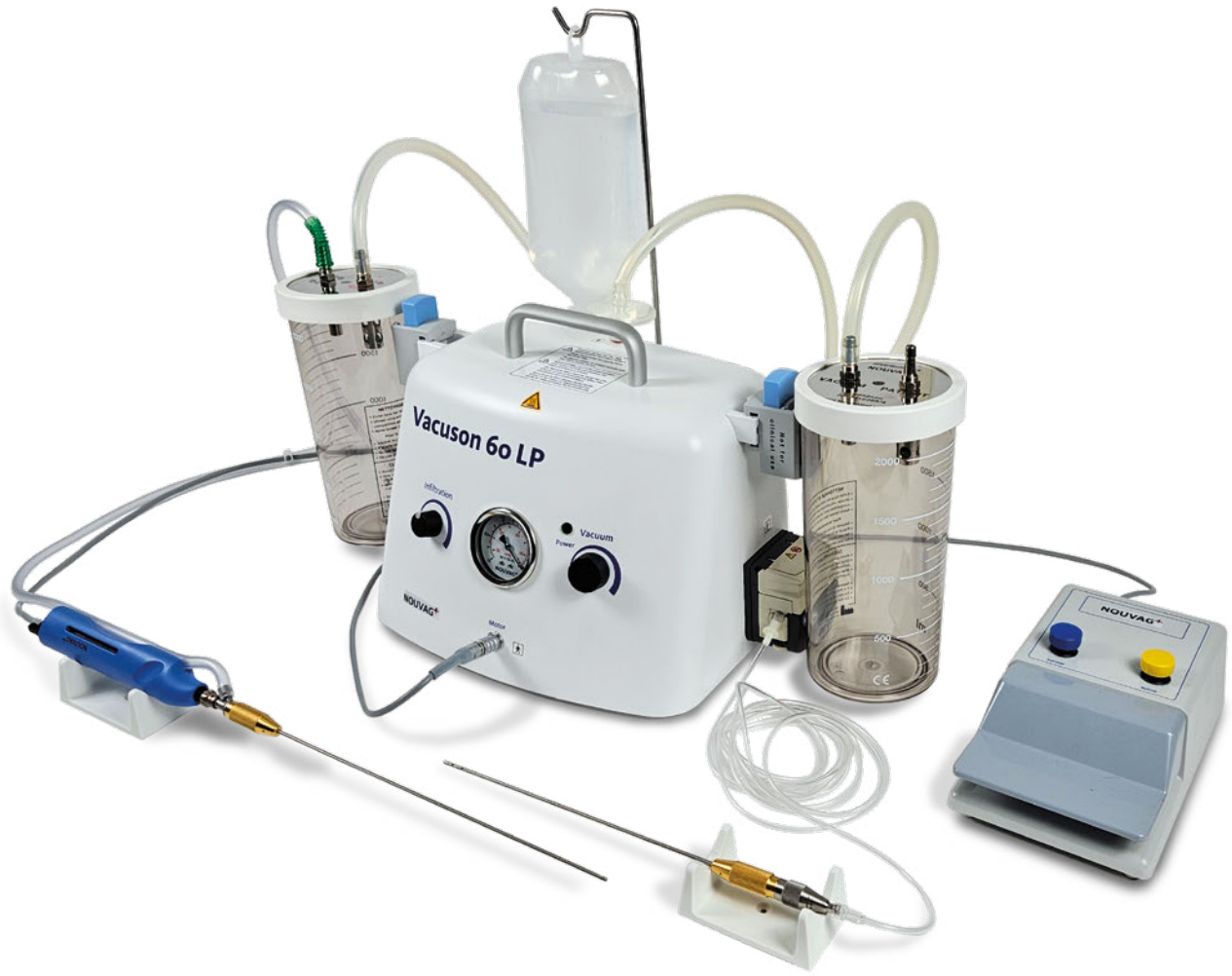
EN

Instructions for use

Vacuson 60 LP

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	 Importer
 Do not use if the package is damaged	 Not for reuse	 Use-by date
 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
 Separate collection required (WEEE)	 Certified by the TÜV Rheinland North America Group	

CONTENT

PRODUCT DESCRIPTION

INTENDED USE AND OPERATION

The Vacuson 60 LP is a useful and precisely coordinated liposuction device combination consisting of an infiltration and suction pump and is used in the following area:

¬ Tissue-sparing liposuction with or without tumescent local anaesthesia

In combination with the appropriate accessories, a gentle treatment can be performed that offers significant advantages for outpatient liposuction. When used correctly, liposuction is easier, less risky and less prone to complications, safer and reduces the costs incurred, which leads to optimal cosmetic results.

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.

Relative or absolute contraindications result from general knowledge of the patient's condition or in cases where the risk for motorised systems is significantly higher.
Relevant cases in the literature must be considered.

AMBIENT CONDITIONS

	TRANSPORT AND STORAGE	DURING USE
Relative humidity	10 % – 90 %	max. 80 %
Temperature	0 °C – 50 °C	10 °C – 60 °C
Atmospheric pressure	700 hPa – 1'060 hPa	800 hPa – 1'060 hPa

SAFETY INFORMATION

It is essential to bear the following information in mind:
Every use of the Vacuson 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 Vacuson 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.

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 Vacuson 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.

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 Vacuson 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.

DURING USE

The device is not sterile on delivery. Please observe the instructions [Cleaning and disinfection >16].

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!

While in operation the control unit of the Vacuson suction pumps must be at least 1 meter above ground.

In extreme cases, the device may heat up excessively.

The use of the Vacuson 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.

SCOPE OF DELIVERY

VACUSON 60 LP SET (REF 4179-115 / REF 4179-230)

REF	DESCRIPTION	QUANTITY
4285-115 4285-230	Vacuson 60 LP (115V) Control unit Vacuson 60 LP (230V) Control unit	1
1861nou	VARIO foot switch with pedal, IPX8	1
4052	Secretion jar, 2 litre, polysulfone, sterilisable	2
4076	Suction tube Ø 8 × 3 × 1700 mm, silicone, sterilisable	1
4246	Bacteria filter for suction pump, Ø 64 mm, PTFE, hydrophobe, disposable	1
4155z	Connecting tube Ø 8 × 3 × 400 mm, from bacteria filter to secretion jar, silicone, sterilisable	1
4190	Connecting tube Ø 8 × 3 × 500 mm, from bacteria filter to secretion jar, silicone, sterilisable	1
2101nou	Electronic motor 21, 12'000 rpm	1
5107	Handle, complete	1
5077nou	Conform cannula handpiece	1
1170	Handpiece tray	1
29061	Clip set, for tubing set attachment to motor cable, PU 5 pcs.	1
4044	Quiver, sterilisable, 400 mm length, with suspension device	1
1770	Stand for irrigation fluid bottle	1
31793	Vacuson 60 LP Instructions for use	1
6022	Disposable tubing set, sterile, 4 m, PU 10 pcs.	1
6026 6026E	Disposable tubing set Ø 9 × 6.5 mm, sterile, 4 m, PU 40 pcs.	1

OPTIONAL SECRETION JARS AND ACCESSORIES

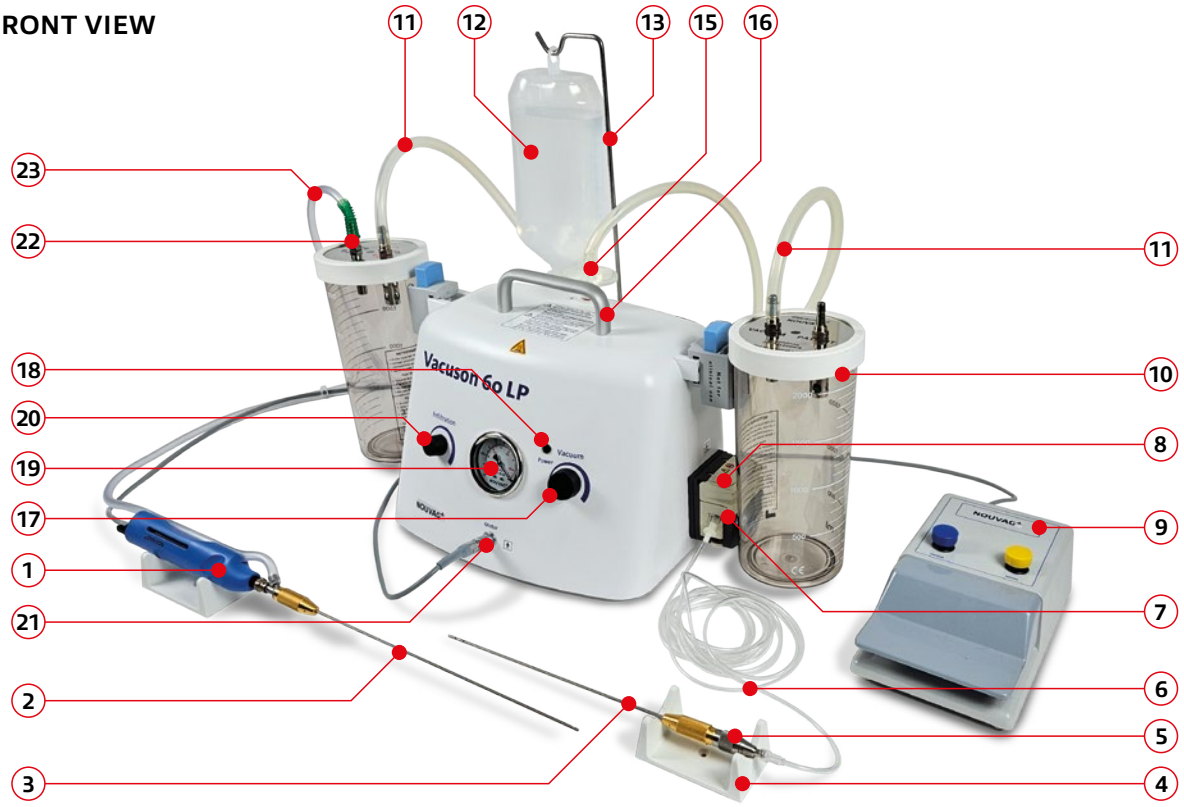
REF	DESCRIPTION	QUANTITY
4052nou 4052usa	Secretion jar, 2 litre, polysulfone, sterilisable	1
4245nou 4245usa	Secretion jar, 5 litre, polysulfone, sterilisable	1
4287	Suction jar 2 l, reusable	1
4288	Suction jar 5 l, reusable	1
4289	Lid for suction jars 2 l / 5 l, reusable	1
4291	Suction jar 3 l, reusable	1
4292	Suction liner 3 l, single-use, PU 70 pcs.	1
4290	Coupling piece 90°, reusable, PU 10 pcs.	1

OPTIONAL POWER CORDS

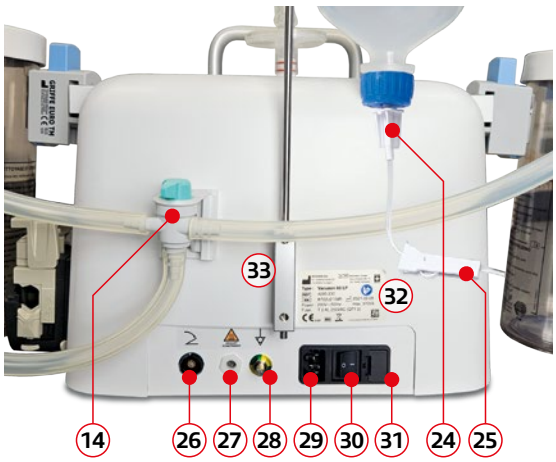
REF	DESCRIPTION	QUANTITY
22261	Power cord CH, with device socket, 3 m	1
22262	Power cord DE, with device socket, 3 m	1
22264	Power cord GB, with device socket, 3 m	1
22266	Power cord US, with device socket, 3 m	1

DEVICE OVERVIEW

FRONT VIEW



REAR VIEW



1 Conform cannula handpiece **2** Suction cannula (optional) **3** Infiltration cannula (optional) **4** Handpiece cradle **5** Cannula adapter with Luer-Lock connection (optional) **6** Tubing set for infiltration **7** Peristaltic pump for infiltration **8** Closing flap of peristaltic pump **9** Electronic foot switch with pedal **10** Secretion jar with lid **11** Connecting tube **12** Bottle with infiltration solution (third-party product) **13** Bottle holder for infiltration solution **14** 2-way tap (optional, REF 4130) **15** Bacteria filter **16** Carrying handle **17** Vacuum control «Vacuum» **18** Indicator light, LED «Power» **19** Vacuum manometer **20** Infiltration control «Infiltration» **21** Motor socket **22** Connection for suction tube **23** Suction tube **24** Spike of infiltration tube set with air vent **25** Roller clamp **26** Pedal socket **27** Hot air exhaust (EXHAUST) **28** Connection for potential equalization **29** Mains connection **30** Power switch «ON/OFF» **31** Fuse compartment **32** Type plate with type designation, reference number, serial number, information on power supply and device fuse **33** Stand holder for infiltration bottle

SETUP

DEVICE SETUP

INSTALLATION LAYOUT

- ¬ Place the Vacuson suction pump 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 manometer must be fully visible at all times.
- ¬ The foot switch must be placed within stepping distance between the patient and the surgeon.
- ¬ 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.
- ¬ The ventilation slots at the housings bottom and sideways of the Vacuson must be kept clear in order to prevent temperature from becoming excessive.
- ¬ While in operation the Vacuson suction pumps must be at least 1 meter above ground.

CONNECTION TO THE POWER SUPPLY

Before switching on, make sure that the power supply unit of the device matches the country's specific service voltage!

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.

Only a tested mains cable may be used to connect the device to the power supply.

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: ⏚

SETUP

PREPARING REUSABLE SECRET JARS

1 **Have an open, sterile secretion jar (2 or 5 litres) ready.**

Follow the instructions for use when installing the secretion jars.

PREPARING SECRETION JARS WITH DISPOSABLE INLAY POUCH

1 **Hold the secretion jar ready with disposable inlay pouch and mounting bracket.**

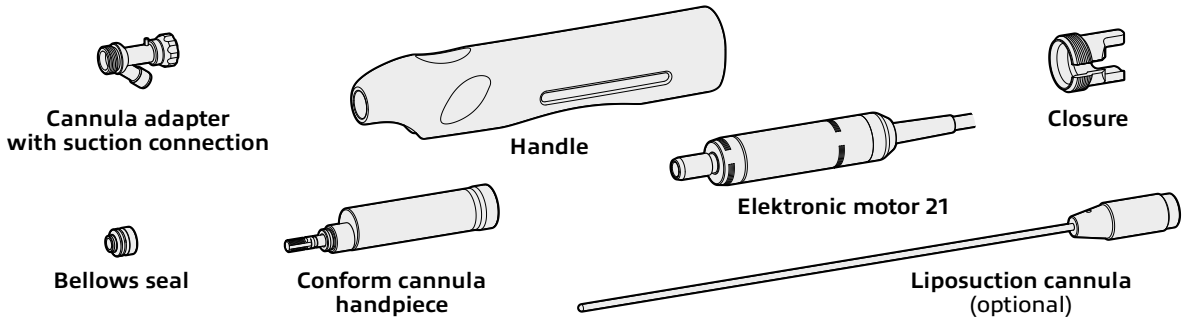
2 **Place the angle connector on the lid (PATIENT), place the insert bag in the jar and close the jar by applying sustained pressure to the lid.**

3 **Hang the holder ring on the Vacuson and attach the jar.**

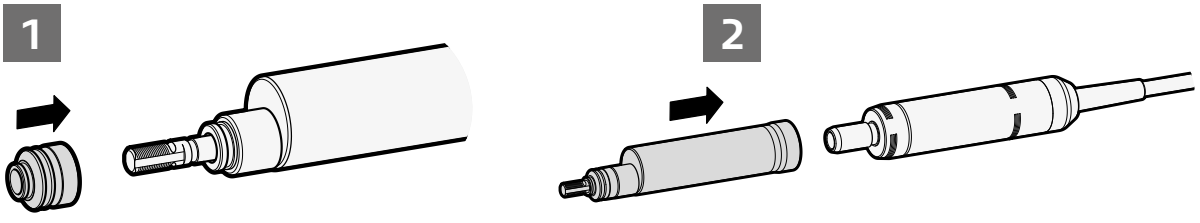
4 **Plug the connecting tube via the tube adapter (REF 4019F) onto the VACUUM tube and the suction tube onto the PATIENT connection.**

PREPARING THE HANDLE WITH CONFORM CANNULA HANDPIECE

Assemble the sterilized Handle with Conform cannula handpiece, electronic motor and all the accessories according to the following instruction.



ASSEMBLING THE HANDLE WITH CONFORM CANNULA HANDPIECE



SETUP

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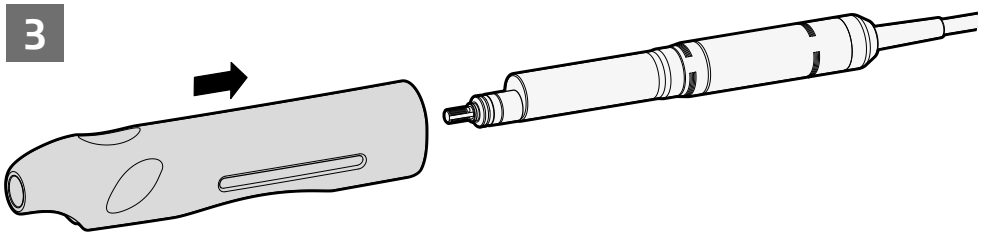

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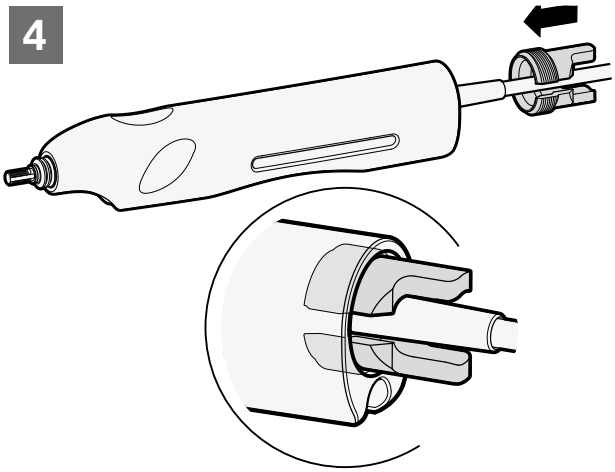

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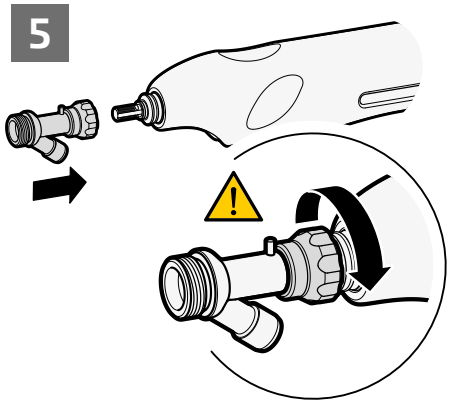

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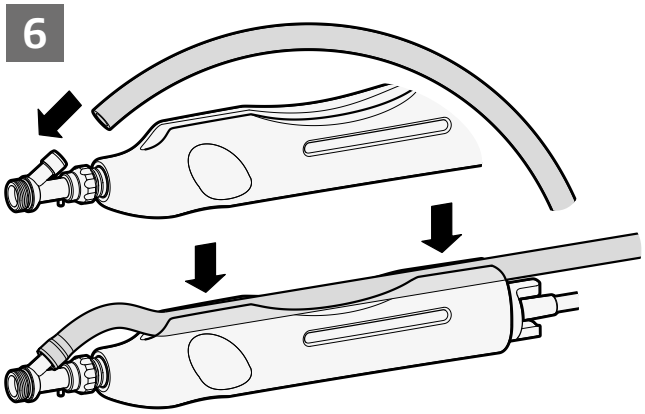

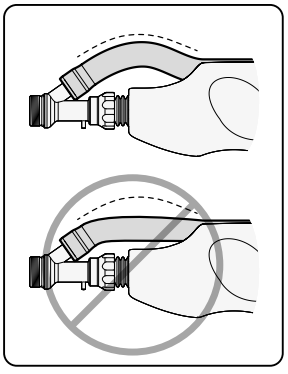

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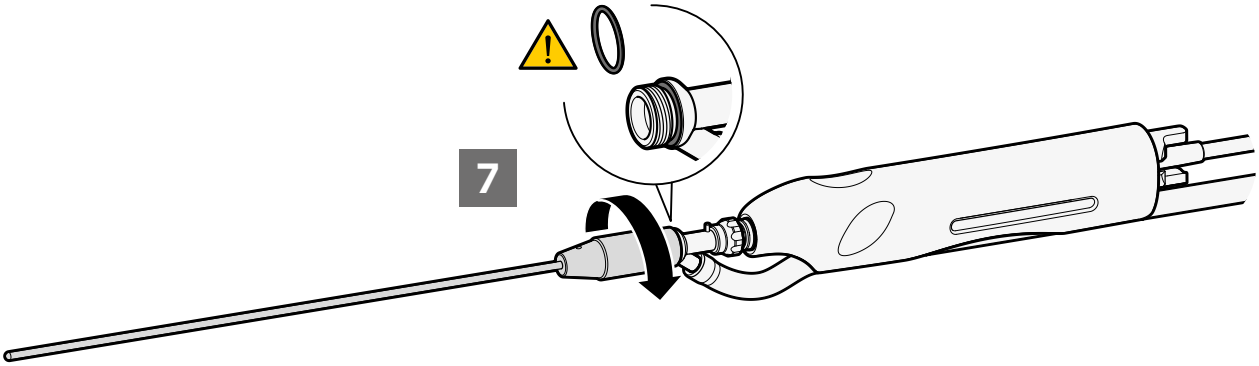


SETUP

DEVICE PREPARATION

Prior to use all sterilizable parts (silicone tubes, cannulas, cannula handle and secretion jars) must be sterilised.

1 **Hang the secretion jars with the lid on and closed in the secretion jar holder on the side of the device.**

2 **Place the VARIO footswitch with pedal on the floor and insert the plug into the socket provided at the back of the device.**

3 **To use the infiltration pump for infiltration, attach the tubing set by opening the cap and inserting the silicone section of the tubing set into the pump.**

Pay attention to the direction of flow!

4 **To fix the tube section, adjust the two tube clamps on the right and left of the infiltration pump. Lock the pump and gently move the tube clamps towards the tube by turning the knurled wheels.**
The tube section remains fixed in this position.

5 **Hang the bottle of infiltration solution on the stand and insert the spike of the tubing set through the rubber membrane of the bottle. Open the bleed valve on the spike.**

6 **Screw the infiltration cannula (optional) onto the cannula adapter. Open the pinch roller as far as it will go.**
The infiltration quantity is controlled by the regulator «Infiltration».

7 **Attach one end of the short silicone tubing (400 mm) to the small connecting sleeve of the bottle cap. Attach the other end of the tubing to the bacteria filter.**

8 **Attach the adapter (REF 28535) to one end of the 4000 mm suction tubing. Connect the other end of the tubing to the Conform cannula handpiece.**

9 **Now attach the short piece of tubing with the bacteria filter to the intake nozzle on the top of the device. Attach the sleeve at the other end of the piece of tubing to the small nozzle (VACUUM) on the lid of the secretion bottle.**

10 **Attach the adapter (REF 28535) of the suction tubing (4000 mm) to the large connection (PATIENT) of the collection jar lid. Place the other end of the tubing with the connected Conform cannula handpiece on the handpiece cradle.**

11 **Connect the mains plug to the power supply.**

OPERATION

SWITCHING THE DEVICE ON AND OFF

The control unit is switched on and off using the main switch «I/O» on the back of the device. Readiness is indicated by a green LED light on the front of the device.
Switching off can take place at any time and is not dependent on a switch-off procedure.

VARYING WITH VARIO PEDAL

1 **Press the «Vacuum» foot switch (blue).**
Vacuum pump is running.

2 **Press the «Motor» foot switch (yellow).**
Electronic motor for driving the cannula stroke on the Conform cannula handpiece is running.

3 **Press the pedal to start the infiltration pump and operate the infiltration volume up to the set maximum value.**

REGULATING THE SUCTION PROCESS

The suction process is controlled by the vacuum regulator «Vacuum» on the front of the device.
Turning clockwise Vacuum increases, suction performance is enhanced
Turn anticlockwise Vacuum decreases, suction performance is reduced

SETTING THE DESIRED SUCTION POWER

1 **Turn the vacuum regulator to the left stop.**
Corresponds to minimum vacuum.

2 **Switch on the device using the main switch «I/O» and press the «Vacuum» foot switch at the VARIO pedal.**
The pump is running and vacuum is being built up.

3 **Crimp suction tube to generate maximal air-tightness of the suction system.**

4 **Turn the vacuum control to the right stop.**
Corresponds to maximum vacuum.

5 **Wait until the pump has built up maximum vacuum.**
Equivalent to ≥ –0,9 bar (relative).

6 **By turning the vacuum control, the suction power can now be adjusted continuously from 0 to –0,9 bar.**

The manometer indicates the current vacuum in the device. Due to the connection of tubes and adapters, the effective vacuum at the cannula may differ from the displayed value.

REGULATION OF INFILTRATION PERFORMANCE

The «Infiltration» controller is used to preset the maximum infiltration performance that can be retrieved by using the pedal. Infiltration is started, varied and stopped by pressing the footplate of the VARIO pedal.
Turning clockwise Delivery of maximal infiltration liquid is increased
Turn anticlockwise Delivery of maximal infiltration liquid is reduced

OPERATION

USING THE CONFORM CANNULA HANDPIECE

Pressing the «Motor» button on the VARIO pedal activates the motor for the stroke movement of the cannula on the Conform cannula handpiece. The motor runs at a constant speed of 10,000 rpm.

EMPTYING SECRETION JARS

The lid of the secretion jar is equipped with an overflow protection. This prevents suction of secretion liquid when the jar is full. Therefor a float gauge is responsible. If the liquid level is too high and the overflow protection closes, the secretion jar must be emptied or replaced with an empty one.

1 **Switch off the device using the main switch «I/O».**

2 **Disconnect the tubes from the lid of the secretion jar.**

3 **Unhinge the full secretion jar from the secretion jar mount and dispose of the secretion fluids according to national disposal regulations.**

4 **Procure the used secretion jars to the reprocessing cycle.**

5 **Connect the disconnected tubes to the second secretion jar that is ready and continue the suction procedure.**

FUNCTION CHECK

To ensure that the suction pump operates smoothly, the individual components and functions must be checked before each treatment.

GENERAL FUNCTION

1 **Switch on the device using the main switch «I/O».**
Standby display (LED) is lit. The fan in the device is running.

Neither the Infiltration pump nor the suction pump or the electronic motor of the Conform cannula handpiece may be actuated without the pedal being pressed.

SUCTION PUMP

1 **Press the «Vacuum» foot switch (blue).**
Vacuum pump is running.

2 **Hold hand in front of the air outlet «EXHAUST» (back of the device).**
Airflow can be felt.

3 **Turn the vacuum controller «Vacuum» to the right stop to get the maximum suction power.**

4 **Check the suction intensity at the cannula opening.**
The pump draws strongly.

5 **Turn the vacuum regulator «Vacuum» to the left stop to get the minimum suction power.**

6 **Check the suction intensity at the cannula opening.**
The pump draws weakly.

7 **Switch off the device via the main switch «I/O».**
Standby display (LED) goes out.

OPERATION

INFILTRATION PUMP

1 **Turn the controller «Infiltration» to the right stop to get the maximum flow rate.**

2 **Press pedal on the VARIO pedal.**
Infiltration pump starts.

3 **Turn the controller «Infiltration» to the left stop to reduce the flow rate.**

4 **Delivery rate decreases until it comes to a standstill.**
No more infiltration solution is delivered.

Once the maximum flow rate has been set on the «Infiltration» control dial, the flow rate can be adjusted up to the set maximum value using the footplate on the VARIO pedal..

CONFORM CANNULA HANDPIECE WITH ELECTRONIC MOTOR

1 **By pressing the foot switch «Motor» (yellow) the electronic motor of the Conform cannula handpiece is activated and runs with a constant speed.**
Vibrations at the Conform cannula handpiece are perceptible.

CLEANING AND DISINFECTION

Perform cleaning, disinfection and sterilization after every treatment!
Always autoclave the material in sterilisation packaging.
Sterilisation packaging may only be filled up to 80%.
Always autoclave the material at 134°C for at least 5 minutes.
If sterilised material is not used immediately, the material packaging must be labeled with the sterilisation date.
NOUVAG recommends including a sterility indicator.

CONTROL UNIT AND VARIO PEDAL

Control unit and pneumatic pedal do not come into contact with the patient. Wipe the outside using tested surface disinfectant or 70% of isopropyl alcohol. The cover of the device is appropriately sealed and can be wiped clean.

SECRETION JAR AND JAR LID

The reprocessing instructions for the secretion jar and jar lid is provided in the operating instructions delivered with the secretion jar.

SECRETION JAR WITH DISPOSABLE INLAY POUCH

The disposable inlay pouches are not to be reprocessed. They have to be discarded off expertly. For reprocessing the reusable outer container (secretion jar) please refer to the operation manual delivered with the product.

BACTERIA FILTER

The bacteria filter is a one way product and cannot be cleaned or sterilised. A periodical replacement of the bacteria filter is recommended after 8 hours of use, but definitely after it came into contact with foam or infectious material.

After contact with watery solutions the bacteria filter locks down, because of its hydrophobic characteristic, to protect the pump from cloaking. Hence the further operation of the pump is not possible. The bacteria filter has to be replaced.

CANNULAS AND CANNULA HANDLE

The optional cannulas and the cannula handle are in contact with the patient and therefore have to be reprocessed adequately. The reprocessing instructions are in the operation instructions, delivered together with the cannula and handle.

QUIVER AND SILICONE TUBES

Clean quiver from debris and soiling. Use a clean, damp cloth and/or an appropriate brush with disinfection agent. Flush tubes sufficiently.

It is important to use a disinfectant that is compatible with polysulfone and polycarbonate.
Note: Quiver and silicone tubes must be disposed of after 250 reprocessings at the latest.

1 **Pack quiver and tubes in individual packaging for sterile items (see DIN 58953).**

2 **Autoclave wrapped quiver and tubing at 134°C for at least 5 minutes.**
Temperature exposure times are based on country-specific guidelines and standards.

3 **A drying cycle must be added in case of autoclaves without a post-vacuum function. Allow quiver to dry in the bag for at least one hour at room temperature with the paper side facing upwards.**

If sterilised quiver and tubing are not used immediately after sterilisation, the material packaging must be labeled with the sterilisation date. Including a sterility indicator is recommended.

CLEANING AND DISINFECTION

ELECTRONIC MOTOR 21

For the reprocessing instructions for the electronic motor, please refer to the operation instructions supplied with the electronic motor.

Reprocessing restrictions	Frequent reprocessing has little effect on the products. The end of product life is usually determined by wear and tear and damage through use.

INSTRUCTIONS

At location of use	No special requirements.
Storage and transport	No special requirements. Long holding times before reprocessing have to be avoided due to surface drying.
Preparation for cleaning	No special requirements.
Automatic cleaning and disinfection	**Equipment** Washer-disinfector with a special load carrier that ensures the connection of tubes to the washer-disinfector for rinsing. Use only neutral cleaning agents for this purpose. 1. Place silicone tubes in the load carrier. 2. Set a cleaning cycle that offers sufficient cleaning and rinsing. Perform the final rinse with fully deionized water. 3. Perform a 10-minutes rince cycle at 93°C to facilitate thermal disinfection. 4. When removing, check silicone tubes, to verify whether soiling is still visible. If necessary, repeat the cycle or clean manually.
Manual cleaning	**Equipment** Neutral cleaning agent, soft brush, running, demineralized water (< 38°C) **Procedure** 1. Rinse off and brush away surface soiling from the silicone tubes. 2. Rinse silicone tubes thoroughly under running water.
Manual disinfection	For manual disinfection, submerge silicone tubes in chlorinefree disinfection solution.
Drying	Allow silicone tubes to dry sufficiently in a drying cabinet.
Inspection and maintenance	Perform a visual inspection to check for damage, corrosion and wear.
Packaging	**Individual** Pack silicone tubes in individual packaging for sterile items. **Sets** Sort silicone tubes on trays intended for this purpose or place them on allpurpose sterilisation trays.
Sterilisation	Autoclave in vacuum autoclave at 134°C for at least 5 minutes. When sterilizing several items during one sterilisation cycle, do not exceed the maximum sterilizer load. A drying cycle must be added in case of autoclaves without a post-vacuum function. Allow the silicone tubes to dry in the bag for at least one hour at room temperature with the paper side facing upwards. * Temperature exposure times are based on country-specific guidelines and standards.
Storage	No special requirements. If sterilized silicone tubes are not used immediately after sterilisation, the material packaging must be labeled with the sterilisation date. Including a sterility indicator is recommended.

The effectiveness of the sterilisation instructions provided above for reprocessing this medical product has been validated by NOUVAG AG. The user is responsible for ensuring that the sterilisation procedure performed achieves the required results. This requires validation and routine monitoring of the procedure. The staff member who completes the procedure bears sole responsibility for any deviation on his part from the instructions provided. Deviations necessitate revalidation of the effectiveness of the procedure as well as of the technical resilence of the reprocessed items with regard to the modified sterilisation process.

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 next to the power switch:

1 **Switch off device.**

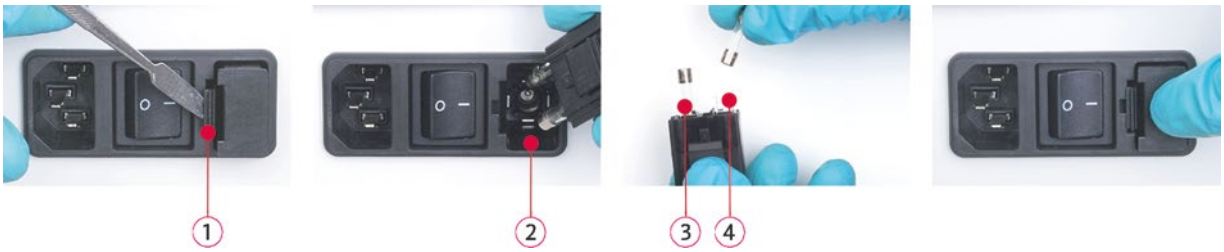
2 **Unplug the power cord.**

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

4 **Replace the faulty fuse T 4 AL, 250 V AC (115 V model) / T 2 AL, 250 V AC (230 V model).**

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

6 **Plug in the power cord 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 Vacuson 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 >23]. For further information please contact our technical service department.

BACTERIA FILTER

A periodical replacement of the bacteria filter is recommended after 8 hours of use, but definitely after it came into contact with foam or infectious material. For reordering refer to chapter [Accessories and spare parts >21].

SECRETION JAR

The influxing mixture of air and secretion fluids into the secretion jar causes the build up of foam. It's recommended to use an antifoam agent to suppress the build up of foam. Prior use of the secretion jar fill an anti foam agent into the clean, dry jar. Don't use disinfection solution, because most of them benefit the build up of foam. Make sure the secretion jars are in good condition. Check the jars routinely for cracks and rifts and be sure the jars flange is immaculate. It's important to guarantee full air tightness of the system which is responsible for trouble-free operation of the pump.

MAINTENANCE

FUNCTION CONTROL OF FLOAT GAUGE VALVE

The proper functioning of the overflow protection system has to be checked periodically.

Please refer to the instructions for use of the secretion jars.

MALFUNCTIONS AND TROUBLESHOOTING

MALFUNCTION	CAUSE	SOLUTION	REFER TO INSTRUCTIONS FOR USE
Device is not operational	Control unit not switched on	Set the power switch «I/O» to «I»	[SWITCHING THE DEVICE ON AND OFF >13]
	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 >18]
Pedal is not functioning	VARIO pedal not connected	Connect VARIO pedal with device at rear	[DEVICE PREPARATION >12]
	Control unit is not switched on	Set the power switch «I/O» to «I»	[SWITCHING THE DEVICE ON AND OFF >13]
	Incorrect operation	Check instructions for use	
Suction pump does not work	Vacuum pump is not switched on	Press the connected VARIO pedal	[VARYING WITH VARIO PEDAL >13]
	Vacuum-system is not air tight	Check all seals and tubes	[PREPARING REUSABLE SECRET JARS >10] [PREPARING SECRETION JARS WITH DISPOSABLE INLAY POUCH >10] [DEVICE PREPARATION >12]
		Make sure char lid is properly closed	
	Connection cap for connecting the pedal is not fitted	Place cap on pedal connection	[DEVICE PREPARATION >12]
	Tubes are connected wrong	Connect tubes correctly	[DEVICE PREPARATION >12]
	Jar is full and overflow protection has locked down	Replace full jar by a fresh, empty jar	[EMPTYING SECRETION JARS >14]
	Incorrect operation	Check instructions for use	
Suction pump does not suck properly	Vacuum controller «Vacuum» is not open enough	Turn vacuum controller «Vacuum» clockwise	[REGULATING THE SUCTION PROCESS >13]
	Vacuum-system is not air tight	Check all seals and tubes	[PREPARING REUSABLE SECRET JARS >10] [PREPARING SECRETION JARS WITH DISPOSABLE INLAY POUCH >10] [DEVICE PREPARATION >12]
		Make sure char lid is properly closed	

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 >23].

ACCESSORIES AND SPARE PARTS

DESCRIPTION	REF
O-ring Ø 11.1 × 1.6 mm, silicone	4063
Connecting tube Ø 8 × 3 × 400 mm, from bacteria filter to secretion jar, silicone, sterilisable	4155z
Suction tube Ø 8 × 3 × 1700 mm, silicone, sterilisable	4076
Connecting tube Ø 8 × 3 × 500 mm, from bacteria filter to secretion jar, silicone, sterilisable	4190
FLOVAC® suction jar system, for disposable bags, 2 litres, with mounting bracket	4030F
Disposable inlay pouches, 2 litres, including lid, for the FLOVAC® system	4035F
FLOVAC® tubing adapter (yellow), for attachement on the VACUUM connection on the lid of the inlay pouch	4019F
Inlay pouches, 2 litres, for the FLOVAC® system, sterilisable	4036F
Mounting bracket for the FLOVAC® system, for mounting secretion jars on Vacuson 40/60 pump	4037F
Bacteria filter for suction pump, Ø 64 mm, PTFE, hydrophobe, disposable	4246
Two way tap for switching between the secretion jars, including connection tube Ø 8 × 3 × 400 mm	4130
Disposable tubing set, sterile, 4 m, PU 10 pcs.	6022
Disposable tubing set Ø 9 × 6.5 mm, sterile, 4 m, PU 40 pcs.	6026/6026E
Secretion jar, 2 litre, polysulfone, sterilisable	4052nou/4052usa
Secretion jar, 5 litre, polysulfone, sterilisable	4245nou/4245usa
Suction jar 2 l, reusable	4287
Suction jar 5 l, reusable	4288
Lid for suction jars 2 l / 5 l, reusable	4289
Suction jar 3 l, reusable	4291
Suction liner 3 l, single-use, PU 70 pcs.	4292

SUCTION CANNULAS FOR LIPOSUCTION

DESCRIPTION	REF
Yankauer suction cannula, Ø 2.0 mm, length 280 mm	4446
Andrews cannula, Ø 2.0 mm, length 240 mm	4449
Cannula handle with opening for false air ventilation, Luer-Lock connection, sterilisable	4391
Cannula handle without opening, Luer-Lock connection, sterilisable	4390
Curved cannula, for femoral liposuction, Ø 3 mm, length 200 mm, 22 openings 1.5 mm	4362
Curved cannula, for femoral liposuction, Ø 3 mm, length 300 mm, 30 openings 1.5 mm	4365
Curved cannula, for femoral liposuction, Ø 4 mm, length 200 mm, 22 openings 1.5 mm	4368
Curved cannula, for femoral liposuction, Ø 4 mm, length 300 mm, 30 openings 1.5 mm	4372
Angled cannula, 30°, for femoral liposuction, Ø 3 mm, length 200 mm, 22 openings 1.5 mm	4381
Straight cannula, Ø 1.5 mm, length 150 mm, 1 oval opening	4361
Straight cannula, Ø 2 mm, length 150 mm, 1 oval opening	4364
Straight cannula, Ø 2 mm, length 150 mm, 18 opening 1.0 mm	4373
Straight cannula, Ø 3 mm, length 150 mm, 18 openings 1.5 mm	4374
Straight cannula, Ø 3 mm, length 200 mm, 22 openings 1.5 mm	4378
Straight cannula, Ø 3 mm, length 300 mm, 30 openings 1.5 mm	4387
Straight cannula, Ø 4 mm, length 200 mm, 22 openings 2.0 mm	4379
Straight cannula, Ø 4 mm, length 300 mm, 30 openings 1.5 mm	4388

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

ACCESSORIES AND SPARE PARTS

INFORMATION ON DISPOSAL

When disposing of the device, device components and accessories, the regulations issued by the legislator must be followed.

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

Disused electrical and electronic appliances are hazardous waste and must not be disposed of with household waste. Old appliances can be returned to the dealer or manufacturer.

TECHNICAL DATA

Voltage		115 V~ / 60 Hz, 230 V~ / 50 Hz
Power consumption		370 VA
Fuse power supply	115 V Model 230 V Model	2 fuses, T 4 AL, 250 V AC 2 fuses, T 2 AL, 250 V AC
Protection class		Class I
Applied part		Type BF
Pressure max.	relative absolute	– 0.9 bar at 675 mmHg 0.1 bar at 675 mmHg
Suction capacity vacuum pump		60 l/min.
Accuracy of pressure gauge		± 5 %
Speed of Conform cannula handpiece		10 000 rpm = 3600 strokes/min.
Dimensions (W x D x H)		360 x 300 x 280 mm
Net weight control unit		14 kg

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

If you have any complaints in relation to the use of the medical device, please contact the manufacturer immediately by e-mail complaint@nouvag.com or by phone.

In order to provide adequate information, please complete the complaint form:
Nouvag.com > Contact > Complaint Form.

SERVICE POINTS

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A complete list of all NOUVAG authorised service points worldwide can be found at
Nouvag.com > Service > Global Service Centres

APPENDIX

Electromagnetic compatibility (EMC)

Remark:
The **Product** subsequently referred to herein always denotes the Vacuson 18 / 40 / 60.

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 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.

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.

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	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 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 for power supply lines +/- 1 kV for input/output lines	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	+/- 1 kV differential mode +/- 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 sec	< 5 % U_T (> 95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 sec	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 from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 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.			

APPENDIX

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 150 kHz to 80 MHz outside ISM bands	3 V rms 150 kHz to 80 MHz outside ISM bands	$d = 0{,}35\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = 0{,}35\sqrt{P}$ 80 MHz to 800 MHz $d = 0{,}7\sqrt{P}$ 800 MHz to 2,5 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.			

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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