative humidity in % 10 to 65, non-condensing Air pressure in mbar 600 to 1040	
Applied standards, conformity to standards	CISPR 11:2015 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013, IEC 61000-3-2:2014, IEC 61000-3-3:2013, IEC 61000-3-3:2013/AMD1:2017, IEC 61000-4-28:1999, IEC 61000-4-28:1999/AMD1:2001, IEC 61000-4-28:1999/AMD2:2009 EU Group Differences, EU Special National Conditions, EU A-Deviations Canada (CA) and United States of America (US)	
Dimensions	approx. 58 x 58 x 310 mm	
Weight with cable / without cable	approx. 1,5 kg / approx. 1,25 kg	

REF 48-100-00 - 48-100-01
48-105-00 - 48-105-01
48-110-45 - 48-190-99



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13 Explanation of symbols

Symbol	Explanation
	Manufacturer
	Production date
REF	Order number
LOT	Batch number
SN	Serial number

Symbol	Explanation
	Observe user manual
	ATTENTION
	Non-Sterile
	Keep away from sunlight
	Protect from moisture

Symbol	Explanation
GS1	GS1 Germany
MD	Medical device
QTY	Quantity
UDI	Unique Device Identification
	Risk of electric shock

Symbol	Erklärung
	CE Marking

AS MEDIZINTECHNIK GMBH DOES NOT ACCEPT RESPONSIBILITY IF THIS CUSTOMER INFORMATION HAS BEEN VIOLATED PROVABLY.