EN

Instructions for use

Vacuson 40 | Vacuson 60

Medical Suction Pumps

NOUVAG+

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Vorwort

Herzlichen Glückwunsch zum Kauf eines Produktes der Firma NOUVAG AG. Wir freuen uns, dass Sie sich für ein NOUVAG Erzeugnis entschieden haben und danken Ihnen für Ihr entgegengebrachtes Vertrauen.
Diese Bedienungsanleitung wird Sie mit dem Gerät und seinen Eigenschaften vertraut machen, damit eine möglichst lange und problemlose Funktion gewährleistet werden kann.
Im Anhang finden Sie die Konformitätserklärung und unsere autorisierten Servicestellen.

- **Bitte lesen Sie diese Anleitung vor Inbetriebnahme aufmerksam durch!**

Foreword

Congratulations on your purchase of a NOUVAG AG product. Thank you for the confidence shown in our products.
Please consult the instruction manual for the use and maintenance of the device in order to ensure that it will function properly and efficiently for many years.
You will find the conformity statement and list of authorized service representatives attached.

- **Please read instructions carefully before operating!**

Préface

Félicitations vous venez d'acheter un produit NOUVAG AG. Merci de la confiance que vous montrez en nos produits.
Merci de consulter le mode d'emploi pour l'utilisation et l'entretien de cet appareil de manière à vous assurer qu'il fonctionnera correctement et efficacement pendant de nombreuses années.
Vous trouverez ci-joint les déclarations de conformité et la liste des agents agréés pour l'entretien.

- **Lire soigneusement les instructions avant utilisation!**

Prefazione

Ci congratuliamo con Lei per l'acquisto di un prodotto NOUVAG AG e le auguriamo un susseguirsi di successi professionali.
Questo manuale l'aiuterà a conoscere meglio l'apparecchiatura e le sue caratteristiche. Contiene indicazioni utili che le assicureranno un funzionamento efficiente ed una lunga durata.
Qui allegato troverete la dichiarazione di conformità e la lista dei rivenditori autorizzati.

- **Prego leggere attentamente le istruzioni per l'uso prima di mettere in funzionamento!**

Preposición

Muchas gracias por la compra de un producto NOUVAG AG.
Felicidades por la elección y la confianza depositada en nuestros productos.
Para garantizar una función duradera y eficiente del aparato, por favor consultar el manual de instrucciones.
El Certificado de Conformidad y la lista de Centros de Servicio se encuentran en el apéndice.

- **Por favor leer las instrucciones detenidamente antes de poner en marcha el aparato!**

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1 Product description

1.1 Intended use and operation

The Vacuson 40/60 is a suction pump for the use in medical, chemical and laboratory envirnonments. In the medical field the suction pump is used as following:

- Surgery pump
- Lipectomy pump for subcoutaneous liposuction
- Curettage pump for the aspiration of uteringe tissue in Gynecology
- Universal pump
- Extractor pump in obsterics

The Vacuson 40/60 function is to aspirate fluids and secretions. The suction power of the pump can be adjusted continuously by a vacuum regulator and can be monitored by the pressure gauge.

Patient population is not restricted in respect of age, weight and gender.

Configuration and operation of the Vacuson 40/60 shall be performed only by surgeons or highly qualified and trained medical personnel.

1.2 Contraindications

a) Infected wounds have poorly vascularized and necrotic tissue.
b) Poor physical health of patient.
c) Patients who underwent crash dieting immediately prior to consultation.
d) Morbid (mega-liposuction controversial due to higher risk of mortality from fluid shifts).
e) Relative or absolute contraindications may result from the general medical findings or in special cases in which the patients risk for motor-driven tools is significantly increased.

Cases described in the relevant literature must be taken into account.

1.3 Technical data, Vacuson 40/60

	Vacuson 40	Vacuson 60
Voltage:	115 V~at 60 Hz; 230 V~at 50 Hz	115 V~at 60 Hz; 230 V~at 50 Hz
Power consumption:	Max. 180 VA for 115 V version Max. 170 VA for 230 V version	Max. 370 VA for 115 V version Max. 400 VA for 230 V version
Fuses for 115 V model: **Fuses for 230 V model:**	2 x T4 AL, 250 V AC 2 x T2 AL, 250 V AC	2 x T4 AL, 250 V AC 2 x T2 AL, 250 V AC
Protection class:	Class I	Class I
Applied part:	Type BF	Type BF
Adjustable vacuum:	– 0.9 bar at 686 mmHg	– 0.9 bar at 675 mmHg
Dimensions, W x H x D:	360 x 300 x 280 mm	360 x 300 x 280 mm
Weight:	10 kg	12 kg
Accuracy limit, Manometer:	± 5 %	± 5 %
Suction Pump Capacity:	35 l/min	60 l/min

1.4 Ambient conditions

	Transport and storage:	Operation:
Relative humidity:	10 % – 90 %	Max. 80 %
Temperature:	0 – 60°C, (32 – 140°F)	10 – 30°C, (50 – 86°F)
Atmospheric pressure:	700 – 1060 hPa	800 – 1060 hPa

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1.5 Warranty coverage

Purchasing a Vacuson 40 or Vacuson 60 suction pump entitles you to a 1-year warranty. If you return the warranty card for registration within four weeks of the date of purchase, warranty coverage will be extended for a further **6 month**.
Consumable parts are not covered by the warranty. Improper use or repair, or failure to observe these instructions, relieve us from any obligations arising from warranty provisions or other claims.

2 Explanation of symbols

	Important information		Autoclavable at 134°C
	Warning		Suitable for thermal disinfection
	Date of manufacturing		Protective ground
	Manufacturer		Observe the instructions for use
	Type BF applied part is the filling tube with connected instrumentsn		Electrical and electronic devices that have reached the end of their service life comprise hazardous waste and may not be disposed of together with household waste. Valid local disposal regulations apply.
IPX8	Protection continual submerging.	SN	Symbol indicating the serial number with the date of manufacture (year/month).
	Pedal	REF	Symbol indicating the order number.
	Date of expiry	LOT	Symbol indicating the lot number.
CE 0197	CE symbol with notified body		Not for reuse
	Warning: Hot surfaces		Equipontential (Equality of potential)
	Air-Exhaust port		Autoclavable at 121°C
EC REP	European authorized representative		

3 Safety information

Your safety, the safety of your team, and of course that of your patients is very important to us. It is therefore essential to bear the following information in mind:

Every use of the Vacuson 40/60 different to the product description defined in „chapter Intended use and operation“, causes risks for patients and trained personnel. If physical examinations and therapies are carried out without use of the devices then the devices must be removed form the place of treatment. Avoid any connection or close adjacency to other devices.

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3.1 EMC Manufacturer’s Declaration of Conformity

The use of (RF) Radio Frequency emitting devices and equipment as well as the occurance of negative environmental factors in the close area of the Vacuson 40/60 may cause unexpected or adverse operation. The connection or the placing of other devices in close vicinity is not allowed.

The Product is suitable for use in establishments of the industrial sector and hospitals. When used in the domestic establishments, this unit may not provide adequate protection for radio services. The user must take remedial measures such as implementation or reorientation of the product.

Use only accessories and cables as spezified in the product description. Further observe the EMC manufacturer declaration of conformity.

3.2 Modification and misuse

- Modification or manipulation of the Vacuson 40/60 suction pumps and its accessories is prohibited. The manufacturer is not liable for any damages resulting from unauthorized modifications or manipulations. The warranty will be canceled.
- Use of the Vacuson 40/60 suction pumps outside the indications described in Section 1.1 is prohibited. The user or operator is solely responsible for any such use.

3.3 Essential requirements

The Vacuson 40/60 suction pumps may only be operated under constant supervision of qualified and trained personnel!

Improper use or repair of the device and failure to observe these instructions relieve us from any obligation arising from warranty provisions or other claims!

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

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.

Repairs may only be performed by authorized NOUVAG service technicians.

3.4 During use

The device is not sterile on delivery. All sterilizable parts must be sterilized before use (refer to chapter 8 “Cleaning, disinfection and sterilization”).

At the choosing of the instrument the operator has to make sure it’s biocompatible, according to EN ISO 10993.

While in operation the control unit of the Vacuson 40/60 suction pumps must be at least 1 meter above ground.

Do not use the device in the vicinity of flammable mixtures.

In extreme cases, the device may heat up excessively.

4 Scope of delivery

REF	Description	Quantity
	Vacuson 40 set (REF 4227-115 V/4227-230 V)	
4275	Control unit Vacuson 40	1
15012	ON/OFF-pneumatic pedal to switch the device on and off	1
4076	Suction tube 8 x 3 x 1700 mm, silicone, sterilizable	1
4246	Bacteria filter for suction pump, Ø 64 mm, PTFE, hydrophobe, disposable	10
31997	Operating instructions on CD-ROM	1
	Vacuson 60 set (REF 4237-115 V/4237-230 V)	
4280	Control unit Vacuson 60	1
15012	ON/OFF-pneumatic pedal to switch the device on and off	1
4076	Suction tube 8 x 3 x 1700 mm, silicone, sterilizable	1
4246	Bacteria filter for suction pump, Ø 64 mm, PTFE, hydrophobe, disposable	10
31997	Operating instructions on CD-ROM	1
	Optional:	
4155	Connecting tube, 8 x 3 x 400 mm, from bacteria filter to secretion jar, silicone, sterilisable	1
4190	Connecting tube, 8 x 3 x 500 mm, from bacteria filter to secretion jar, silicone, sterilisable	1
6026	Disposable suction tube 9 x 6.5 x 4000 mm, sterile	1
4242	Vario-AIR-Pedal	1
4052	Secretion jar, 2 liter, polysulfone, sterilisable, including operation manual	1
4245	Secretion jar, 5 liter, polysulfone, sterilisable, including operation manual	1
4058	Secretion jar lid with overflow protection system for 2 and 5 liter secretion jars, sterilisable	1
4035F	2 liter disposable secretion pouches including lid for the FLOVAC system	50
4019F	FLOVAC tubing adapter (yellow), for the attachement at the VACUUM line at the lid of the inlay pouch	25
4036F	2 liter inlay pouches for the FLOVAC system, sterilizable at 121°C	1
4037F	Mounting bracket for the FLOVAC system for mounting secretion jars on Vacuson 40/60 pump	1
4043	Quiver, sterilisable, 30 cm length, with suspension device	1
4044	Quiver, sterilisable, 40 cm length, with suspension device	1
4130	Two way tap to switch between the two secretion jars, including connection tube 8 x 3 x 400 mm	1
28535	Angled connector (VACUUM) for more convenient tube connection of the suction tube	1
	Optionai power cords:	
22261	Power cord CH with appliance plug, 3 m length	1
22262	Power cord D with appliance plug, 3 m lengt	1
22264	Power cord GB with appliance plug, 3 m lengt	1
22266	Power cord USA with appliance plug, 3 m lengte	1

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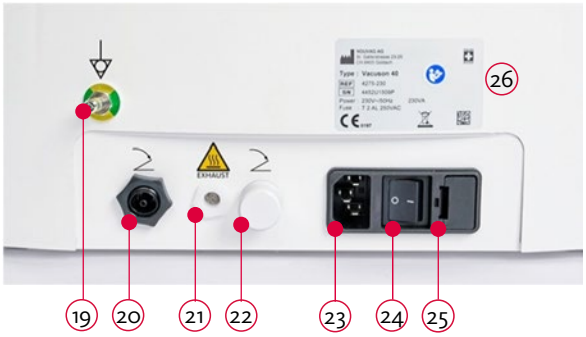
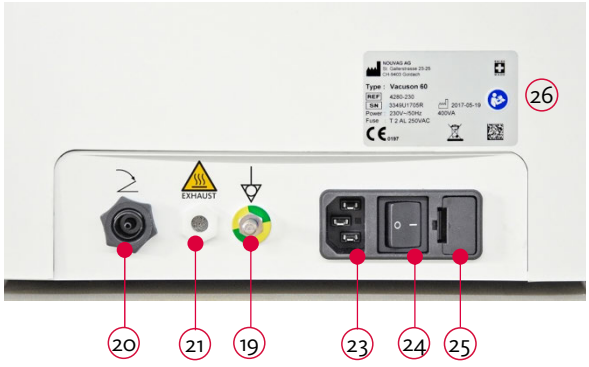
5 Device overview

Front view

Rear view of Vacuson 40



Rear view of Vacuson 60



1. Suction cannula (optional)
2. Filling tube (1700 mm), silicone
3. Secretion jar (Example 2 Liter)
4. Overflow protection system
5. Secretion jar lid
6. Connection for connecting tube (VACUUM)
7. Turn an tilting lever
8. Connection for filling tube (PATIENT)
9. Connecting tube, silicone
10. Bacteria filter
11. Two way cock (optional, REF 4130)
12. Carrying handle
13. Secretion jar mount
14. Ready indication, LED
15. Manometer
16. ON/OFF pneumatic pedal
17. Vacuum regulator (VACUUM)
18. Ventilation intake
19. Potential equalization
20. Port for pneumatic ON/OFF-pedal
21. Air exhaust port (EXHAUST)
22. Connection for VARIO-Air pedal
23. Power plug socket
24. Main switch ON/OFF
25. Fuse compartment
26. Type plate with type designation, reference number, serial number, information on power supply and device fuse.

6 Startup

6.1 Device setup

- Installations-Layout

- Place the Vacuson 40/60 suction pump and all required accessories and instruments on an even, non-slip surface and make sure you have good access to all controls.
- The installation of the device in close proximity to other devices is prohibited due to EMC – please see section 3.1 and the manufacturer's EMC declaration in the appendix of this manual.
- Do not allow the operating range of the device (including cable) and the connected cnstrument to be compromised by limiting factors.
- The manometer must be fully visible at all times.
- The On/Off-AIR-Pedal must be placed within stepping distance between the patient and the surgeon.
- It must be explicitly ensured that no objects can fall on the pedal.
- 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 40/60 must be kept clear in order to prevent temperature from becoming excessive.
- While in operation the Vacuson 40/60 suction pumps must be at least 1 meter above ground.

6.2 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!

The power supply unit of the Vacuson 40/60 pumps is not swichable to the country specific service voltage. The device has to be ordered according to the country specific service voltage.

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

Zum Anschluss des Gerätes an die Spannungsversorgung darf nur ein geprüftes Netzkabel verwendet werden.

The power plug socket is located at the rear of the device.

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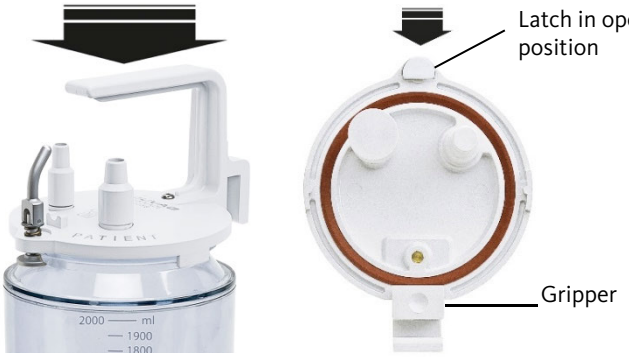
6.3 Preparation of secretion jars

1. Hold open secretion jars (2 or 5 liter) or FLOVAC-jar available.

2. Press jar lid with turn and tilting lever in open-position firmly onto the jar (the latch of the locking system is in open-position).

Turn and tilting lever open-position.



3. Rotate turn and tilting lever by 180° (turn and tilting lever now facing away from the grasp). Make sure the gripper catches the rim of the jar.

Turn and tilting lever in locked position.

4. Flap down turn and tilting lever into the designated groove.

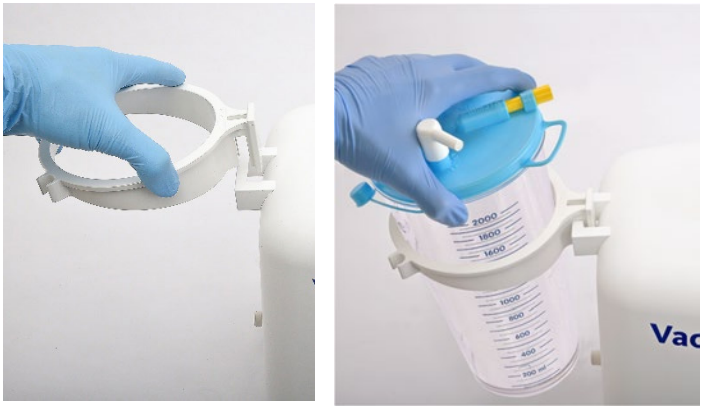
Turn and tilting lever locked and secured.

6.4 Preparing the FLOVAC secretion jar system

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

2. Insert the disposable inlay pouch into the FLOVAC secretion jar and make sure the tube connector is on the lid. Close the container with sustained pressure on the lid.

3. Place the FLOVAC bottle holder ring in the secretion jar bracket of the Vacuson pump.



4. Graft the connecting tube to the tubing adapter (4019F) of the (VACUUM)-line and the suction tube to the (PATIENT)-line.

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6.5 Device preparation

1. Prior to use all sterilizable parts (Tubes, Cannulas, Cannula handlebar, char lid and bottles) must be sterilized.

2. Attach secretion jars with mounted and locked lid to the device.

3. Lay the pneumatic pedal on the floor and plug the connection tube into the port for the pneumatic pedal.

4. The Vario-AIR-Pedal (optional) is connected to the air inlet port at the control unit by the connection tube. If not in use the port is covered with a lid. Make sure to cover the port again when Vario-AIR-Pedal is not connected.

5. Attach the short connection tube (400 mm) on one end with the bacteria filter and the other end with the narrow connector (VACUUM) of the jar lid.

6. Attach the filling tube (1700 mm) on one end with the angled connector (optional REF 28535) and the other end of the tube with the instrument.

7. Mount connection tube with bacteria filter onto the intake nozzle at the top of the Vacuson pump. Graft the other end of the connection tube with the narrow connector onto the smaller nozzle of the secretion jar (VACUUM).

8. Graft the angled connector (optional REF 28535) of the filling tube (1700 mm) onto the wider nozle (PATIENT) of the secretion jar. Hang the other end of the filling tube with the instrument into the quiver.

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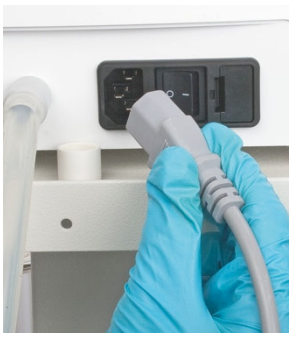
9. Screw suction cannula (optional) onto the cannula handlebar (Vacuson 60, Liposuction) and hang it back into the quiver.

10. Connect the device socket with the wall socket, using the devices power cord.



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

7 Operation

7.1 Switching device on and off (Mains switch)

Use the power switch **"I/O"**, at the rear of the device, to switch the device on and off.
The standby is signalized by the LED status light at front of the device.
The device can be switched off at any time, irrespective of any procedure for device switch-off.

The pneumatic ON/OFF pendal has to be connected, because the pump is only starting by a press on the pedal.

7.2 Pump activation by pneumatic pedal

The included standard pneumatic ON/OFF-pedal when pushed activates a switch in the Vacuson pump, to switch the pump on and off. This is maintained by an air pillow.
After the device was switched on, the pneumatic pedal has to be pressed to activate the pump and generate vacuum. Pressed again the pump is deactivated.
The pump can only be activated by the pedal. The last used state befor switch-off stays active.

If vacuum has built up, the pump may not be switched on. In this case release the vacuum via the vacuum regulator and press the pneumatic pedal again.

7.3 Variegate with Vario-AIR-Pedal

Handsfree regulation of the vacuum can be maintained by using the Vario-AIR-Pedal (optional, REF 4242). When pressed, the Vario-AIR-Pedal opens a valve and the vacuum is reduced by forced ventilation of the pressure system. The more the pedal is pressed the less vacuum can build up, hence the suction performace decreases.
If the suction performace is controlled by the Vario-AIR-Pedal, the Vacuum Controller on the front side of the device ideally remains in maximal position.
The Vario-AIR-Pedal is normally used together with the pneumatic pedal.

7.4 Regulating suction process

The suction process is regulated by the Vacuum controller at the front side of the device.

Rotate clockwise:	*Vacuum increases, suction performance is enhanced.*
Rotating anticlockwise:	*Vacuum decreases, suction performance is reduced.*

Establishing airtightness of the suction system:

1. Turn Vacuum Controller anticlockwise all the way to the stop (equivalent to vacuum minimum).
2. Switch on mains switch (I/O) of the pump and press On/Off pedal shortly. Pump is running and building up vacuum.
3. Crimp suchtion tube to generate maximal air-tightness of the suction system.
4. Turn Vacuum Controler clockwise (equivalent to vacuum maximum).
5. Wait for maximum build up of vacuum (equivalent to ≥ – 0.9 bar).
6. Now by turning the Vacuum Controller the suction performance can be regulated steplessly from 0 to – 0.9 bar.

The vacuum manometer shows the current vacuum in the device – due to the connection of tubes and adapters, the effective vacuum at the cannula can deviate from the displayed value.

7.5 Emptying secretion jar

The jar lid of the secretion jar is equipped with an overflow protection system to prevent the vacuum system from being flooded by secretion fluids at high filling levels of the secretion jar. Therefor a float gauge is responsible.
At high filling levels of the secretion jar and the resulting locking of the overflow protection system the secretion jar has to be emptied or replaced by another secretion jar.

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1. Swich off suction pump.
2. Disconnect tubes from the secretion jar lid.
3. Unhinge full secretion jar from the secretion jar mount and dispose of secretion fluids according to national disposal regulations.
4. Procure used secretion jars to the reprocessing cycle.
5. Connect suspended tubes with new, ready to use secretion jar.

7.6 Function control

To obtain trouble-free operation of the suction pump all the components and functions of the pump system have to be tested prior every assignment.

General functions:

1. Use the power switch “I/O”, at the rear of the device, to switch the device on, LED is illuminated.
2. Device fan is running.

Suction pump with pneumatic pedal:

1. Use the power switch “I/O”, at the rear of the device, to switch the device on, LED is illuminated.
2. Device fan is running.
3. Hold hand in front of the «Exhaust» (Rear of the device). Airflow is perceptible.
4. Press pneumatic pedal shortly to activate the suction pump.
5. Turn Vacuum Controler clockwise (equivalent to vacuum maximum).
6. Control vacuum intensity at the opening of the cannula. Strong suction performance.
7. Turn Vacuum Controller anticlockwise all the way to the stop (equivalent to vacuum minimum).
8. Control vacuum intensity at the opening of the cannula. Weak suction performance.
9. Use the power switch “I/O”, at the rear of the device, to switch off device, LED is not illuminated.

Suction pump with pneumatic pedal and Vario-AIR-Pedal:

1. Use the power switch “I/O”, at the rear of the device, to switch the device on, LED is illuminated.
2. Device fan is running.
3. Hold hand in front of the «Exhaust» (Rear of the device). Airflow is perceptible.
4. Press pneumatic pedal shortly to activate the suction pump.
5. Turn Vacuum Controler clockwise (equivalent to vacuum maximum).
6. Control vacuum intensity at the cannulas opening. Strong suction performance.
7. Press Vario-AIR-Pedal. The more it is pressed, the weaker the suction performance at the cannula.
8. Turn Vacuum Controller anticlockwise all the way to the stop (equivalent to vacuum minimum).
9. Control vacuum intensity at the cannulas opening. Weak suction performance.
10. Press Vario-AIR-Pedal. The more it is pressed, the weaker the suction performance at the cannula. The suction performance now is not perceptible anymore.
11. Use the power switch “I/O”, at the rear of the device, to switch off device, LED is not illuminated.

Malfunctions and troubleshooting:

To solve problems refer to chapter 10 “Malfunctions and troubleshooting”.

8 Cleaning, disinfection and sterilization

The following points in particular are important with regard to caring for the material:

- Perform cleaning, disinfection and sterilization after every treatment!
- Always autoclave the material in sterilization packaging.
- Make sure that sterilization packaging is no more than 80 % full.
- Always autoclave the material at 134°C for at least 5 minutes.
- If sterilized material is not used immediately, the material packaging must be labeled with the sterilization date.
- Nouvag AG recommends including a sterility indicator.

8.1 Control unit and pneumatic pedal

Control unit and pneumatic pedal do not come into contact with the patient.
Wipe the outside using micro-biologically tested surface disinfectant or a 70 % isopropyl solution. The front plate of the control unit is sealed for this purpose and can be wiped clean.

8.2 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.

8.3 FLOVAC secretion jar with disposable inlay pouch

The disposable FLOVAC 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.

8.4 Bacteria filter

The bacteria filter located on top of the Vacuson pump is a one way product and cannot be cleaned or sterilized.
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.

8.5 Silicone tubes

REF 4075, connection tube 8 x 3 x 400 mm from bacteria filter to secretion jar, silicone, sterilizable
REF 4076, suction tube 8 x 3 x 1700 mm, from secretion jar to suction cannula, silicone, sterilizable

Reprocessing restrictions	Frequent reprocessing of the silicon tubes has only a limited impact. The end of the product service life is normally determined by wear 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 sterilization trays.
Sterilization 	Autoclave in vacuum autoclave at 134°C for at least 5 minutes. When sterilizing several items during one sterilization 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 sterilization, the material packaging must be labeled with the sterilization date. Including a sterility indicator is recommended.

The effectiveness of the sterilization instructions provided above for reprocessing this medical product has been validated by Nouvag AG. The user is responsible for ensuring that the sterilization 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 sterilization process.

- The tube set REF 6026 (optional) is delivered in sterile condition. It is determined for single use and may not be resterilized!
- Contaminated tube sets have to be disposed of expertly!

8.6 Cannulas and cannula handlebar

The optional cannulas and the cannula hadlebare 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 handlebar.

8.7 Quiver

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

1. Attention, it's important to use a disinfection agent compatibel with polycarbonate.
2. Pack quiver in individual packaging for sterile items (siehe DIN 58953).
3. Autoclave wrapped quiver **at 134°C for at least 5 minutes***.
4. 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 sterilized quiver is not used immediately after sterilization, the material packaging must be labeled with the sterilization date. Including a sterility indicator is recommended.

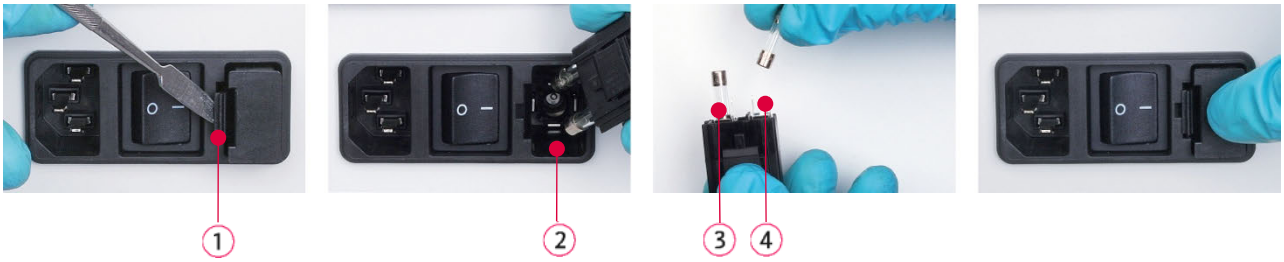
** Temperature exposure times are based on country-specific guidelines and standards.*

9 Maintenance

9.1 Replacing the control unit fuse

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:

- Unplug the power plug.
- Open the fuse slot using a screw driver.
- Replace defective fuses T 4 AL, 250 V AC (115 V model)/ T 2 AL, 250 V AC (230 V model).
- Slide the fuse holder back in and close the fuse slot.
- Plug in the power plug again.



1. Fuse slot locking mechanism
2. Fuse slot
3. Fuse 1
4. Fuse 2

9.2 Safety inspections

The essential requirements have been defined and within the risk analysis assessed. The approved results have been filed in the Riskmanagement act with 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 of this measure 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 40/60 shall be executed every 2 years by authorised experts. Results shall be documented.

The service manual, wiring diagrams, and descriptions are available upon request from Manufacturer.

NOUVAG AG offers a safety inspection service for its customers. Addresses can be found in the appendix of this operation manual under “Service centers”. For further information please contact our technical service department.

Further international service centers are listed on the Nouvag website:

www.nouvag.com › Service › Service centers

EN

9.3 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 11 to retrieve the article number.

9.4 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 troublefree operation of the pump.

9.5 Function control of float gauge valve

The proper functioning of the overflow protection system, built in the jar lid, has to be checked periodically.

1. Connect jar lid (VACUUM) with bacteria filter, using the connection tube (8 x 3 x 400 mm).
2. Turn Vacuum Controler clockwise (equivalent to vacuum maximum) all the way to the stop.
3. Press pneumatic pedal to generate vacuum.
4. Press the float gauge of the overflow protection system towards the lid.
5. The manometer shows increasing values up to the maximum. (> – 0.9 bar).

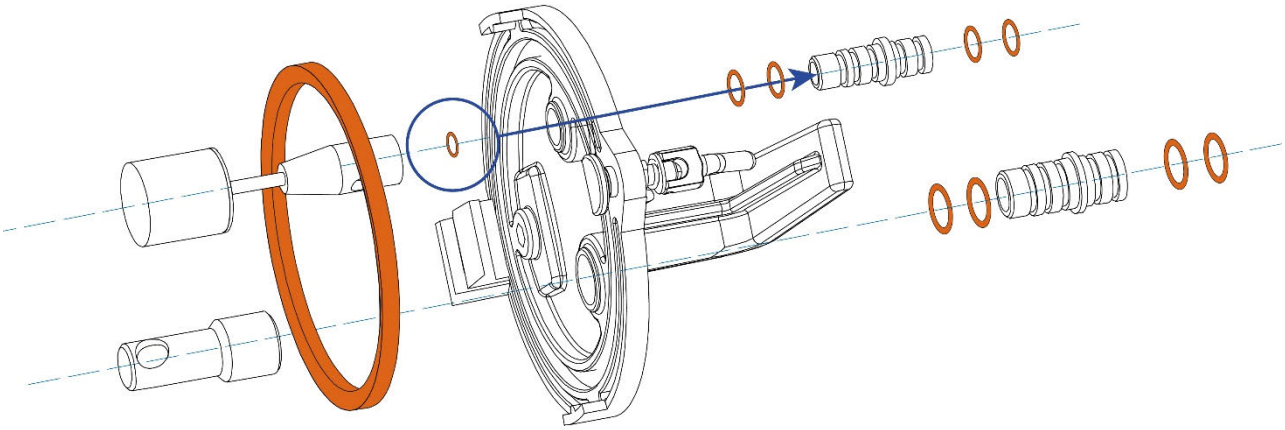
If the manometer doesn't show maximal vacuum (> – 0.9 bar), the overflow protection system has to be disassembled, cleaned and the seals have to be replaced.

9.6 Disassembly of the Overflow Protection System

1. Unscrew threaded Overflow Protection connector.
2. Remove seal from inside connector (O-Ring acc. picture).
3. Clean Overflow Protection System and float gauge.
4. Install new seal (O-Ring acc. picture).
5. Reasseble of Overflow Protection connector.

Function control after reassembly:

6. Hold lid perpendicularly.
7. Press flaut gauge repeatedly towards the lid.
8. Float gauge must fall back in place by itself.



If the float gauge doesn't fall back in place by itself the cleaning procedure has to be repeated and the sitting of the O-Ring seal has to be checked and corrected.

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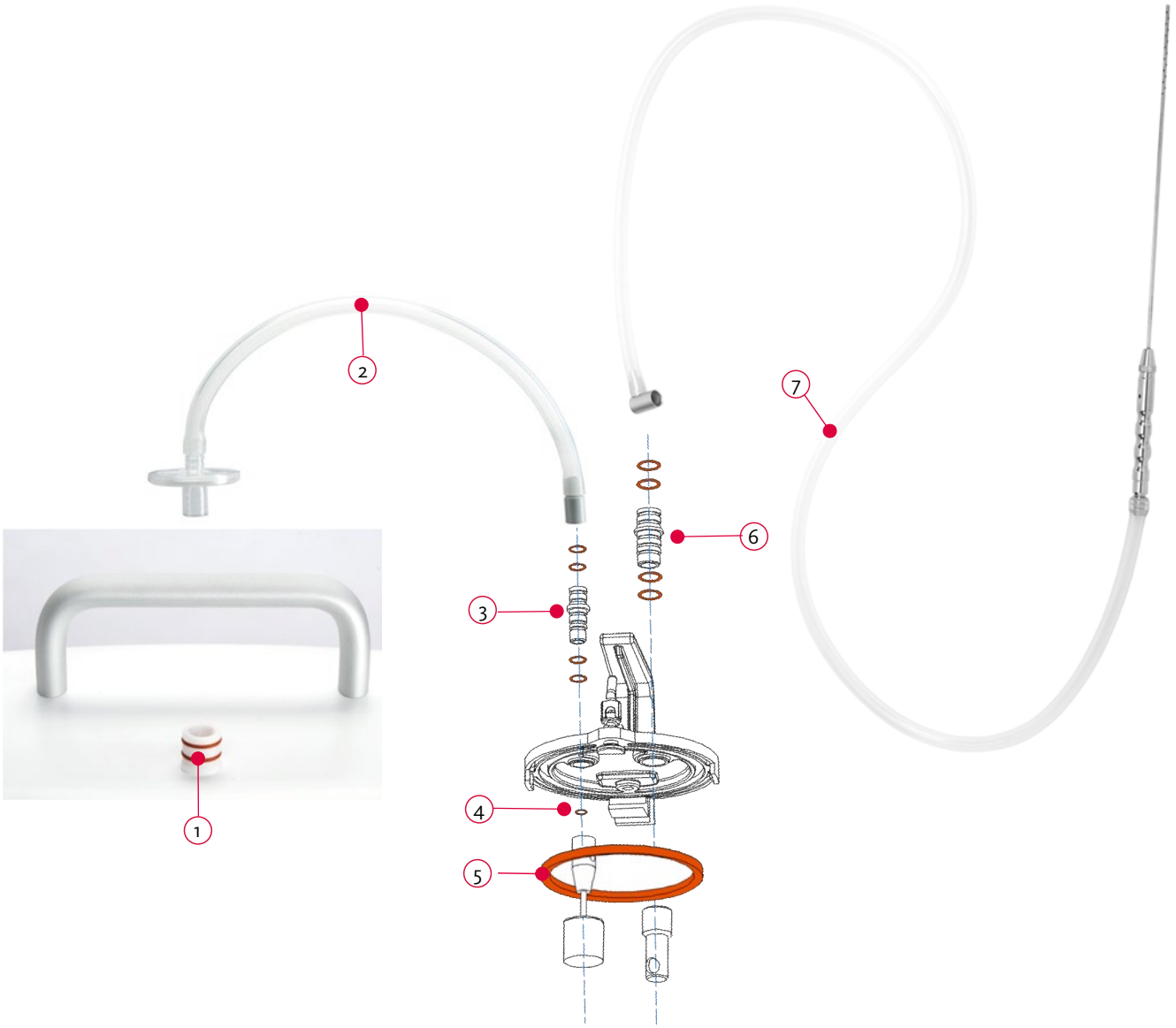
9.7 Seals and tubes

To insure proper function of the Suction Pump, all tubes and seals must be periodically checked, and replaced after at most 250 sterilization cycles or five years of operation. Only when in perfect order can sufficient vacuum be built up.

Defective seals and tubes must be replaced.



1.	Seal (O-Ring) at intake nozzle of control unit for connection with bacteria filter	2 units	REF 4063
2.	Connecting tube between bacteria filter and secretion jar lid (VACUUM)	1 unit	REF 4155
3.	Seal (O-Ring) at connection nozzle (unscrewable, VACUUM) at secretion jar lid	4 units	REF 4064
4.	Seal (O-Ring) at overflow protection system at jar lid	1 unit	REF 28958
5.	Main seal between jar lid and jar	1 unit	REF 28957
6.	Seal (O-Ring) at connection nozzle (unscrewable, PATIENT) of secretion jar lid	4 units	REF 4063
7.	Filling tube between connection nozzle (PATIENT) and cannula	1 unit	REF 4076

10 Malfunction and troubleshooting

Malfunction	Cause	Solution	Reference in manual
Device is not operational	Pump is not switched on	Switch main switch “I/O” to “I”	7.1 Switching device on and off
	No connection to electricity-supply	Connect power cord to electricity-supply	6.4 Device preparation
	Wrong voltage	Check power supply of your Pump	6.2 Connection to the power supply
	Defective fuses	Replace fuse	9.1 Replacing the control unit fuse
Pedal is not functioning	On/Off-AIR-Pedal is not connected	Connect On/Off-AIR-Pedal with device at rear	7.2 Pump activation by pneumatic pedal
	Control unit is not switched on	Switch main switch “I/O” to “I”	7.1 Switching device on and off
	Incorrect operation	Read instruction manual carefully	
Suction pump is not functioning	Vacuum pump is not switched on	Connect On/Off-AIR-Pedal at the rear of the device	7.2 Pump activation by pneumatic pedal
	Vacuum-system is not air tight	Check all seals and tubes. Make sure char lid is properly closed	6.3 Preparation of secretion jar 6.4 Device preparation 9.7 Seals and tubes
	Air inlet port at rear of the device is open	Close air inlet port with its cap.	6.4 Device preparation
	Tubes are connected wrong	Connect tubes correctly	6.4 Device preparation
	Jar is full and Overflow protection has locked down	Replace full jar by a fresh, empty jar	7.5 Emptying secretion jar
	Incorrect operation	Read instruction manual carefully	
Suction pump is not working properly	Vacuum controller is not opend wide enough	Turn Vacuum controller clockwise	7.4 Regulating suction process
	Vacuum-systemis not air tight	Check all seals and tubes. Make sure char lid is properly closed	6.3 Preparation of secretion jar 6.4 Device preparation 9.7 Seals and tubes

If a fault cannot be rectified, please contact your supplier or an authorized service center. The addresses are provided on the last page of tis operating instructions.

11 Accessories and spare parts

Seals	REF
(Refer to 9.7 Seals and tubes)	

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Connection elements	REF
Standard straight wide connector (PATIENT) at secretion jar lid, attached to filling tube	4056
Standard straight narrow connector (VACUUM) at secretion jar lid, attached to connecting tube	4047
Angled connector (VACUUM) for more convenient tube connection with filling tube	28535

Tube elements	REF
Connecting tube, Silicone, bacteria filter to jar lid, (Outer-Ø x inner-Ø x length) 8 x 3 x 400 mm	4155
Connecting tube, Silicone, bacteria filter to jar lid, (Outer-Ø x inner-Ø x length) 8 x 3 x 500 mm	4190
Single use filling tube Polypropylene, sterile, (Outer-Ø x inner-Ø x length) 6.5 x 9 x 4000 mm	6026

Accessories	REF
Secretion jar, 2 liter, polysulfone, sterilisable, including operation manual	4052
Secretion jar, 5 liter, polysulfone, sterilisable, including operation manual	4245
FLOVAC, secretion jar system with jars for 2 liter disposable pouches, with mounting bracket	4030F
FLOVAC, 2 liter disposable pouches including lid, 50 units	4035F
FLOVAC, tubing adapter delivered with 25 pieces per packaging unit	4019F
FLOVAC, 2 liter inlay jar, sterilisable	6036F
FLOVAC, mounting bracket for suspending the FLOVAC system	4037F
Bacteria filter for all NOUVAG Vacuson suction pumps, disposable, hydrophobe	4246
Secretion jar lid with overflow protection system for 2 and 5 liter secretion jars, complete	4058
Quiver, sterilizable, 30 cm length, with suspension device	4043
Quiver, sterilizable, 40 cm length, with suspension device	4044
Suction cups for obstetrics with Ø 60 mm	4053
Suction cups for obstetrics with Ø 70 mm	4054
Two way tap to switch between the two secretion jars, including connecting tube 8 x 3 x 400 mm	4130

Suction Cannulas for Liposuction	REF
Cannula handlebar with opening for false air ventilation	4391
Cannula handlebar without opening	4390
Yankauer suction cannula, length 28 cm, Ø 2.0 mm	4446
Andrews cannula, length 24 cm, Ø 2.0 mm	4449
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 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 additional parts, please contact our customer service department.

12 Information on disposal

When disposing of the device, device parts and accessories, the stipulated statutory regulations must be followed.

Do not dispose of devices with household waste!
To ensure environmental protection, old devices can be returned to the dealer or manufacturer.

Motors that have reached the end of their service life may not be disposed of with household waste. Motors must be sterilized before disposal. Please observe currently valid national disposal regulations for infectious waste.

Contaminated single-use tubing sets are subject to specific disposal requirements. Please observe currently valid national disposal regulations for infectious waste.

Anhang DE
Appendix EN
Appendice FR
Appendice IT
Apéndice ES
Appendix NL
додаток UK

NOUVAG

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.

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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Service center

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EC REP

A complete list of Nouvag certified service centers are found on the Nouvag website at:
www.nouvag.com/service

Post market surveillance

In the event of problems with the product or in the event of a serious incident, please immediately download, compile and send the following form

https://nouvag.com/media/attachments/2022/05/19/for_8-308.pdf

as a PDF to this address: **complaint@nouvag.com**

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