Technical manual / User manual

Purisole Lift

Rev. U

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The Purisole Lift is manufactured by FIDICA GmbH & Co. KG and distributed.

FIDICA GmbH & Co. KG reserves the right to update portions of this document or portions of the data contained therein.

The Purisole Lift is a class 1 active medical device.

The Purisole Lift must only be operated in VDE 0107-compliant medical facilities.

Only qualified staff are authorized to perform assembly, upgrades, adjustments, modifications, or repairs!

May contain errors, revisions made without notice.

Conformity declaration

We declare that his product meets the medical device

requirements in Directive EU 2017/745 (MDR).

Table of Contents

1 Overview

This user manual describes the assembly and operation of a Purisole Lift (also container lift).

The user manual must be read prior to initial startup!

The supporting documentation - operating instructions with assembly instructions are elements of the unit and must be stored in its immediate proximity in a protective sleeve suited for permanent display.

The Fidica GmbH & Co. KG service staff are available to assist you in the event of a malfunction.

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1.1 Warnings and safety instructions

Symbol	Meaning
	**WARNING !** Possibly threatening danger! Failure to observe these instructions may result in serious injury. Information that draws the user's attention to the fact that failure to observe the correct operation can result in damage to the device or negative effects on persons.
	**ATTENTION!** Dangerous situation! Failure to observe these instructions may result in injury or damage to property. Information that draws the user's attention to the fact that a desired function will not work or will not work properly if the specified steps are not followed, or that a desired effect will not occur.

The following warning and safety instructions must be observed and implemented:

ATTENTION!

The Purisole Lift must only be operated under the specified conditions (see Section 6 - Technical Specifications, page 18 ff.).

ATTENTION!

If a control unit is defective, the type of failure (failure mode) must be noted prior to dismantling.

ATTENTION!

The control unit must be protected against humidity and moisture. It must never come into contact with spraywater or condensation.

ATTENTION!

The maximum load of 55 kg must be adhered to!

ATTENTION!

The maximum rated lifting force per hook is 12 kg.

Warning

Changing the ME-device is not allowed.

WARNING !

If used improperly, the entire Purisole Lift can detach from the ceiling anchors and can therefore present a hazard for the patient and user.

WARNING !

Do not reach into the openings for the suspension while the Purisole Lift is in operation.

WARNING !

The electrical installation may only be carried out by a qualified electrician!

Before commissioning, an electrical test in accordance with DIN EN62353 must be carried out by a qualified electrician!

The appliance is then ready for use and no further commissioning by a trained technician is required

ATTENTION!

The unit must only be serviced by FIDICA GmbH & Co. KG or a facility expressly authorized by us.

ATTENTION!

Assemblies and applications that deviate from the description must be expressly approved by Fidica GmbH & Co. KG.

WARNING !

The portable unit must be installed and operated at least 25 cm outside of the surgery
environment.

WARNING !

Always observe sufficient clearance when lifting the load. Always monitor the lifting operation and ensure that no objects (e.g. furnishings and body parts) can be pinched or dragged along.

ATTENTION!

Medical procedures must only be performed with medical devices and rinsing solutions designated for this purpose.

WARNING !

If used improperly, the canister can dislodge or the attached bag can tear off. This can result in a hazard for the patient and user. Ensure that the bag and canister are properly seated.

WARNING !

Users must not lean against the unit, or support themselves against, sit on, or step onto the unit.

No objects must be placed onto the unit.

ATTENTION!

The equi-potential bond of the unit must be connected if the unit can be touched by the patient and/or user while in use.

WARNING !

The user must not touch the Purisole Lift and the patient at the same time. The Purisole Lift must also not be touched while in operation.

WARNING !

Electromagnetic waves
No devices that radiate electromagnetic waves (e.g. portable radios, wireless phones (mobile phones), CB radios) must be operated in the vicinity of a running Purisole Lift. This can result in radio interference.

Warning

Do not press both buttons for lifting and lowering (arrow up + arrow down) at the same time for each hook number!

Warning

When moving the hooks, a pause time of 5s must be observed before each direction reversal.

2 Applications and purpose

This Purisole Lift, conventionally also referred to as container lift, is employed to hoist rinsing solution containers for gravity rinsing of organs. This is accomplished by electrically adjusting the rinsing solution to the height requested by the doctor. Possible applications include rinsing joints for arthroscopy procedures, rinsing the bladder for urology procedures, and rinsing the uterus for gynecology procedures.

The assembled height of the lift should be 3 meters in order to perform the aforementioned procedures. Based on empirical experience, the rinsing solution is set to approx. 80 cm above the organ level for filling the bladder; approx. 1,80 - 1.95 m above the organ level to rinse the uterus, and approx. 3 m and higher above the organ level to rinse joints.

The unit is suited for wall or ceiling installation. The included user manual contains detailed instructions.

The unit is always operational if installed properly and properly connected electrically.

ATTENTION!

The following instructions must be observed to comply with the approvals and regulations associated with this equipment.

This unit is not approved for use in ATEX environments.

3 Equipment Description

3.1 Design and Function

The Purisole Lift consists of two motor gearbox units that are both fastened to an assembly plate. A leadscrew connects these motor gearbox units to the canister suspension. When needed, the manual switch is used to actuate one or both motors. This means that one or two rinsing canisters can be adjusted independently from each other to the respective surgical field.

The manual switch features two buttons used to enable upward or downward travel of the drive units. A ca. 3 meter long cable connects the manual switch via plug-in connection to the Purisole Lift.

For safety reasons, each drive unit is equipped with two internal shut-off controls. These shut-off controls prevent damage to the lift if used improperly.

3.2 Operation

3.2.1 Lifting the load

The load of the desired lift is raised with the up-arrow button (marked yellow in the figure) above the corresponding number (one or two).

Press the switch until the desired hook position has been reached.

3.2.2 Lowering the load

The load of the desired lift is lowered with the down-arrow button (marked blue in the figure) above the corresponding number (one or two).

Press the switch until the desired hook position has been reached.

Warning

Do not press both buttons for lifting and lowering (arrow up + arrow down) at the same time for each hook number!

Warning

When moving the hooks, a pause time of 5s must be observed before each direction reversal.

Duty cycle:	Periodic intermittent operation S3
	Duty cycle ED = 20% (2 minutes per 10 minutes)
Operating modes:	Manual switch
Control circuit:	Only one motor can be in operation at any time; both directions of travel are limited by a limit switch
Lifting force:	12 kg per lift

3.3 Supplied scope

Bill of materials	Count
Installation frame	1
Purisole Lift, base unit	1
Manual switch with cable	1
Control cable, length: 3 m, with Schuko plug	1
Technical manual / User manual	1
Fastener hardware kit	1
Socket head cap screw DIN 912 M6x16	6
Spring clip DIN 127-A2, B6	10
Washer 6.4 OD 20 (body washer)	6
Heavy-duty dowel FBN 6/10	4
Washers DIN 125, d 6.4 mm, A2	4
Sealing caps for the upper installation holes for wall-mounted installation	8
Drill template	1

Purisole Lift, base unit Equi-potential bond

Figure 3.1 Supplied Scope - Purisole Lift, base unit

3.4 Supplied scope - installation frame

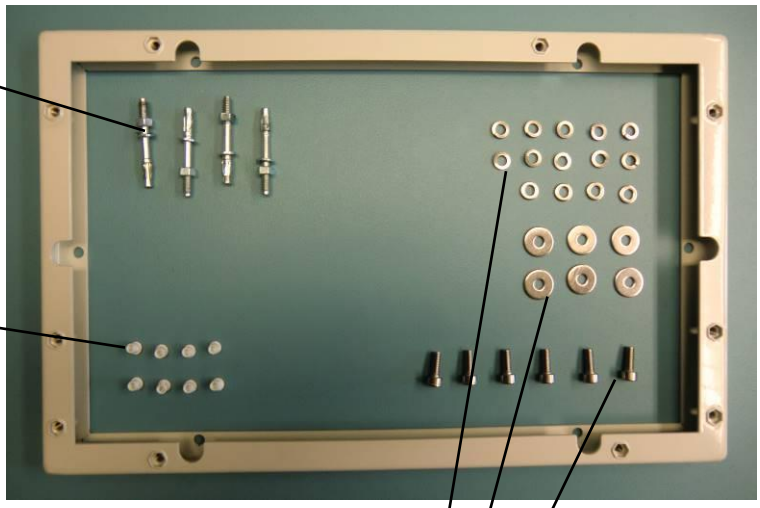


Figure 3.2 Supplied Scope - installation frame

4 Assembly instructions

Unpacking

- Open equipment packaging
- Remove the installation frame, the fastener hardware kit, and the manual switch
- Pull the packaging unit from the carton

Comment: Only the U-shaped sheetmetal enclosure is removed to screw the unit to the already attached installation frame

4.1 Site preparation

WARNING!

If the Purisole-Lift is to be permanently connected, a 2-pole mains disconnection device must be provided.

Since the Purisole-Lift has no internal switch, this 2-pole mains disconnection device must be accessible at all times in order to be able to disconnect the Purisole-Lift from the mains supply in the event of a fault.

The following applies for a hardwired electrical connection:

- Electrical cable, approx. 50 cm freely suspended at the height of the installed unit. Exit from the hung ceiling within the intended installation frame, cable: PE/N/L with AC 230 V / 50 Hz.
- Retainer bolts and a ceiling mount are installed at the site into the load-bearing ceiling of the building carcass as per Figure 5.1 (sketch: installation with hung ceiling) at the height of the hung ceiling (not in the supplied scope).
  1. Remove sheetmetal enclosures.
  2. Install power cable on the power supply board terminals.
  3. Remove lower cable gland (M16 x 1.5) and seal with a blind plug (hardware kit).
  4. Guide power cable through the newly positioned cable gland and install on power supply board terminals **(note polarity)!**
  5. Reinstall all sheetmetal enclosures.

4.2 Wall installation

1. Mark dowel holes using the installation frame / drill template;∅then use a 6 mm drill to drill 40 mm deep holes.
2. Align the threaded tip of the dowel screws flush with the hole.
3. Then slide installation frame onto the dowel screws upright, e.g. with the 6 each M6 weld nuts facing up, *see sketch* Figure 5.4 and secure with DIN M6 nuts and spring clips (use spanner wrench SW10).
4. Remove side enclosure on Purisole Lift (loosen 8 screws).

5. Fasten Purisole unit to the installation frame with the included M6x16 screws.

WARNING!

All screws and nuts must be secured with lock washers.

6. Seal housing frame with side enclosure.

4.3 Ceiling installation

Comment: The ceiling installation procedure must be adapted to the respective local conditions and can only be illustrated here.

WARNING !

The installation must be designed with a safety factor of 12 (660 kg). The load-bearing capacity of the ceiling must be confirmed by the responsible architect if not otherwise verifiable.

For hung ceilings, auxiliary installation frames are installed at the site on the load-bearing ceiling of the building carcass (also refer to Figure 5.1, sketch: Auxiliary frame for hung ceiling).

1. The Purisole Lift installation frame is mounted to the auxiliary frame with 4xstandoffs, 4xnuts DIN 970-M6-8 and washers DIN 125-A 6.4 mm (note thickness of the hung ceiling).
2. Proceed similar to Section Wall installation Steps 1-7 for installations without hung ceiling.
3. Fasten housing to the installation frame with M6x40 screws.
4. Note orientation of frame (see Figure 5.3 Installation Frame).

WARNING !

All screws and nuts must secured with lock washers.

5. Install side enclosure

ATTENTION !

The installation instructions only apply to load-bearing brick or concrete walls and ceilings. (normal concrete C20/25)

The load-bearing capacity of the wall or ceiling must be confirmed by an architect, unless otherwise verifiable.

5 Startup and shutdown

5.1 Startup preparations (Electrical connection)

WARNING !

Device of protection class 1:

To avoid the risk of electric shock, this device must only be connected to a mains supply with protective earth conductor.

WARNING!

The electrical installation may only be carried out by a qualified electrician!

Before commissioning, an electrical test in accordance with DIN EN62353 must be carried out by a qualified electrician!

The appliance is then ready for use and no further commissioning by a trained technician is required

WARNING !

The Purisole-Lift is disconnected from the mains supply via the mains plug of the mains connection cable.

For this reason, the mains cable must be installed in such a way that it can be disconnected from the mains supply at any time. The mains plug of the mains connection cable must be accessible at all times and without obstructions.

When the included power cable with Schuko plug is used, the electrical connection (230 Volt AC) is established with a 2-pole disconnectable Schuko outlet, protected, with max. 6 A Fl.

5.2 Startup

The Purisole Lift underwent a mechanical and electrical inspection during manufacturing.

However, at least all screw fasteners should be retightened once again after the unit is fastened to the installation frame and/or before the U-shaped sheetmetal enclosure is reinstalled. The sheetmetal enclosure can be screwed back on after this inspection has been completed. It is essential that the screws with the lock washers be screwed back into the same location.

The plug for the manual control device is then plugged into the 7-pole flanged socket on the unit. The screw cap on the plug is then securely screwed onto the flanged socket.

For connections with Schuko outlets, the Schuko plug is plugged into the Schuko outlet, and the 2-pole switch before the Schuko outlet is switched on.

The Purosile Lift is now operational.

5.3 Assembly and installation drawings

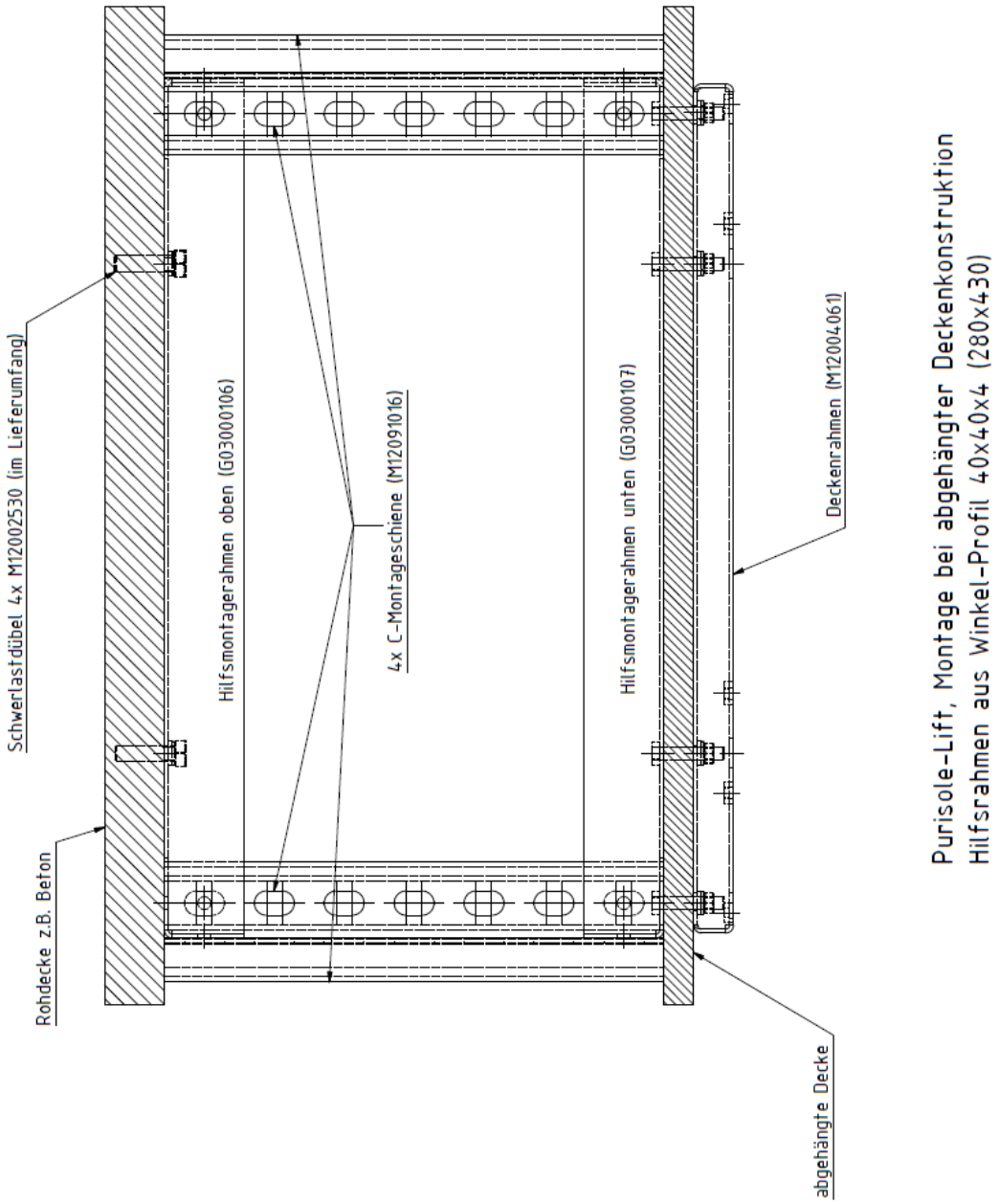


Figure 5.1: Purisole Lift, installation with hung ceiling structure, PL outside of hung ceiling

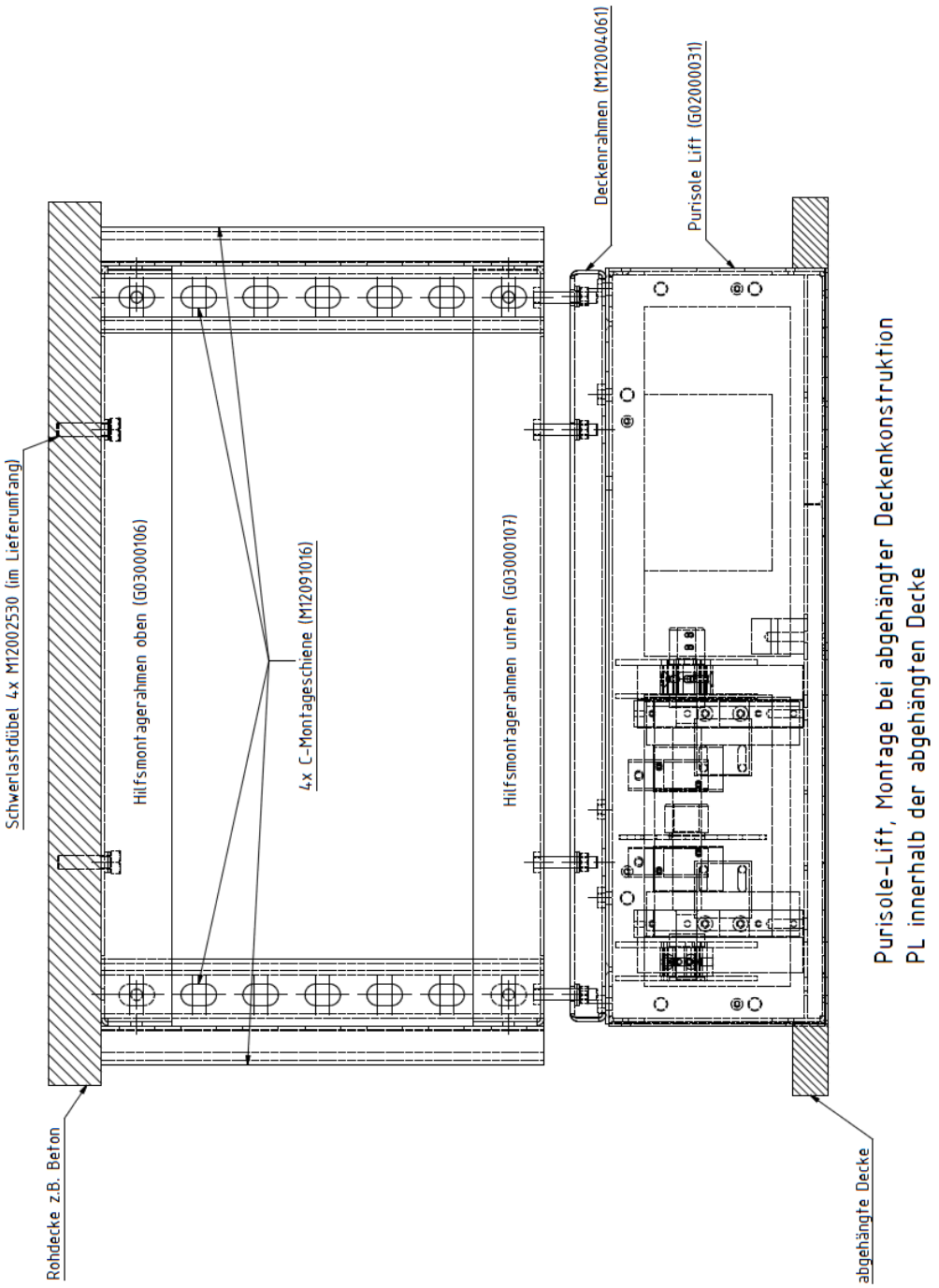


Figure 5.2: Purisole Lift, installation with hung ceiling structure, PL inside of hung ceiling

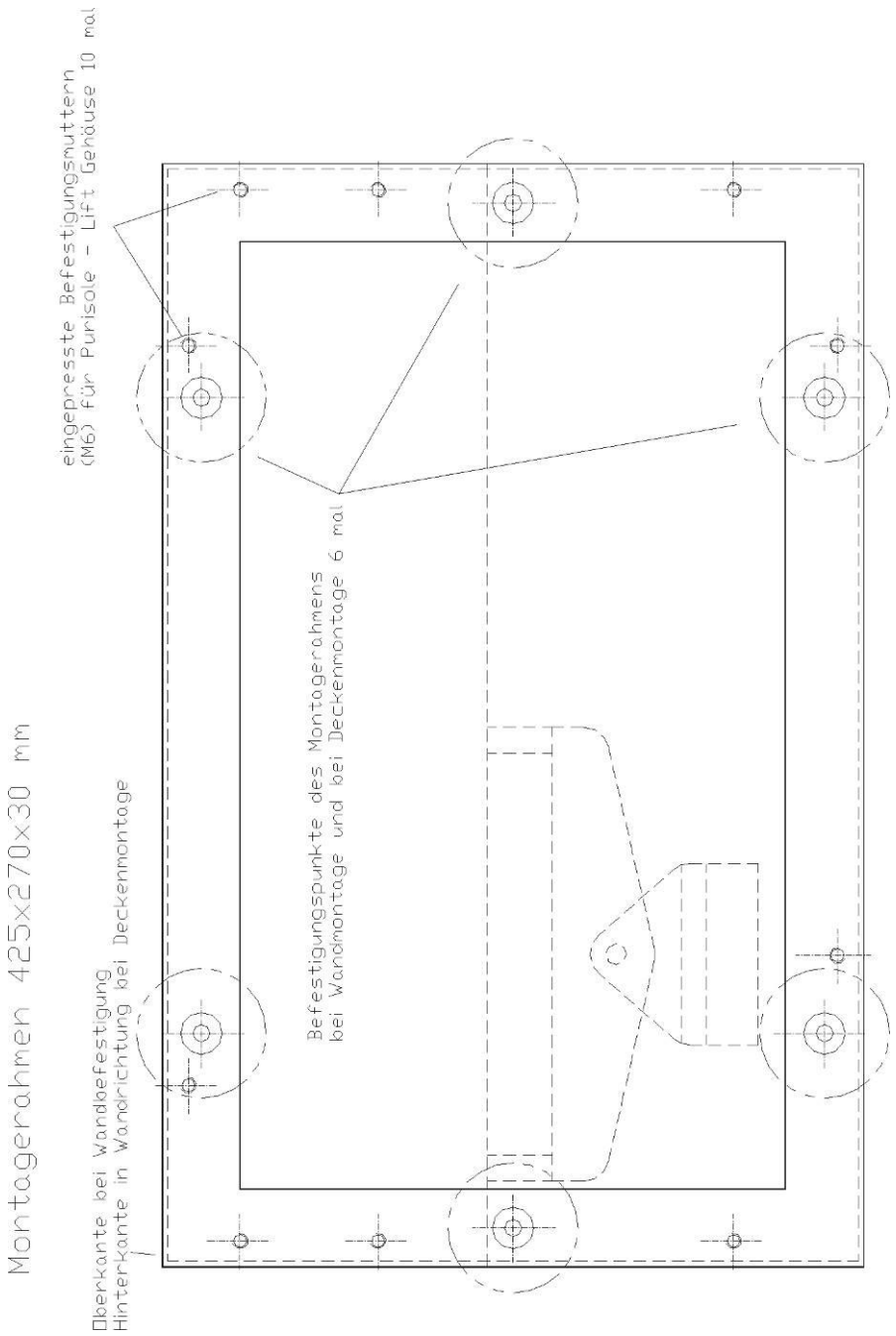


Figure 5.3: Installation frame: 425 x 270 x 30 mm

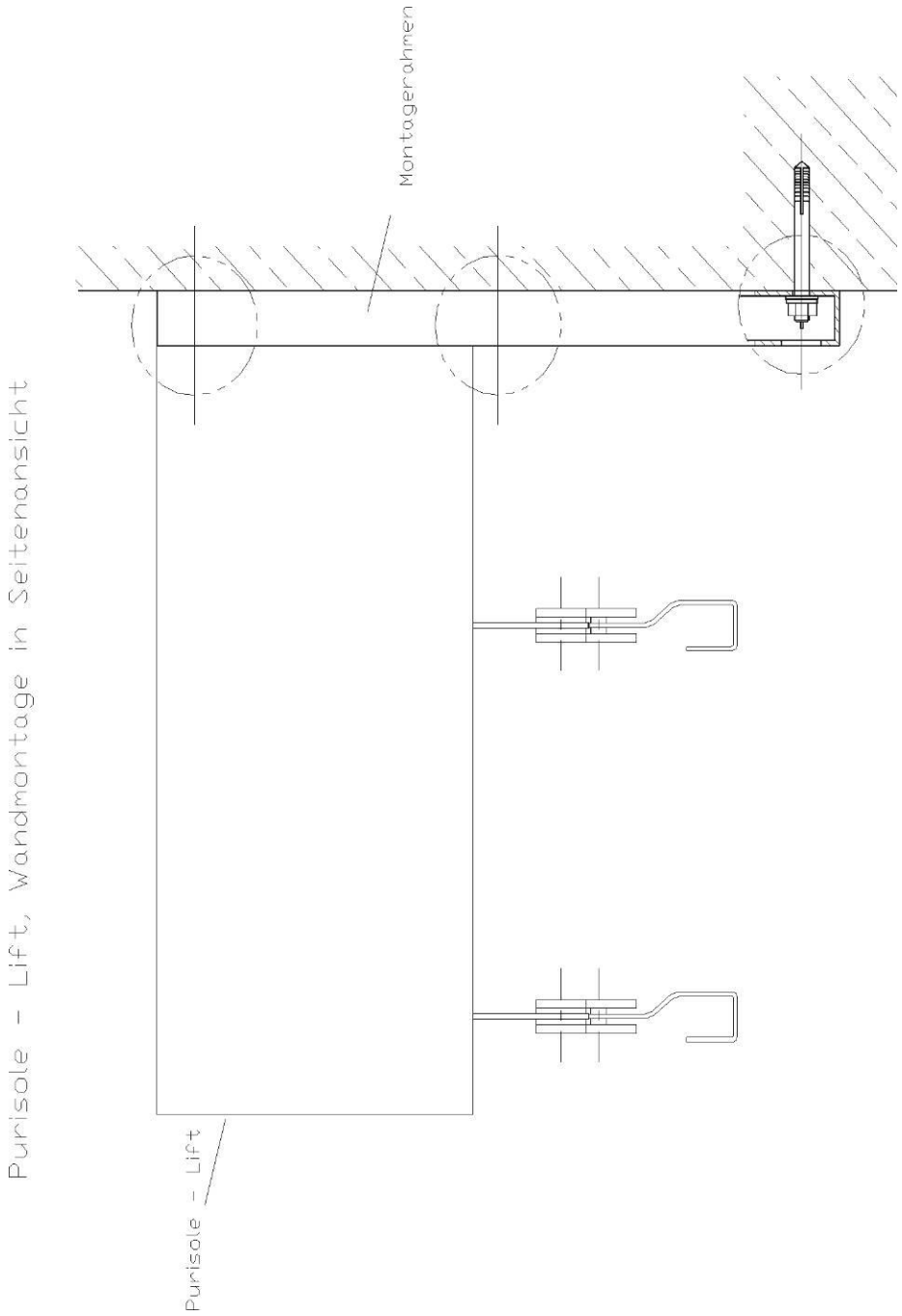


Figure 5.4: Purisole lift, side view of wall installation, 1:2 scale

5.4 Shut down

For decommissioning, the hooks are unloaded and completely retracted. Subsequently shutdown is accomplished by pulling the Schuko plug from the Schuko outlet.

6 Technical specifications

6.1 General information

Duty cycle:	KB 5 min. (short duty cycle of 5 minutes)
Operating modes:	Manual switch
Control circuit:	Only one motor can be in operation at any time; both directions of travel are limited by a limit switch
Lifting force per lift	12 kg each
Max. belt length	2.3m ±0.1m
W/H/D	428 / 273 / 145 mm
Attachment method	suited for wall and ceiling installation
Weight	approx. 18 kg
Material	VA 1.4301 / AL Mg 3 powder-coated
Connected electrical load	
Mains connection	Power cable (length: 3 m) H 05 VV – F3 GO, 75 with Schuko plug
Current draw:	0.45 A
Power consumption:	80 W
Device protection:	2 x fine wire fuse 0.5 A m (F1, F2)
Protection class	I
Radio interference protection rating	EN 60601-1-2 Class B
Electro Magnetic Environments	The Purisole Lift is intended for the operation of the environment in professional health care facilities. For example: independent surgery centers, independent birth centers, polyclinics, clinics (emergency rooms, hospital rooms, intensive care, operating rooms except in the vicinity of electrosurgical equipment, outside the RF-shielded room of an ME system for magnetic resonance imaging).
Disposal	The unit must be disposed in compliance with applicable statutory regulations.

6.2 Operating conditions

Ambient temperature	15° - 30°C
Rel. humidity	Max. 80 %, non-condensing
Air pressure	700 hPa to 1150 hPa
Installation height	Up to 3000m
Equi-potential bond	The equi-potential bond must be connected in compliance with national statutory regulations (e.g in Germany: VDE 0100-710,

edition 11.2002).

The equi-potential bond must be connected on the underside of the unit if so required by statutory regulations at the installation location (e.g. iaw. DIN VDE 0100-710 in group 2 application rooms).

6.3 Transportation and storage conditions

Note

Do not tip.

Temperature range -20°C to 50°C

Note

Do not allow to fall.

Air pressure 500 hPa to 1150 hPa

Note

Do not drop.

Rel. humidity Max. 90 %, non-condensing

6.4 Electrical supply

Electrical supply	
Mains voltage IT networks	~ 230 V protected by max 6 A circuit breaker
Mains voltage other networks	~ 230 V protect by max 6 A circuit breaker and 30 mA FI circuit breaker
Frequency	50 / 60 Hz
Current draw	approx. 1.0 A

6.5 Surface cleaning

Warning

Pull the power plug from the outlet before cleaning the unit to avoid accidents.

Note

Do no use abrasives or aggressive cleaning agents and solvents.

Remove dust and dirt from the housing surface with a soft cloth or a brush.

If the housing of the Purisole-Lift and / or the handset is heavily soiled, wipe any heavily soiled areas of the housing with a moist cloth. Use water or small volumes of an antiseptic cleaning agent to wet the cloth. We recommend the product Freka-Nol.

The safety instructions of the cleaning agent manufacturer must be observed!

6.6 Disposal

At the end of its useful life, the unit must be disposed in compliance with statutory regulations.

Compliance with German Electrical and Electronic Device Act (ElektroG)

The equipment must not be disposed in the household waste.

6.7 Reporting of serious incidents

All serious incidents related to the device shall be reported to the manufacturer and to the competent authority of the Member State where the user and/or the patient is established.

6.8 Manufacturer's declaration for German Electromagnetic Compatibility Directive (EMV) (IEC 60601-1-2)

The unit completed and passed EMC testing.

Note

The device should not be installed directly next to other electrical devices. Avoid using this device directly next to other devices or with other stacked devices.

The installation requirements are specified in the user manual (installation requirements).

When operation next to other electrical equipment is necessary, a review must determine whether the performance of a device is impaired by unintended electromagnetic coupling.

WARNING!

Portable Radio Frequency communication devices (radio equipment) (including their accessories such as antenna cables and external antennas) should not be used within 30 cm (or 12 inches) of the Purisole Lift and its handset.

Failure to do so may result in a reduction in the performance of the device.

WARNING!

To maintain safety and function with regard to electromagnetic disturbances, the tests specified in Chapter 7 must be carried out and the instructions given there must be observed.

6.8.1 Electromagnetic emission

Störaussendung EN 55011 (2009)

Anschluss	Frequenzbereich	Grenzwerte	Grund-norm	Anwend-barkeit	Bemerkung	Bewertung
Gehäuse	30 MHz bis 230 MHz	30 dB(µV/m) Quasispitzenwert in 10 m Messentfernung 40 dB(µV/m) Quasispitzenwert in 3 m Messentfernung	IEC/ CISPR 11		Die Messentfernung beträgt 3 m, damit erhöht sich der in der Norm angegebene Grenzwert um 10 dB.	bestanden
	230 MHz bis 1000 MHz	37 dB(µV/m) Quasispitzenwert in 10 m Messentfernung 47 dB(µV/m) Quasispitzenwert in 3 m Messentfernung				
Wechsel-spannungs-Netzanschluss	0 Hz bis 2 kHz		IEC 61000-3-2 IEC 61000-3-3		Flicker/ Oberwellen	bestanden
	0,15 MHz bis 0,50 MHz	66 dB(µV) bis 56 dB(µV) QP 56 dB(µV) bis 46 dB(µV) AV	IEC/ CISPR 11 IEC/ CISPR 11			bestanden
	0,50 MHz bis 5 MHz	56 dB(µV) Quasispitzenwert 46 dB(µV) Mittelwert				
	5 MHz bis 30 MHz	60 dB(µV) Quasispitzenwert 50 dB(µV) Mittelwert				

Anmerkungen:

zu Gehäuse:

zu Niederspannungs-Wechselspannungs-Stromversorgungsanschluss: ***Prüfung erfolgte mit einer Handnachbildung am Hand-Bedienschalter.***

6.8.2 Electromagnetic immunity

Störfestigkeit - Gehäuse **60601-1-2 (2015)**

	Umgebungs-Phänomen		Prüfstörgröße	Einheiten	Grundnorm	Bemerkung	Kr.	Bewertung
1.1	Magnetfeld mit energietechnischer Frequenz		30 50, 60	A/m Hz	IEC 61000-4-8	bei Versorgungsfrequenz siehe [a]	A [b]	entfällt
1.2	Elektromagnetisches HF-Feld, amplitudenmoduliert		80 bis 1000 3 (**10 bei häuslicher Anwend.**) 80 Verweilzeit ≥ 1 sec.	MHz V/m % AM (1 kHz)	IEC 61000-4-3 [c]	der festgelegte Prüfpegel ist der Effektivwert des unmodulierten Trägers	A	bestanden
1.3	Elektromagnetisches HF-Feld, amplitudenmoduliert		1,4 bis 2,0 3 (**10 bei häuslicher Anwend.**) 80 Verweilzeit ≥ 1 sec.	GHz V/m % AM (1 kHz)	IEC 61000-4-3 [c]	der festgelegte Prüfpegel ist der Effektivwert des unmodulierten Trägers [d]	A	bestanden
1.4	Elektromagnetisches HF-Feld, amplitudenmoduliert		2,0 bis 2,7 3 (**10 bei häuslicher Anwend.**) 80 Verweilzeit ≥ 1 sec.	GHz V/m % AM (1 kHz)	IEC 61000-4-3 [c]	der festgelegte Prüfpegel ist der Effektivwert des unmodulierten Trägers [d]	A	bestanden
1.5	ESD	Kontaktentl. Luftentl.	+/- 8 +/- 2, 4, 8, 15	kV kV	IEC 61000-4-2	Siehe Grundnorm zur Anwendbarkeit der Kontakt- und/oder der Luftentladung	B B	bestanden

Anmerkungen:

zu 1.1 entfällt, da keine entsprechenden Komponenten verbaut.
zu 1.2 es wurde mit 10 V/m geprüft, um auch den Anforderungen der häuslichen Umgebung gerecht zu werden. Überwachungskriterium war der Abstand des Holzbalkens zur oberen Kante des Hakenbleches. (21,5 cm, keine Veränderungen)
zu 1.3 es wurde mit 10 V/m geprüft, um auch den Anforderungen der häuslichen Umgebung gerecht zu werden. Überwachungskriterium war der Abstand des Holzbalkens zur oberen Kante des Hakenbleches. (21,5 cm, keine Veränderungen)
zu 1.4 es wurde mit 10 V/m geprüft, um auch den Anforderungen der häuslichen Umgebung gerecht zu werden. Überwachungskriterium war der Abstand des Holzbalkens zur oberen Kante des Hakenbleches. (21,5 cm, keine Veränderungen)
zu 1.5

Störfestigkeit - direkte Nähe von drahtlosen Kommunikationsgeräten **60601-1-2 (2015)**

Prüffrequenz MHz	Frequenzband [a] MHz	Funkdienst [a]	Modulation [b]	Maximale Leistung W	Entfernung m	STÖRFESTIGKEITS-PRÜFPEGEL V/m
385	380 bis 390	TETRA 400	Pulsmodulation [b] 18 Hz	1,8	0,3	27
450	430 bis 470	GMRS 460, FRS 460	FM [c] ± 5 kHz Hub 1 kHz Sinus	2	0,3	28
710	704 bis 787	LTE Band 13, 17	Pulsmodulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 bis 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulsmodulation [b] 18 Hz	2	0,3	28
870						
930						
1 720	1 700 bis 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulsmodulation [b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 bis 2 570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulsmodulation [b] 217 Hz	2	0,3	28
5 240	5 100 bis 5 800	WLAN 802.11 a/n	Pulsmodulation [b] 217 Hz	0,2	0,3	9
5 500						
5 785						

ANMERKUNG Falls notwendig, kann zum Erreichen der STÖRFESTIGKEITS-PRÜFPEGEL der Abstand zwischen der Sendeantenne und dem ME-GERÄT oder ME-SYSTEM auf 1 m verringert werden. Die 1-m-Prüfentfernung ist nach IEC 61000-4-3 gestattet.

[a] Für manche Funkdienste wurden nur die Frequenzen für die Funkverbindung vom mobilen Kommunikationsgerät zur Basisstation (en: uplink) in die Tabelle aufgenommen.

[b] Der Träger muss mit einem Rechtecksignal mit 50 % Tastverhältnis moduliert werden.

[c] Alternativ zur Frequenzmodulation (FM) kann eine Pulsmodulation mit 50 % Tastverhältnis mit 18 Hz verwendet werden, da diese, wenn auch nicht die tatsächliche Modulation, so doch den schlimmsten Fall darstellen würde.

Anmerkung: Die Prüfung wurde nur bis 2700 MHz durchgeführt.

Note

The test of the interference immunity against high-frequency wireless communication devices was not tested in the 5-6 GHz range, since no processors or components are used in the control which operate with such clock frequencies and an influence of these components is not thinkable.

Störfestigkeit - Signalanschlüsse **60601-1-2 (2015)**

	Umgebungs-Phänomen	Prüfstörgröße		Einheiten	Grundnorm	Bemerkung	Kr.	Bewertung
2.1	Hochfrequenz, asymetrisch	0,15 bis 80 3 (**6 in den ISM-Bändern**) 80 Verweilzeit ≥ 1 sec.		MHz V % AM (1 kHz)	IEC 61000-4-6	Der festgelegte Prüfpegel ist der Effektivwert des [a] [b]	A	bestanden
2.2	Schnelle Transienten	+/- 1 5/50 100		kV Tr/Th ns kHz	IEC 61000-4-4	Verwendung der kapazitiven Koppelzange. [b]	B	bestanden
2.3	Stoßspannungen unsym. (Leitung gegen Erde)	1,2/50 (8/20) +/- 2		Tr/Th µs kV	IEC 61000-4-5		B	entfällt
2.4	ESD	Kontakte ntl. Luftentl.	+/- 8 +/- 2, 4, 8, 15	kV kV	IEC 61000-4-2	Siehe Grundnorm zur Anwendbarkeit der Kontakt- und/oder der Luftentladung	B B	bestanden

Anmerkungen:

zu 2.1 Überwachungskriterium war der Abstand des Holzbalkens zur oberen Kante des Hakenbleches. (21,5 cm, keine Veränderungen)
zu 2.2 Überwachungskriterium war der Abstand des Holzbalkens zur oberen Kante des Hakenbleches. (21,5 cm, keine Veränderungen)
zu 2.3
zu 2.4 entfällt, da keine Leitungslängen im Außenbereich.

Störfestigkeit - Wechselstrom Netzein- und ausgänge **60601-1-2 (2015)**

	Umgebungs-Phänomen	Prüfstörgröße	Einheiten	Grundnorm	Bemerkung	Kr.	Bewertung
4.1	Hochfrequenz, asymetrisch	0,15 bis 80 3 (**6 in den ISM-Bändern**) 80 Verweilzeit ≥ 1 sec.	MHz V % AM (1 kHz)	IEC 61000-4-6	Der festgelegte Prüfpegel ist der Effektivwert des unmodulierten Trägers. [a]	A	bestanden
4.2	Spannungseinbrüche	0 0,5 (bei 0, 45, 90, 135, 180, 225, 270, und 315 Grad Phase)	% Restsp. Zyklen	IEC 61000-4-11	Spannungssprung beim Nulldurchgang. [b]	B	bestanden
		0 1	% Restsp. Zyklen			B	bestanden
		70 25/30 bei 50/60 Hz	% Restsp. Zyklen			C	bestanden
4.3	Spannungsunterbrechungen	0 250/300 bei 50/60Hz	% Restspg. Zyklen	IEC 61000-4-11	Spannungssprung beim Nulldurchgang. [b]	C	bestanden
4.4	Stoßspannungen unsym. (Leitung gegen Erde) sym. (Leitung gegen Leitung)	1,2/50 (8/20) +/- 0,5, +/- 1, +/- 2 +/- 0,5, +/- 1	Tr/Th µs kV kV	IEC 61000-4-5		B	bestanden
4.5	Schnelle Transienten	+/- 2 5/50 100	kV Tr/Th ns kHz	IEC 61000-4-4		B	bestanden

6.8.3 Recommended protective distances between portable and mobile HF telecommunication devices and the unit

Recommended protective distances between portable and mobile HF telecommunication devices and the Purisole Lift

The Purisole Lift is intended for operation in an electromagnetic environment in which HF interference is controlled. The customer or user of the Purisole Lift can help to avoid electromagnetic interference by complying with the minimum distance between portable and mobile HF telecommunications devices (transmitters) and the Pursiole Lift - depending on the output power of the communications device, as indicated below.

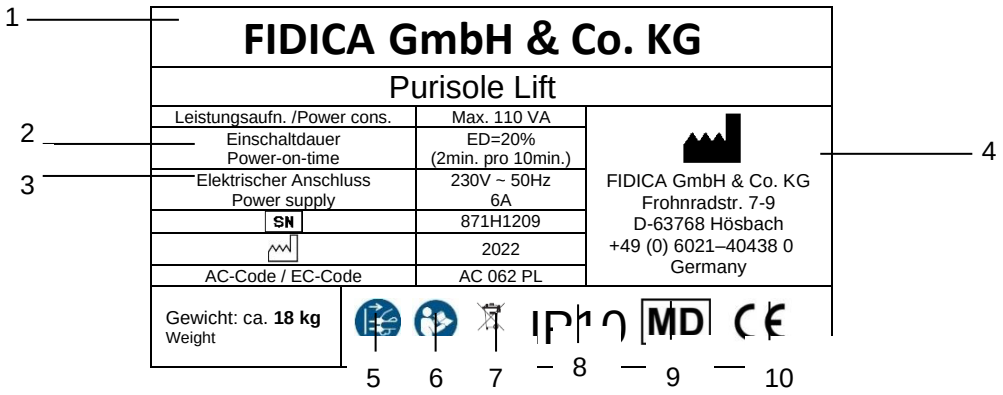
Nominal power of transmitter W	Protective distance as a function of transmission frequency m		
	150 kHz to < 80 MHz d = 1.17 √P	80 MHz to < 800 MHz d = 1.17 √P	800 MHz to 2.5 GHz d = 2.33 √P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.7	11.7	23.3

For transmitters whose nominal output is not indicated in the above table, the recommend protective distance d in meters (m) can be determined by employing the equation associated with the relevant column, wherein *P* is the maximum nominal output of the transmitter in watts (W) as per the transmitter manufacturer specifications.

Note 1: The higher frequency range applies for 80 MHz and 800 MHz.

Note 2: These guidelines may not apply in all cases. The propagation of electromagnetic phenomena is influenced by the absorption and reflection of buildings, objects and persons.

6.9 Type tag



1. Type label
2. Serial number
3. Date of production
4. Manufacturer
5. Disconnect the power plug before opening the housing!
6. Comply with user manual
7. Labeling of electrical and electronic devices
8. Protection against ingress of solid foreign particles ≥ 50 mm
9. Medical Device
10. CE label

7 Maintenance

WARNING !

The Purisole lift must not be serviced while in use or in general operation.

WARNING !

Before opening the housing, disconnect the Purisole-Lift from the power supply and secure it against being switched back on. To do this, the mains plug must be removed or the power supply must be disconnected from the mains isolating device.

WARNING !

After every repair or after every intervention on the device, a test of the electrical safety according to VDE 0751-1/DIN EN62353 is necessary.

ATTENTION !

The mains connection cable can be replaced by the maintenance personnel. The instructions under item 7.6 must be strictly observed and followed.

ATTENTION !

If components other than those listed below have to be replaced, the manufacturer must be contacted and the device sent in due to possible risks during the repair work.

An electrical safety inspection in accordance with VDE 0751-1 is required following every repair and any procedure performed on the unit.

The following annual inspections must be performed on the unit:

1. suspension and belts must be free of dirt or visible damage that can impair safe operation. This involves fully raising and lowering each belt, while inspecting the requirement.
2. The manual switch and connected cables must be inspected for proper function, dirt, and insulation damage.
3. Any influences affecting the strength of the suspension of the lift must be eliminated immediately.
4. Labels and stickers must be legible!

7.1 Spare parts list

Manual switch with interface cable:	Part No. G09000030
Equipment fuse slow 5x20mm 0.5AH SPT:	Part No. E09600018
Installation frame:	Part No. M12004061
Auxiliary and installation frame for hung ceilings:	Part No. G03000105
Mains connection cable with mains plug:	Part No. M11000360

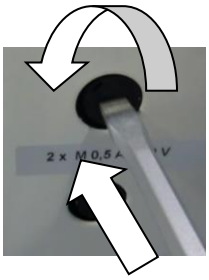
Initial values

SN:	.....	Protective conductor resistance:	mOhm
Date:	.....	Ground leakage current NC:	µA
Name:	.....	Ground leakage current SFC:	µA

7.2 Circuit diagrams

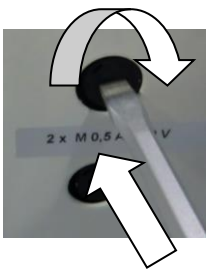
The manufacturer will on request supply circuit diagrams, component lists, and descriptions.

7.3 Replacing the fuse



In order to remove the old fuse from the Purisole Lift, use a screwdriver to lightly press the retainer inward and then rotate the retainer counter-clockwise.

The retainer will now spring out slightly and can then be removed. The fuse can now be pulled from the retainer. Now insert a fuse of the indicated type: T 0,5AH, 250V



Reinstall the retainer with the new fuse by positioning it back in the opening. Then use a screwdriver to push the retainer into the opening and engage by rotating in clockwise direction.

7.5 Replacing the manual switch with connection cable

WARNING!

The use of accessories and cables other than those specified here may result in increased electromagnetic interference emissions or reduced electromagnetic immunity of the device and may lead to faulty operation.

To replace the manual switch, proceed as follows.

Turn the outer aluminium sleeve of the handset plug at the Purisole lift connector to the left. You can then unplug the plug and remove the handset.

When connecting the new handset, make sure that the alignment of the centering pin matches the recess groove in the connection socket. The pin at the edge of the connector must match the recess at the socket. Connect the plug aligned and turn the black sleeve to the right again. Now you can use the new handset

7.6 Replace the mains cable with mains plug:

WARNING !

The mains connection cable must have a nominal cross section of 0.75 mm² per conductor core.

Power supply cords for this unit must not be less resistant than standard flexible rubber hose cords (IEC 60245-1 :2003, Annex A marking 53) or standard flexible PVC hose cords (IEC 60227-1 :2003, Annex A, marking 53).

Therefore, only use the mains cable with mains plug, No. M11000360, provided by the manufacturer.

WARNING !

The blue and brown cores of the supplied mains connection cable must be shortened in such a way that the green-yellow protective conductor (PE) breaks at last if the strain relief fails when the mains cable is pulled.

WARNING!

The use of accessories and cables other than those specified here may result in increased electromagnetic interference emissions or reduced electromagnetic immunity of the device and may lead to faulty operation.

Required tools:

- Phillips-tip screwdriver

- Slotted screwdriver

- 22 mm open-end wrench

1. Pull out the mains plug!

WARNING !

Secure against being switched on again.

Make sure that the power plug cannot be easily reconnected.

2. open the housing on the right side
3. loosen the blue, brown and green-yellow wires at the terminal strip
4. open cable gland and pull out power cable
5. Installation in reverse order. Make sure that the power supply cable is routed in a clean bend from the cable gland to the terminal strip. The cable must not be stretched.

   The blue and brown cores of the supplied mains connection cable must be shortened in such a way that the green-yellow protective conductor (PE) breaks off at last if the strain relief fails when the mains cable is pulled.
6. Tighten the cable gland to a torque of 1Nm.

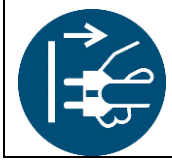
WARNING !

Make sure that the cable gland is securely tightened and sealed.

7. After installation and closing of the housing, a VDE 0751-1 measurement must be carried out!

8 Terminology and symbols

	Comply with user manual
SN	The serial number consists of the unit number (first three digits), the manufacturer ID (fourth digit), and a sequential number for each unit (last four digits)
	Manufacturer's address: FIDICA GmbH & Co. KG 63768 Hösbach Germany Tel.: +49 (0) 6021 -40438 0
	Equi-potential bond
	Labeling of electrical and electronic devices
CE	The CE marking confirms that basic requirements mandated in the Medical Device Regulation, MDR (2017/745) have been met and that the product underwent a conformity review.
IP10	Protection against ingress of solid foreign particles ≥ 50 mm; no protection against water.
1 2	Hook Nr. 1 and hook Nr. 2
	The hand control must always be at least 25 cm outside the surgery area. It must be installed and operated at least 25 cm outside the surgery environment.
2x T 0,5 AH, 250 V	Sticker next to the two black fuse holders. There are two fuses with the characteristic: T= slow-blow, 0.5A rated current, H = high breaking capacity 1500 A, nominal voltage = 250V AC.
	A hook may only be loaded with a maximum of 12 kg.

	Disconnect the power plug before opening the housing!