INSTRUCTIONS FOR USE

30.200.20 230 Volt version
30.200.10 120 Volt version

EN

Plaster saw "Electronic Power"

TABLE OF CONTENTS

1. Explanation of symbols

Please read these instructions for use carefully and follow all instructions precisely.

	Attention
	Follow the instructions for use
	Risk of electric shock
	Disconnect the mains plug from the power supply
	Double insulation, protection class II
	Medical application part type BF
~	Alternating current sign
CE	CE conformity mark
0 / I	Switching the ME device off or on
	Symbol for disposal instructions
MD	Medical device
	Symbol for "fragile"
	Symbol for "Protect from moisture"
	Symbol for "Protect from heat"
	Symbol for "Temperature MIN-MAX"
	Symbol for "Top"
	Symbol for "MIN-MAX humidity"
	Symbol for "air pressure"
	Manufacturer
UDI	UDI (Unique Device Identification)
SRN	Single Registration Number

2. Warnings

2.1. Instructions for use

The user must read these instructions for use carefully and follow and apply them precisely. By carefully reading these instructions for use, the user must familiarize himself with the range of functions and the mode of operation.

2.2. General

It is prohibited to open the ME device or to replace or modify the mains cable or the mains plug. Furthermore, any modifications or changes to the ME device are prohibited.

It is forbidden to use the power cable for purposes other than its intended use, for example to hang up the ME appliance. Keep the mains cable away from heat, oil, sharp edges or moving parts of the appliance. Damaged or coiled mains cables must be repaired.

The user must ensure the functional safety and proper condition of the ME device before each use of the ME device.

Never touch the ME appliance plug or the mains 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 ME device.

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

The ME device must be switched off and disconnected from the power supply after each use.

2.3. Restrictions

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

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

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

Only use sharp saw blades, observe chapter 5.1.5.1.

The oscillation rate at level 5 or 6 should only be used in extremely exceptional cases. ME devices that are operated almost continuously or permanently at level 5 or 6 are subject to greater wear and tear and therefore have a shorter service life.

2.4. Application and safety instructions

Wear personal protective equipment such as safety goggles, a dust mask and hearing protection for yourself and the people in the vicinity. Observe and follow the guidelines of the employers' liability insurance association and equivalent organizations**.**

Wear at least a dust mask and protective goggles while cutting a dressing to prevent inhalation of the dust and wait until the dust has settled (and the working area has been cleaned if necessary) before removing the personal protective equipment.

Caution Risk of injury, saw blades have sharp cutting edges. This warning must always be observed when using on patients and when changing saw blades.

Before changing the saw blades, wait a few minutes to allow the saw blade to cool down to room temperature.

For patients who are sensitive to noise or anxious, such as children, adolescents or older people, we recommend setting the ME device to a low vibration level (level 1 or 2).

Persons who wear a hearing aid (e.g. hearing aid, hearing amplifier or similar) must remove, take off and switch off these devices. We recommend using the ME device at 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 ME device may only be operated at a low vibration level (level 1 or 2) for such patients.

2.5. Ambient conditions

The ME device may only be installed or used in rooms intended for this purpose (clinics, registered medical practices). The electrical installations and their electrical systems must be installed at least in accordance with the applicable IEC standards and must comply with the applicable national laws, regulations and requirements.

The ME 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 with oxygen,

b.) in which flammable or ignitable mixtures of anesthetics with air, oxygen, nitrous oxide or other anesthetic gases,

c.) in which flammable or ignitable mixtures,

d.) in which highly flammable or ignitable or explosive chemicals, such as skin or surface disinfectants,

no matter in which aggregate state (solid, liquid or gaseous), is enriched, can be enriched, could be enriched or will be enriched.

For safety reasons, the ME device must never, and at no time, be stored, temporarily stored or put away 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 with regard to 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 can lead to increased emissions or reduced interference immunity of the ME device.

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

2.7. Additional information

The following additional information must be observed and complied with for the ME device.

MPBetreibV

3. Product description

3.1. Product scope Plaster saw

1 piece	ME device Plaster saw
1 piece	Saw blade Ø50 mm
1 piece	Saw blade Ø65 mm
1 pair	Disposable wrench 11 mm

The basic equipment may vary depending on the scope of the order.

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

3.2. Electric plaster saw

The ME device is an oscillating saw, i.e. the saw blade does not rotate a full 360 degrees, as with a circular saw, for example, but swings (oscillates) a few degrees clockwise and then back again in an anti-clockwise direction, similar to a pendulum or a (children's) swing. This ensures, among other things, that the sawdust does not spread throughout the room or the surrounding area.

3.3. Saw blades

The medical device (saw blade) usually consists of a circular or semi-circular geometry in different diameters and blade widths. Depending on the design, the saw blades are fitted with sharp teeth at a specific angle. The teeth serve as cutting teeth and ensure the appropriate removal of the materials to be sawn (plaster material). The saw blades can be mechanically attached to the plaster saws by means of a screw. The saw blades are reusable medical products, but cannot be reprocessed.

3.4. Extraction plaster saw

This product (not a medical device) is a suction system (electric) 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 for separating plaster casts.

3.5. Intended use

The term "intended purpose" is to be equated with the term "intended use".

3.5.1. Plaster saw

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

3.5.2. Saw blades

The saw blades are designed exclusively for cutting plaster casts to remove them.

3.5.3. Extraction unit for plaster saw

Removal of plaster material.

3.6. Indication

The following examples describe the use of oscillating plaster saws with accessories:

- Removal of a plaster cast for reassessment
- Removal of a cast or if the medical history indicates an underlying foreign body
- Removal of a cast to rule out an underlying infection in connection with sepsis
- Cutting a cast for air travel (often prescribed by airlines before boarding)

3.7. Contraindication

The ME device must not be used on patients who have, possess or complain of skin irritations and / or skin injuries.
The ME device must also not be used on patients with burns or chemical burns.
The ME device is contraindicated for all applications other than the technology specified in the intended use.

3.8. Risks with the product

⚠ Cut injuries due to user error when touching the skin.

Risk of burns from 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.

Thromboses (especially with immobilization of the lower extremity - thrombosis prophylaxis).

Pressure points with skin necrosis (especially in prominent areas such as the wrist, head of the fibula, elbow, ... constrictions.

Compartment syndrome.

Misalignments.

3.9.2. Complications with the product

⚠ Nerve damage.

Injuries when removing the bandage.

Skin irritation.

In the course of monitoring the market, further potential risks from competitors were identified, e.g. electric shocks or short circuits.

4. Intended use

⚠ Carry out cutting tests and practise! To do this, apply a bandage to a log with a diameter of approx. 7 to 10 cm in accordance with the bandage manufacturer's instructions. Practice cutting until you cannot see any cutting 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 application. Only plaster casts with safety strips should be applied.

4.1. Qualification of the user

⚠ The ME device may only be used by medically qualified personnel (medical specialists, doctors and specialist staff) with sufficient experience in the respective field of application "plaster treatment".

5. ME device, operating instructions

5.1. ME device, commissioning

Make sure that the ME device is switched off as shown in Figure 2.

Then connect the mains plug to the mains socket.

5.1.1. ME device, serial number

The serial number SN# of the ME device can be found at the position shown in Figure 1.

Figure 1

5.1.2. ME device, switch OFF

If the digit "0" (zero) is visible, as shown in Figure 2, the ME device is in the OFF state (the ME device is switched off).

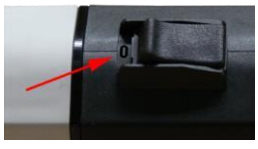


Figure 2

If the ME device is switched on, the lock can be released by pressing the rocker switch as shown in Figure 3 and the ME device switches off (the ME device is switched off).

Figure 3

5.1.3. ME device, switch ON

If the number "I" (one) is visible, as shown in Figure 4, the ME device is in the ON state (the ME device is switched on). The ME device is switched on by pushing the rocker switch forwards. The rocker switch must engage noticeably.

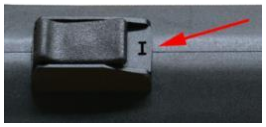


Figure 4

5.1.4. ME device, speed control

The speed control can be used to set the optimum oscillation rate of the saw blades in relation to the saw blade diameter, saw blade coating and bandage material. The oscillation rate can be set continuously by turning the control wheel, as shown in Figure 5.

Figure 5

Level	Oscillation frequency
1	3500 / min
2	7000 / min
3	12000 / min
4	17000 / min
5	21000 / min
6	24000 / min

5.1.5. Saw blades Saw blade service 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. This makes it possible to remove the saw blade and replace it rotated by 90 degrees. You can now continue working with a sharp saw blade area. You can repeat this process until all four 90 degree saw blade areas are worn down. **Failure to observe this can lead to irreparable damage to the ME device and endanger the patient**.

Approx. 3 to 5 bandages can be cut per 90 degree segment area, 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 Detail enlargement

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 needs to be replaced or rotated by 90 degrees.

Figure 7 Detail enlargement

5.1.6. Saw blades, visual differentiation

a. Saw blades with a shiny metallic surface are intended exclusively for cutting natural plaster dressings. Item no. 30.210.65, 30.213.65, 30.215.65
Art. No. 30.217.17, 30.217.06, 30.210.45
Dimensions and appearance can be found in chapter 11 "Accessories". Recommended vibration level: Level 2 to 4.

b. Saw blades with a matt light gray surface are intended for cutting natural plaster dressings and synthetic hard dressings.
Item no. 30.211.50, 30.211.65, 30.214.65, 30.216.65
Item no. 30.217.18, 30.217.11, 30.211.45
Dimensions and appearance can be found in chapter 11 "Accessories". Recommended vibration level: Level 3 to 4.

c. Saw blades with a black surface are designed for cutting natural plaster dressings and the latest generation of synthetic hard dressings.
Item no. 30.212.50, 30.212.65

Dimensions and appearance can be found in chapter 11 "Accessories". Recommended vibration level: Level 3 to 4.

5.1.7. Saw blades, usage matrix

NGV	SHV	Item no.	
+	-	30.210.50	NGV = Natural Plaster Association SHV = Synthetic Hard bandage - Not usable + Good usability ++ Very good usability +++ Best usability
+++	++	30.211.50	
+++	+++	30.212.50	
+	-	30.210.65	
+++	++	30.211.65	
+++	+++	30.212.65	
+	-	30.213.65	
+++	++	30.214.65	
+	-	30.215.65	
+++	++	30.216.65	
+	-	30.217.17	
+++	++	30.217.18	
+	-	30.217.06	
+++	++	30.217.11	
+	-	30.210.45	
+++	++	30.214.45	

5.1.8. Saw blades, structure

5.1.8.1 Tightening or loosening saw blades

Figure 8 shows how the saw blade must be fitted correctly to prevent damage to mechanical parts.

Please only use the supplied wrench (item no. 30.210.02) 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 meet the specifications, this will result in undefined tightening conditions.

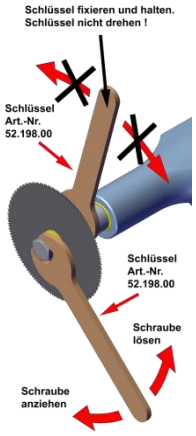


Figure 8

5.1.8.2 Structure, saw blade only

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

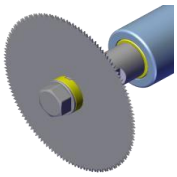


Figure 9

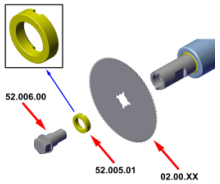


Figure 10

5.1.8.2 Structure, with depth limiting disk

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

Use the optionally available eccentric depth limiting disk (can only be used in conjunction with Ø65 mm saw blades). With the aid of this depth limiting disk, constant cutting depths of 4 to 11 mm can be achieved, as shown in Figure 11. This allows the cutting depth to be set very accurately and prevents injury to the patient if the depth limiting disk is used correctly.

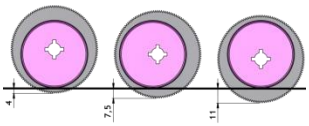


Figure 11

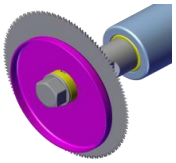


Figure 12

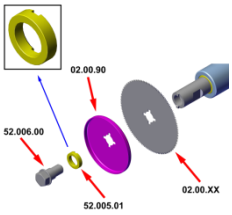


Figure 13

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

5.2. Decommissioning

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

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

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

5.3. Troubleshooting / fault, electrical

I. The ME device switches off during use for no apparent reason: As the ME appliance has a temperature monitoring system for the motor winding, the temperature limit value may be exceeded under certain circumstances, such as when the ventilation slot is closed. Remedy: Follow the instructions under point 5.2 "Decommissioning" and wait 10 minutes until the ME appliance has cooled down and can be put back into operation.

II. The ME device can no longer be put back into operation as described under "I.". Remedy: The appliance fuse may be defective. The ME appliance must be repaired.

III. The ME appliance is not running smoothly: If the ME appliance has been in use for more than one hundred operating hours, this behavior indicates worn carbon brushes. Remedy: The carbon brushes must be replaced and the ME appliance must be repaired by the manufacturer.

IV. The ME appliance no longer allows speed control or only rotates at maximum speed. Remedy: Carry out the instructions as described in section 5.2 "Decommissioning". This error indicates a defect in the control electronics. The ME appliance must no longer be used and must be repaired by the manufacturer.

V. The ME device cannot be restarted after a power failure. The ME device is equipped with undervoltage protection, i.e. the ME device will not start up automatically after the power supply has been restored. Remedy: Switch the ME device off at the ON/OFF switch as described. Remove the mains plug from the mains socket. CAUTION Be aware of the risk of electric shock. Wait approx. 5 minutes, then you can put the ME appliance back into operation as described.

5.4. Troubleshooting / malfunction, mechanical

I. The ME appliance suddenly makes unfamiliar and loud noises. Remedy: Immediately carry out the instructions as described in section 5.2 "Decommissioning". There is a mechanical defect. The ME appliance may no longer be used and must be repaired by the manufacturer.

II. The ME device loses drops of oil in the transition area between the shaft and the neck section (handle section). Remedy: Remove the oil droplets with an absorbent disposable cloth. This behavior does not constitute a defect. With new ME devices and / or after long periods of use, any excess oil will become thinner due to the heat generated at the lubrication point and may leak out. This process disappears after a short time so that no more oil will escape at the lubrication point.

III. The ME device is leaking oil or grease in the transition area from the neck section (handle section) to the motor. Remedy: Remove the oil or grease with an absorbent disposable cloth. This behavior does not constitute a defect. With new ME devices and / or after long periods of use, any excess oil or grease will become thinner due to the heat generated at the lubrication point and may leak out. This process disappears after a short time so that no more oil or grease will escape at the transition points.

6. B2B warranty

We grant a B2B warranty of one year from the date of purchase (proof of invoice required) for demonstrably faulty parts or defective workmanship. Wearing parts such as carbon brushes, ball bearings, saw blades, etc. are excluded. Defective mains cables or plugs, cable breaks, 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 / damage / consequential damage caused by incorrect operation or non-compliance with these instructions for use is not covered by the guarantee or warranty claims.

7. Cleaning / Sterilization

7.1. Cleaning / sterilization, ME device

If necessary, the outer surfaces of the ME device must be cleaned with the surface disinfectant "schülke mikrozid® universal wipes premium maxi" using wipe disinfection.

Mechanical cleaning / disinfection / sterilization is prohibited. Before carrying out any cleaning work, disconnect the ME appliance from the mains (pull the mains plug out of the mains socket).

7.2. Cleaning / sterilization, saw blades

If necessary, the saw blades should be cleaned with the disinfectant and cleaning agent "Schülke gigasept® instru AF" using wipe disinfection.

Mechanical cleaning / disinfection / sterilization is prohibited.

8. Maintenance / repairs / overhauls

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

A delivery bill with the following information must be enclosed for the return of the ME device: Customer address, telephone number, item number, description of the problem, contact person, and evidence of decontamination**.**

9. Definition, application part type BF

The saw blades 30.21x.xx are defined as application parts of type BF, see Figure 14.

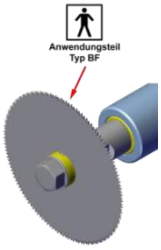


Figure 14

10. Environmental protection, disposal

At the end of its service life, the ME device must be disposed of properly in accordance with the European WEEE Directive 2012/19/EU. The ME device must not be disposed of with household waste.
The saw blades should be adequately protected against cutting injuries and disposed of in accordance with national regulations and laws.

11. Accessories and combination products

Article no.	Article naming
30.210.50	Saw blade Ø50 mm, for natural plaster dressings
30.211.50	Saw blade Ø50 mm, for synthetic hard composites
30.212.50	Saw blade Ø50 mm, PTFE coated, for synthetic hard composites

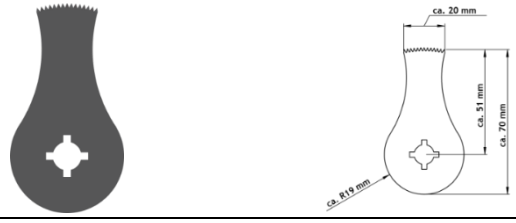
30.210.65	Saw blade Ø65 mm, for natural plaster dressings
30.211.65	Saw blade Ø65 mm, for synthetic hard composites
30.212.65	Saw blade Ø65 mm, PTFE coated, for synthetic hard composites

30.213.65	Saw blade segment 50/65 mm, for natural plaster dressings
30.214.65	Saw blade segment 50/65 mm, for synthetic hard composites

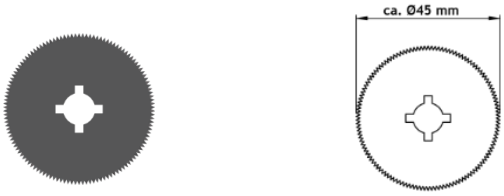
30.215.65	Saw blade segment 65/65 mm, for natural plaster dressings
30.216.65	Saw blade segment 65/65 mm, for synthetic hard composites

30.217.17	Depth saw blade 8 mm, for natural plaster dressings
30.217.18	Depth saw blade 8 mm, for synthetic hard composites

30.217.06	Depth saw blade 20 mm, for natural plaster dressings
30.217.11	Depth saw blade 20 mm, for synthetic hard composites



30.210.45	Saw blade Ø45 mm, for natural plaster dressings
30.211.45	Saw blade Ø45 mm, for synthetic hard composites



30.218.17	Depth limiting washer, eccentric

12. Spare parts

Article no.	Designation
30.200.93	Carbon brushes 230 Volt, pair
30.200.93	Carbon brushes 120 Volt, pair
30.210.06	Locking ring for saw blade
30.210.07	Cheese head screw for saw blade
30.210.02	Combination wrench 11 mm, pair

13. 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 patient is located.

14. Distributor

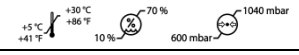
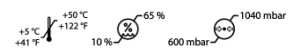
Dimeda Instruments GmbH
Gänsäcker 54+58
78532 Tuttlingen
Tel: +49 (0) 7462 / 9461-0
Fax: +49 (0) 7462 / 9461-33
http://www.dimeda.de
info@dimeda.de
DE-MF-000005584

15. Manufacturer

MST-Instruments GmbH
In widths 13
78589 Dürbheim / Germany
Phone +49 (0)7424 - 905921
Fax +49 (0)7424 - 905922
Email info@mst-instrumente.de
Web www.mst-instrumente.de
SRN DE-MF-000005503

EAR Foundation - WEEE reg. no.
DE92201287
Grüner Punkt - Duales System Deutschland GmbH - Reg. no.
5563454 / DE1375317665915
Central Agency Packaging Register Foundation (ZSVR) LUCID - Reg. no.
DE1375317665915

16. Technical description / data

Model			Plaster saw, electronic power	
Item number			30.200.20	30.200.10
Mains voltage			230 V, AC	120 V, AC
Mains frequency			50 Hz	60 Hz
Mains cable length in meters			approx. 5 (unshielded)	approx. 3 (unshielded)
Mains cable cross-section in mm²			2 x 0,75	2 x 1,31
Mains plug			Euro plug, 2-pin	US plug, NEMA-1 (type A), 2-pin
Primary fuse			T 10A / 250V	T 10A / 250V
Oscillations, vibrations			Typically 1.3 to 6.0 grms, under unfavorable conditions up to 12.5 grms (m / s²). Depending on the set oscillation rate, the saw blade shape, the saw blade condition (sharp / blunt) and the cutting force used	
Audible sound energy			approx. 65 - 85 dB(A) ± 5 dB(A) (level 1 to 3), depending on the set vibration, under unfavorable operating conditions approx. 95 dB(A) ± 5 dB(A) (level 4 to 6)	
Power consumption			500 W (Watt)	
Vibrations			3500 to 24000 per minute, infinitely variable	
Vibration angle in degrees			6	
Classification	Protection against electric shock		Protection class II	
	Medical application part		Type BF	
	Protection against harmful ingress of water or solid substances		IP20	
	Sterilization ME device / saw blades		Not allowed	
	Suitability for use in oxygen-enriched environments		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 transportation 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			IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME IEC CB TEST CERTIFICATE Ref. Certif. No. CH-8855 (IECEE CB Scheme) Test Report Ref. No. 15-EL-0329.S01 + .S20 + .E01(EMC) + .E02(EMC)	
			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 in mm			approx. 58 x 58 x 310	
Weight with cable / without cable, in kg			approx. 1.5 / approx. 1.25	
Expected service life			$Lebensdauer\ in\ Jahren = \frac{\left(Technische\ Lebensdauer\ in\ h \times 60\ \frac{min.}{h} \times \frac{\%\_Satz\ für\ reparierbare\ Produkte}{100\%}\right)}{\left(Anzahl\ \frac{Patienten}{Tag} \times 365\ \frac{Tage}{Jahr} \times Einsatzdauer\ \frac{min.}{Patient}\right)}$ $LD = \frac{\left(3000\ h \times 60\ \frac{min.}{h} \times \frac{120\%}{100\%}\right)}{\left(8\ \frac{Patienten}{Tag} \times 365\ \frac{Tage}{Jahr} \times 10\ \frac{min.}{Patient}\right)} = 7{,}4\ Jahre \approx 7\ Jahre$	

17. Electromagnetic compatibility

17.1. Guidelines and manufacturer's declaration

The ME device is intended for operation/use in the electromagnetic environment specified below.
The user / operator of the ME device must ensure the following:

a. That the ME device is operated in such an environment.
b. That the ME device can be operated in such an environment.

17.1.1. Electromagnetic emissions

Table 1 - Guidelines and manufacturer's declaration - Electromagnetic emissions

The ME device is intended for use in the electromagnetic environment specified below. The user of the ME device should assure that it is used in such an environment.

Emission measurements	Compliance	Electromagnetic environment - Guideline
Radiated RF emission according to CISPR 11	Agree, group 1	The ME device uses RF energy exclusively for its internal function. Therefore, the RF emission is very low and it is unlikely that neighboring electronic devices will be disturbed.
Conducted RF emission according to CISPR 11	Agrees, class B	The ME appliance is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics according to IEC 61000-3-2	Complies, class A	
Voltage fluctuations / flicker according to IEC 61000-3-3	Agrees	

17.1.2. Electromagnetic immunity

Table 2a - Guidelines and manufacturer's declaration - Electromagnetic immunity

The ME device is intended for use in the electromagnetic environment specified below. The user of the ME device should assure that it is used in such an environment.

Interference immunity tests	IEC 60601 Test level	Compliance level	Electromagnetic environment - Guidelines
Discharge of static electricity (ESD) according to IEC 61000-4-2	±2, ±4, ±6 kV Contact discharge ±2, ±4, ±8 kV Air discharge	± 6 kV Contact discharge ± 8 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 disturbances (burst) according to IEC 61000-4-4	± 2 kV for mains cables	± 2 kV for mains cables	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Surges according to IEC 61000-4-5	± 1 kV outer conductor to outer conductor ± 2 kV phase conductor to earth	± 1 kV outer conductor to outer conductor ± 2 kV phase conductor to earth	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Voltage dips and short-time interruptions according to EN 61000-4-11	<5% U / 0.01 sec. 40% U / 0.10 sec. 70% U / 0.50 sec. <5% U / 5.00 sec. Short-term interruption	<5% U / 0.01 sec. 40% U / 0.10 sec. 70% U / 0.50 sec. <5% U / 5.00 sec Short-term interruption	The quality of the supply voltage should correspond to that of a typical business or hospital environment. If the user requires continued operation even when the power supply is interrupted, it is recommended that the ME device is powered from an uninterruptible power supply or a battery.
Magnetic field at the frequency of the supply voltage according to IEC-61000-4-8	3 A/m	3 A/m	Magnetic fields at mains frequency should correspond to the typical values of a business or hospital environment.

Table 2b - Guidance and manufacturer's declaration - Electromagnetic immunity - For non-life-sustaining medical electrical equipment

The ME device is intended for use in the electromagnetic environment specified below. The user of the ME device should assure that it is used in such an environment.

Interference immunity tests	IEC 60601 Test level	Compliance level	Electromagnetic environment - Guidelines
Radiated RF fields according to IEC 61000-4-3	80 MHz - 2.5 GHz, 3 V/m	80 MHz - 2.5 GHz, 3 V/m	Portable and mobile RF communications equipment should be used no closer to the ME device, including cables, than the separation distances given in Table 3 of the protection table below.
Conducted radio frequency according to IEC 61000-4-6	150 kHz - < 80 MHz, 3 V_{eff}	150 kHz - < 80 MHz, 3 V_{eff}	distances is specified. The field strength of stationary radio transmitters should be lower than the compliance level at all frequencies according to an on-site investigation.

These guidelines may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and people. Field strengths from fixed transmitters, such as base stations for radiotelephones 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 transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ME device is used exceeds the applicable RF compliance level above, the ME device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ME device.

17.1.3. Recommended safety distances

Table 3 - Recommended safety distances between portable and mobile (RF) telecommunications equipment and the ME device

The ME device is intended for use in the electromagnetic environment specified below, in which radiated RF disturbances are controlled. The user of the device can help prevent electromagnetic interference by maintaining a minimum separation distance "a" between portable and mobile RF communications equipment (transmitters) and the ME device as recommended below, according to the maximum output power rating "N" of the communications equipment. The user of the ME device should ensure that the ME device is operated in such an environment. The ME device is intended for use in the electromagnetic environment specified above - Table 1, line 3. The user should assure that the ME device is used in such an environment.

a = Minimum safety distance, depending on the transmission frequency, in meters / N = Maximum rated power (maximum transmission power) of the transmitter, in watts

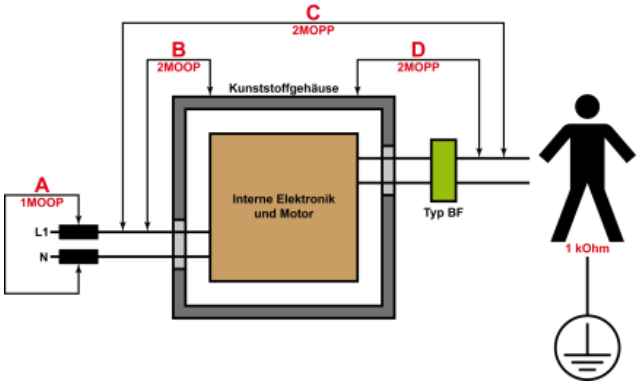
Maximum rated power **N**	150 kHz to < 80 MHz $a = \left(\frac{3,5}{X}\right) \times \sqrt{N}$		80 MHz to < 800 MHz $a = \left(\frac{3,5}{X}\right) \times \sqrt{N}$		800 MHz to < 2.5 GHz $a = \left(\frac{7}{X}\right) \times \sqrt{N}$	
	$X = 3\ ^{V}_{m}$	$X = 10\ ^{V}_{m}$	$X = 3\ ^{V}_{m}$	$X = 10\ ^{V}_{m}$	$X = 3\ ^{V}_{m}$	$X = 10\ ^{V}_{m}$
0,01	0,12	0,04	0,12	0,04	0,23	0,07
0,1	0,37	0,11	0,37	0,11	0,74	0,22
1	1,17	0,35	1,17	0,35	2,33	0,70
2	**1,65**	**0,49**	**1,65**	**0,49**	**3,30**	**0,99**
10	3,69	1,11	3,69	1,11	7,38	2,21
100	11,67	3,50	11,67	3,50	23,33	7,00

In the D1 and D2 bands, this results in a safety distance of approx. 1.65 m from cell phones whose transmission power is limited to 2 watts (assumption: 3 V/m compliance level, ME device not life-sustaining). In the E-band, this results in a safety distance of approx. 3.30 m from cell phones whose transmission power is limited to 2 watts (assumption: 3 V/m compliance level, ME device not life-sustaining). For transmitters whose maximum rated power N is not specified in the table above, the recommended separation distance a in meters can be determined using the equation associated with the relevant column, where N is the maximum rated power of the transmitter in watts as specified by the transmitter manufacturer. These guidelines may not apply in all cases. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and people.

17.1.4. Insulation tables / insulation diagram

Classification of material groups, Table 9	IIIb, 100 ≤ CTI < 175	
Classification of the degree of pollution, section 8.9.1.8	Pollution degree 3	
Multiplication factor "Mf" for airborne connectors, for altitudes up to 5000 m, rated operating altitude "a" in meters, MOOP (Means Of Operator Protection), MOPP (Means Of Patient Protection), Tab. 8	4000 < a ≤ 5000, Mf_{MOOP} = 1.48, Mf_{MOPP} = 1.29	
Mains voltage peak, Table 10	V_{eff} = 300 V, Cat. II = $_{V\text{-peak}}$ 2500 V	V_{eff} = 150 V, Cat. II = $_{V\text{-peak}}$ 1500 V

Test voltage for solid insulation materials that form a protective measure	A - D, Table 6					
	Peak operating voltage Vpeak	212 V < U ≤ 354 V			71 V < U ≤ 184 V	
	Protection from the power supply unit	Operator protection		Patient protection	Operator protection	Patient protection
	Protection MOOP / MOPP	MOOP		MOPP	MOOP	MOPP
		1 x	2 x	2 x	1 x	2 x	2 x
	AC test voltage V_{eff}	1500 V	3000 V	4000 V	1000 V	2000 V	3000 V
	Condition / test	fulfilled	fulfilled	fulfilled	fulfilled	fulfilled	fulfilled
Minimum creepage distances and clearances between Sharing opposite Polarity in the power supply unit	A, Table 11, L1(N) against N(L1)					
	Operating voltage V_{eff}	250 V			125 V	
	Distance in mm	Creepage distance		Air section	Creepage distance	Air section
		3,0		1,6 x 1,48 = 2,37	2,0	1,0 x 1,48 = 1,48
	Condition / Test	fulfilled		fulfilled	fulfilled	fulfilled
Minimum air gaps, which represent a protective measure for operator protection against the power supply unit	B, Table 13, L1(N) against housing not connected to protective conductor					
	Mains voltage peak	2500 V			1510 V	
	Operating voltage V_{eff}	300 V			150 V	
	Degree of soiling	3			3	
	Operator protection MOOP	2 x			2 x	
	Distance in mm	4,0 x 1,48 = 5,92			2,6 x 1, .8 = 3,85	
	Condition / Test	fulfilled			inventedfilled	
Minimum creepage distances, which are a protective measure for operator protection	B, Table 16, L1(N) against housing not connected to protective conductor					
	Operating voltage V_{eff}	250 V			125 V	
	Degree of soiling	3			3	
	Material group	IIIa or IIIb			IIIa o he IIIb	
	Operator protection MOOP	2 x			2 x	
	Distance in mm	8,0			4,8	
	Condition / Test	fulfilled			inventedfilled	
Minimum creepage distances and clearances as Protective measure for Patient protection	C, Table 12, L1(N) against application part					
	D, Table 12, housing not connected to protective earth against applied part, highest mains voltage					
	Operating voltage V_{eff}	250 V			125 V	
	Patient protection MOPP	2 x		2 x	2 x	2 x
	Distance in mm	Creepage distance		Air section	Creepage distance	Air section
		8,0		5,0 x 1,29 = 6,45	6,0	3,2 x 1,29 = 4,13
	Condition / test	fulfilled		fulfilled	fulfilled	fulfilled



18. Circuit diagram / block diagram