EN

Instructions for use

Dispenser DP 30

NOUVAG

CONGRATULATIONS ON YOUR PURCHASE OF A PRODUCT FROM NOUVAG.

We are pleased that you have chosen a quality product from NOUVAG and thank you very much for the trust you have placed in us.

These instructions for use will familiarize you with the device and its functions so that you can apply and use them correctly.

SYMBOLS

 General warning sign	 General mandatory action	 Refer to instructions for use
 Manufacturer	 Date of manufacture	 Use-by date
 Do not use if the package is damaged	 Not for reuse	 Separate collection required (WEEE)
 Biological hazard	 Not made with natural rubber latex	 Contains or presence of Phthalate
 Batch code	 Catalog number	 Serial number
 Medical device	 Sterilized using ethylene oxide	 Authorized representative in the European Community
 Water resistance	 Equipotentiality	 Indication of pump flow direction
 Type BF applied part	 Foot switch	 European Conformity mark
 Certified by the TÜV Rheinland North America Group		

CONTENT

PRODUCT DESCRIPTION

INTENDED USE AND OPERATION

The Dispenser DP 30 serves as Infiltration pump into the connective tissue and is used in the following field of applications:

¬ Tumescent infiltration for liposuction and vein treatment, varicose veins (phlebology)

The Dispenser DP 30 may only be operated by trained and qualified personnel in professional settings.

TARGET GROUP

Adult patients, in good health status.

CONTRAINDICATIONS

Infectious wounds Liposuction may only be performed after the treatment of the infection and necrotic tissue.
In principle, generally poor health of the patient.
Liposuction shortly after a strict diet of the patient.
Morbid obesity (obesity) Large suction volumes increase the risk of death due to fluid shifts.
Intravascular infusion of liquids.
Infiltration of excessive volume of tumescent solution (mutiple liters).
Treatment of a excessive surface area.

Relevant cases in the literature must be considered.

AMBIENT CONDITIONS

	TRANSPORT AND STORAGE	DURING USE
Relative humidity	max. 90 %	max. 80 %
Temperature	0 °C – 50 °C	10 °C – 30 °C
Atmospheric pressure	700 – 1’060 hPa	800 – 1’060 hPa

SAFETY INFORMATION

It is essential to bear the following information in mind:
Every use of the Dispenser DP 30 different to the product description defined in section [INTENDED USE AND OPERATION >4] causes risks for patients and trained personnel. If physical examinations and therapies are carried out without use of the devices then the device must be removed from the place of treatment.

EMC MANUFACTURER'S DECLARATION OF CONFORMITY

The use of (RF) Radio Frequency emitting devices and equipment as well as the occurrence of negative environmental factors in the close area of the Dispenser DP 30 may cause unexpected or adverse operation. The connection or the placing of other devices in close vicinity is not allowed.
Use only accessories and cables as specified in the product description. Further observe the EMC manufacturer declaration of conformity.

INTEGRATED PERISTALTIC PUMP

The integrated peristaltic pump is used for infiltration of watery solutions into the human connective tissue. The infiltration pump is not designed for intravascular infusion of liquids.

POSSIBLE RISKS AND SIDE EFFECTS

- Improper use can result in tissue or organ injuries to the patient or cuts to the user or a third person.
- In rare cases, a treatment can lead to mild neurological disorders. In very rare cases, a treatment can lead to endovenous heat-induced thrombosis.

SAFETY INFORMATION

MODIFICATIONS AND MISUSE

Modifications/manipulations on the Dispenser DP 30 and its accessories are not permitted. Failure to follow these instructions can have unpredictable consequences for the user, the patient or third parties. For consequential complications, resulting from illicit modifications/manipulations the manufacturer assumes no responsibility and the guarantee is void.

NOUVAG recommends the use of Klein tumescent anesthesia solution. The use of other solutions is on the responsibility of the surgeon. When infiltrating tumescent anesthesia solution, do not exceed 0.05% w/w anesthetic concentration.

ESSENTIAL REQUIREMENTS

Do not use the device if the shipping box has holes/cracks on the flat surfaces, and/or if the Styrofoam protective packaging is broken.

The Dispenser DP 30 may only be operated by qualified and trained personnel!

The use of third-party products is the responsibility of the operator. Functionality and patient safety cannot be guaranteed with third-party accessories.

Repairs may only be performed by authorized NOUVAG service technicians!

Improper use or repair of the device, or failure to observe these instructions, relieves NOUVAG from any obligation arising from warranty provisions or other claims.

Prior to using the device, before startup, and before operation, the user must always ensure that the device and accessories are in good working order and are clean, sterile and operational.

Ensure that the operating voltage setting corresponds to the local mains voltage.

The Dispenser DP 30 may only be operated under constant supervision of medical personnel. The absence of a warning buzz to indicate malfunctions of the device requires the permanent control of the volumetric displacement of the pump.

Exceeding maximal lidocaine dose can cause delayed systemic toxicity in patients.

The flow rate is determined by the user depending on the patient's health condition and the specific application. Do not exceed maximum recommended values.

Maximum dose of lidocaine based on patient weight and health status:
35 mg/kg body weight for liposuction infiltration
15 mg/kg body weight for phlebology.

DURING USE

The device is not sterile on delivery. Please observe the instructions [Cleaning and disinfection >12].

At choice of the instrument the user has to make sure it confirms to EN ISO 10993, means that it's biocompatible.

Do not use device in the vicinity of flammable mixtures!

The use of the Dispenser DP 30 other than that for which it was designed (see [Intended use and operation >4]) is not permitted. The responsibility is solely carried by the operator.

Infiltration in highly vascularized body areas can increase systemic lidocaine absorption.

Recommended flow rate:
for fat removal (liposuction) max 150 ml/min
for vein treatment (phlebology) max 100 ml/min

The choice of flow rate is patient-specific.
Example for patient weighing 70 kg, max lidocaine dose for liposuction:
2450 mg in 4,9 l solution, infiltrated in 33 minutes (150 ml/min)

SCOPE OF DELIVERY

REF	DESCRIPTION	QUANTITY
4180	Dispenser DP 30 control unit	1
1770	Stand for irrigation fluid bottle	1
31678	Dispenser DP 30 Instructions for use	1

SELECTIVELY: SET NO. 4186 – DISPENSER DP 30 CONTROL UNIT WITH ON/OFF FOOT SWITCH

REF	DESCRIPTION	QUANTITY
1513nou	ON/OFF foot switch	1

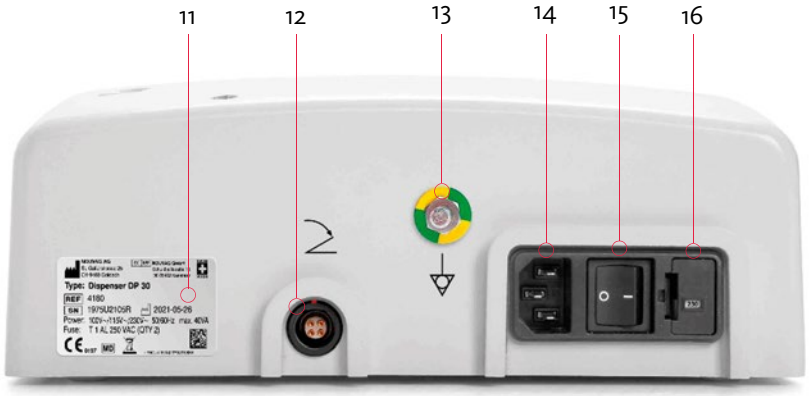
SELECTIVELY: SET NO. 4187 – DISPENSER DP 30 CONTROL UNIT WITH VARIO FOOT SWITCH

REF	DESCRIPTION	QUANTITY
1501nou	VARIO foot switch	1

DEVICE OVERVIEW

FRONT VIEW

REAR VIEW



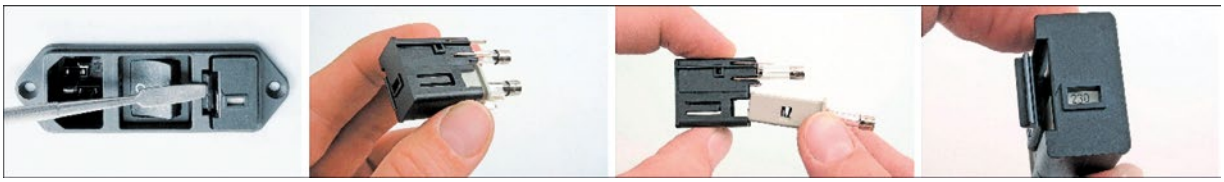
1 Indicator light for Power ON/OFF **2** Operating panel with pump displacement scale **3** Control dial to set pump displacement volume **4** Release key for tubing set bracket **5** Swiveling arm with integrated tubing set holder **6** Tubing set **7** Stand for irrigation fluid bottle **8** Roller clamp **9** Venting valve **10** Irrigation fluid container **11** Type plate with type designation, reference number, serial number, information on power supply and device fuse **12** Foot switch socket (device rear) **13** Potential equalization **14** Power entry module with power plug socket **15** Power entry module with power switch **16** Power entry module with national voltage setting

SETUP

CONNECTION TO THE POWER SUPPLY

In order to prevent the risk of electric shock, the device may only be connected to a power network with a PE protective earth conductor.

If the voltage shown does not correspond to the local mains voltage, the grey fuse holder must be set to the correct voltage:



1 **Switch off device.**

2 **Unplug the power cable.**

3 **Use a screwdriver to open the fuse slot.**

4 **Remove the fuse holder.**

5 **Remove the grey fuse holder and reinsert it so that the local mains voltage setting is shown in the small window.**

6 **Slide the grey fuse holder back in and close the fuse slot.**

7 **Check the mains voltage shown on the fuse slot.**

8 **Plug the power cable back into the device.**

POTENTIAL EQUALIZATION CONNECTION ACCORDING TO DIN 42801

At the back of the device a potential equalization plug is installed, according to DIN 42801.
The additional potential equalization has the task of equalizing potentials between different parts of conductive materials that can be touched at the same time, or reducing potential differences.
This connection must be used, to protect the patient, the user and third parties from touch voltages.

The equipotential plug is marked with the following symbol: ⏚

DEVICE PREPARATION

1 **Insert the stand for the irrigation fluid into the stand holder.**

2 **Plug the foot switch plug into the foot switch socket at the rear of the control unit.**

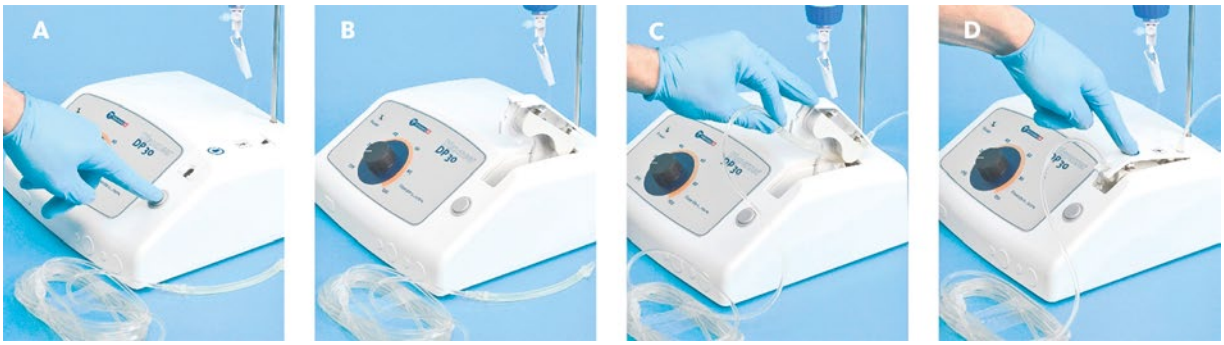
3 **Assemble the tubing set (see images).**

Check the expiry date of the tubing set and ensure that the packaging is not damaged. Using non-sterile tubing sets can result in serious infection, and in extreme cases, can be fatal.

Use only the NOUVAG tubing set REF 6022a/b, otherwise the function cannot be guaranteed.

When inserting the tubing set, notice the arrow marked on the tubing set bracket. It indicates the direction of flow of the infiltration liquid.

SETUP



A **Press the release key for tubing set bracket to open the pump.**

B **The compartment with the integrated tubing bracket opens.**

C **Place the tubing set into the tubing bracket provided in such a way that the end of the tubing set with the spike exits the pump to the rear of the control unit. Check that the tubing is secure.**

D **With the tubing set inserted, press the compartment downwards until it clicks into place.**

4 **Insert the spike at the end of the tubing set into the infiltration fluid bottle and hang the bottle onto the stand.**

5 **Open the roller clamp on the tubing set as far as it will go.**

6 **Open the vent valve at the spike.**

7 **Connect the control unit to the power socket.**

Ensure that the operating voltage setting corresponds to the local mains voltage!

The container of infiltration fluid may weigh a maximum of 2 kg. Heavier containers can cause the device to tip over.

The infiltration fluid flow is regulated via the pump integrated in Dispenser DP 30. Therefore, always leave the roller clamp open to the maximum.

DEVICE SETUP

- ¬ Place the Dispenser DP 30 and all required accessories and instruments on an even, non-slip surface and make sure you have good access to all controls.
- ¬ Do not allow the operating range of the device (including the cable) to be compromised by limiting factors.
- ¬ The system operation panel and the infiltration liquid bottle must be fully visible at all times.
- ¬ It must be explicitly ensured that no objects can fall onto the foot switch.
- ¬ The power plug at the rear of the device must be accessible at all times.

OPERATION

SWITCHING THE DEVICE ON AND OFF

The main switch «I/O» at the back of the unit is used to switch the control unit on and off. Switching off can be done at any time and is not dependent on a switch-off procedure.
The green LED light at the top left of the control panel lights up when the main switch has been activated and the unit is ready for operation.

REGULATION OF THE INFILTRATION PROCESS

Control dial in conjunction with ON/OFF foot switch The desired volumetric displacement is set with the control dial. The pumping process is started by actuating the ON/OFF foot switch. The volumetric displacement can be varied at any time using the control dial.
Control dial in conjunction with VARIO foot switch The maximum volumetric displacement can be varied at any time using the control dial, even while the foot switch is being pressed. Control using the VARIO foot switch regulates the volumetric displacement of the pump up to the set maximum value.

PERISTALTIC PUMP

Turn control dial clockwise from the OFF position. Pump starts, liquid emerges from the open tube end. Turning the dial up to the maximum value controls the increase in volumetric displacement.
The pump stops immediately when the release button of the pump compartment is pressed.

FLOW RATE WITHOUT INFILTRATION NEEDLE

	CONTROL DIAL				
FLOW RATE [ml/min]	20%	40%	60%	80%	100%
without infiltration needle*	46	92	138	184	230

RECOMMENDED SETTINGS FOR USE IN LIPOSUCTION

		CONTROL DIAL				
FLOW RATE [ml/min]		20%	40%	60%	80%	100%
with infiltration needle	Ø 3,00 mm*	45	90	135	—	—
with infiltration needle	Ø 1,20 mm*	45	90	135	—	—

RECOMMENDED SETTINGS FOR USE IN PHLEBOLOGY

		CONTROL DIAL				
FLOW RATE [ml/min]		20%	40%	60%	80%	100%
with infiltration needle	Ø 1,20 mm*	45	90	—	—	—
with infiltration needle	Ø 0,50 mm**	30	40	45	50	50

– not recommended
* Tolerance ± 25 %
** Tolerance ± 25 %, no linearity due to small needle diameter

FUNCTIONAL CHECK

Prior to Dispenser DP 30 startup or use of accessory equipment, the user must always ensure that each individual component is in good working order, free of defects, clean, sterile and operational. The tube set has to correspond with the correct flow direction and the pump has to function. The green LED is on after the device is switched on. To check if the device is in working order, press the foot switch as far as it will go and slowly turn the control dial on the device through the entire performance range. The maximum flow rate must be reached at the top end of the scale at the control dial.
In the event of problems, please check that the roller clamp on the tubing set is open as far as it will go and that the silicon section on the tubing set has been correctly inserted in the tubing bracket.

CLEANING AND DISINFECTION

Clean and disinfect the devices after every treatment!

CONTROL UNIT AND FOOT SWITCH

Wipe the outside using tested surface disinfectant or 70% of isopropyl alcohol. The front plate of the control unit is sealed and can be wiped clean.

TUBING SET REF 6022a/b

Single-use tubing sets may not be reused!

Used tubing sets must be disposed of properly.

Don’t use tube set when pack is already opened or damaged!

Do not use tubing set if expired.

Use only NOUVAG tubing sets with REF 6022a/b.

Sterility cannot be guaranteed by reusing and re-sterilization of tubing sets. The characteristics of the device may change resulting in serious infections or, in worst case, the death of the patient.

MAINTENANCE

REPLACING THE CONTROL UNIT FUSES

Users can replace faulty control unit fuses themselves. These are located at the rear of the device in the fuse slot beside the power switch:

1 **Switch off device.**

2 **Unplug the power plug.**

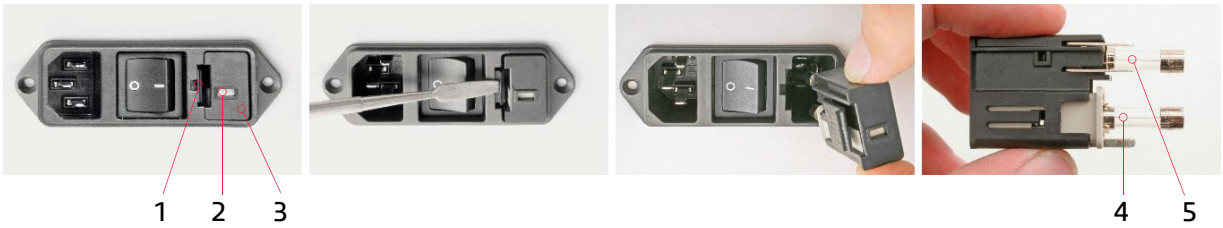
3 **Open the fuse slot using a screwdriver.**

4 **Replace the faulty fuse T 1 A, 250 V AC.**

5 **Slide the fuse holder back in and close the fuse slot.**

6 **Check the mains voltage shown on the fuse slot.**

7 **Plug in the power plug again.**



1 Fuse slot locking mechanism **2** Display window for voltage setting **3** Fuse slot **4** Fuse 1 **5** Fuse 2

SAFETY INSPECTIONS

The essential requirements have been defined and assessed within the risk analysis. The results of the analysis are stored in the risk management file of the manufacturer.

The performance of safety inspections on medical devices is required by law in several countries. The safety inspection is a regular safety check that is compulsory for those operating medical devices. The objective is to ensure that device defects and risks to patients, users or third parties are identified in time.

The STI (Safety Technical Inspection) for the Dispenser DP 30 shall be executed every 2 years by authorized experts. Results shall be documented. The service manual, wiring diagrams, and descriptions are available upon request from the manufacturer.

NOUVAG offers a safety inspection service for its customers. Addresses can be found in the appendix of this instructions for use under [Service points >16]. For further information please contact our technical service department.

MALFUNCTIONS AND TROUBLESHOOTING

MALFUNCTION	CAUSE	SOLUTION	REFER TO INSTRUCTIONS FOR USE
Device is not functional (Indicator light is off)	Control unit not switched on	Set the power switch «I/O» to «I»	[SWITCHING THE DEVICE ON AND OFF >11]
	Power connection not established	Connect the control unit to the mains power supply	[CONNECTION TO THE POWER SUPPLY >9]
	Incorrect operating voltage	Check the mains voltage	[CONNECTION TO THE POWER SUPPLY >9]
	Faulty fuse	Replace fuse	[REPLACING THE CONTROL UNIT FUSES >13]
Pump doesn't work (Indicator light is on)	Infiltration quantity set too low or set to «OFF»	Raise pump performance by turning control switch up	[REGULATION OF THE INFILTRATION PROCESS >11]
	Tubing set incorrectly inserted	Insert tubing set correctly	[DEVICE PREPARATION >9]
	Incorrect operation	Check instructions for use	[DEVICE PREPARATION >9]
	Foot switch was not pressed	Press foot switch down, if infiltration process is controlled via the foot switch	[REGULATION OF THE INFILTRATION PROCESS >11]
	Roller clamp is closed	Open roller clamp all the way	[DEVICE PREPARATION >9]
Foot switch doesn't work (Indicator light is on)	Foot switch is not connected	Connect foot switch with the socket on rear of device	[DEVICE OVERVIEW >8] [DEVICE PREPARATION >9]
	Incorrect operation	Check instructions for use	[DEVICE PREPARATION >9] [REGULATION OF THE INFILTRATION PROCESS >11]

If the problem cannot be solved please contact your supplier or an authorized service center. Addresses can be found in the appendix of this instructions for use under [SERVICE POINTS >16].

ACCESSORIES AND SPARE PARTS

ACCESSORIES

DESCRIPTION	REF
ON/OFF foot switch	1513nou
VARIO foot switch	1501nou
Stand for irrigation fluid bottle	1770
Disposable tubing set with spike and Luer-Lock connection, sterile, 4 m	6022a/b

To order any additional parts, please contact our customer service department.

INFORMATION ON DISPOSAL

When disposing of the device, device components and accessories, the regulations issued by the legislator must be followed.
To ensure environmental protection, old devices can be returned to the dealer or manufacturer.

⚠ Contaminated single-use tubing sets are subject to specific disposal requirements. Please observe prevailing national disposal regulations.

When discarding the device components and accessories, please comply with the issued statutory regulations. With regard to the preservation of the environment old equipment may be returned to the distributor or manufacturer.

TECHNICAL DATA

Voltage, switchable	100 V~ / 115 V~ / 230 V~, 50/60 Hz
Fuse power supply	2 fuses, T 1 A, 250 V AC
Power consumption	40 VA
Volumetric displacement	0–230 ml/min.
Maximum pressure with closed tube set	2,0 bar
Applied part	Type BF*
Protection class	Class I
Dimensions (W x D x H)	260 x 250 x 110 mm
Net weight control unit	2,4 kg
Maximum weight at the stand for the irrigation fluid bottle	2,0 kg

The mentioned volumetric displacement is only valid for aqueous solutions without any instrument connected.
* Applied part is the tube set with its attached instruments.

WARRANTY COVERAGE

NOUVAG warrants this product to be free from defects in workmanship and materials for a period of twelve (12) months from the original date of purchase. If the warranty card is returned for registration or the warranty extension is requested on our website within 4 weeks from the date of purchase, the warranty coverage is extended for a period of 6 months, wear parts are excluded from the warranty. During this warranty period, NOUVAG agrees to either repair or replace the product at its option if the product fails to function properly under normal use and service and such failure is due solely to a defect in workmanship or materials.
This warranty is void if repair or service of the product is performed or attempted by anyone not authorized by NOUVAG to do so, or if a replacement part not authorized by NOUVAG is used in any repair or service.

POST MARKET SURVEILLANCE

In the event of incidents related to the use of the medical device, please contact immediately the manufacturer by email complaint@nouvag.com or by phone.

To provide adequate information, please compile the incident questionnaire at the web address Nouvag.com > Contact us > Incident questionnaire.

SERVICE POINTS

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NOUVAG AG
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info@nouvag.com
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78462 Konstanz

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info-de@nouvag.com
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CE 0197

A complete list of NOUVAG certified service points are found on the NOUVAG website: Nouvag.com > Service

APPENDIX

Electromagnetic compatibility (EMC)

Remark:
The **Product** subsequently referred to herein always denotes the Dispenser DP 30.

Changes or modifications to this product not expressly approved by the manufacturer may result in increased emissions or decreased immunity performance of the product and could cause EMC issues with this or other equipment. This product is designed and tested to comply with applicable regulations regarding EMC and shall be installed and put into service according to the EMC information stated as follows.

WARNING
Use of portable phones or other radio frequency (RF) emitting equipment, including accessories (antennas e.g.) in distances below 30 cm (12 inches) to the product, may cause unexpected or adverse operation.

WARNING
The product is suitable for use in hospitals other than in the vicinity of active devices of the HF surgical devices or except in HF screening rooms used for magnetic resonance imaging.

WARNING
The product shall not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the product shall be tested to verify normal operation in the configuration in which it is being used.

Essential Performance
The essential performance is that the infiltration of tumescent solution in the fat tissue taking into account the infiltration flow rate and pressure is maintained. The maximum infiltration flow rate deviation is ± 25%, the infiltration flowrate is between 60 and 230ml/min and the maximum pressure is 2.5bar.

Compliant Cables and Accessories

WARNING
The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity performance of the product.
The table below lists cables, transducers, and other applicable accessories for which the manufacturer claims EMC compliance.
NOTE: Any supplied accessories that do not affect EMC compliance are not listed.

Description	Length max.
Power supply cord REF 22261 / 22262 / 22264 / 22266	3.0m
Foot pedal IPX8 REF 1501nou / 1513nou	2.9m

Guidance and manufacturer's declaration – electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Product 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	complies	

Guidance and manufacturer's declaration – electromagnetic immunity

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

Immunity tests	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	+/- 2 kV with 100kHz for power supply lines +/- 1 kV with 100kHz for input/output lines	+/- 2 kV with 100kHz for power supply lines +/- 1 kV with 100kHz for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 0.5 kV, +/- 1 kV differential mode +/- 0.5 kV, +/- 1 kV, +/- 2 kV common mode	+/- 0.5 kV, +/- 1 kV differential mode +/- 0.5 kV, +/- 1 kV, +/- 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

APPENDIX

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T; for 0,5 cycle with 0, 45, 90, 135, 180, 225, 270, 315 degree 0 % U_T; for 1 cycle	0 % U_T; for 0,5 cycle with 0, 45, 90, 135, 180, 225, 270, 315 degree 0 % U_T; for 1 cycle	Mains power quality should bet hat of a typical commercial or hospital environment. If the user of the Product requires continued operation during power mains interruptions, it is recommended that the Product be powered
	70 % U_T; for 25/30 cycles 0 % U_T; for 5 sec	70 % U_T; for 25/30 cycles 0 % U_T; for 5 sec	from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity for not life support equipment

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

Immunity tests	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC 61000-4-6	3 V rms 0.15 MHz to 80 MHz 6 V rms inside ISM bands between 150 kHz to 80 MHz 80% AM bei 1 kHz	3 V rms 0.15 MHz to 80 MHz 6 V rms inside ISM bands between 150 kHz to 80 MHz 80% AM bei 1 kHz	$d = 0{,}35\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM bei 1 kHz	3 V/m 80 MHz to 2.7 GHz 80% AM bei 1 kHz	$d = 0{,}35\sqrt{P}$ 80 MHz to 800 MHz $d = 0{,}7\sqrt{P}$ 800 MHz to 2,7 GHz
			Where *P* is the maximum output power rating in the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1:	At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2:	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
a	Fixed strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the Product is used exceeds the applicable RF compliance level above, the Product should b observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Product.
b	over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

APPENDIX

Electromagnetic immunity against high-frequency wireless communication devices						
Test frequency MHz	**Frequency band** MHz	**Communication service**	**Modulation**	**Maximum Performance** W	**distance** m	**Test level** V/m
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM ± 5 kHz Hub 1 kHz Sinus	2	0.3	28
710	704 to 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700 to 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 to 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
8785						

Recommended separation distances between portable and mobile RF communications equipment and the not life support equipment

The Product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Product can help prevent electromagnet interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Product as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 0{,}35\sqrt{P}$	**80 MHz to 800 MHz** $d = 0{,}35\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 0{,}7\sqrt{P}$
0,01	0,04	0,04	0,07
0,1	0,11	0,11	0,22
1	0,35	0,35	0,7
10	1,1	1,1	2,2
100	3,5	3,5	7

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the higher frequency range applies.

Note 1: At 80 MHz and 800 MHz, the separation distance fort the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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