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Instructions for use

Vacuson 60 LP

Liposuction system

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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Table of contents

1 Product description

1.1 Intended use and operation

The VACUSON 60 LP is a sensible and precisely integrated Liposuction device, combining infiltration and suction for protective tissue treatment with or without local anesthetic tumescence.
In combination with the corresponding accessories, safe, conservative treatment is assured, providing a crucial advantage in ambulatory Liposuction treatment. With proper application, the tissue removal procedure is simple, safe, costeffective and delivers optimal cosmetic results.

1.2 Contraindications

a) Infected wounds have poorly vascularized and necrotic tissue.
b) Poor physical health of patient
c) Patient who underwent crash dieting immediately prior to consultation
d) Morbid obesity (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 60 LP

Voltage:	for 115 V model, REF 4285-115: 115 V~at 60 Hz	For 230 V model, REF 4285-230: 230 V~at 50 Hz
Power consumption:	max. 370 VA	
Fuses:	for 115 V model, REF 4285-115: 2 x T4 AL 250 V AC	For 230 V model, REF 4285-230: 2 x T2 AL 250 V AC
Protection class:	Class I	
Applied part:	Type BF	
Max. pressure:	**relative:** – 0,9 bar/675 mmHG; **absolute:** 0,1 bar/675 mmHG	
Dimensions, W x H x D:	360 x 300 x 280 mm	
Weight:	14 kg	
Accuracy limit, Manometer:	± 5 %	
Speed of Conform Cannula Handpiece:	10,000 rpm = 3600 strokes/min.	
Suction Pump Capacity:	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

1.5 Warranty coverage

Purchasing the Vacuson 60 LP Liposuction system 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.

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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		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 against 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: Surfaces can become hot		Don't touch mechanical parts
	Observe the flow direction		Equipotential (potential equalization)
	Hot air exhaust port		Autoclavable at 121°C
	Dangerous goods, Lithium-ion batteries		Dangerous goods, Lithium metal battereies
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 60 LP 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.

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 60 LP 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.

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3.2 Modification and misuse

- Modification or manipulation on the Vacuson 60 LP liposuction pump system 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 60 LP suction pump 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 60 LP suction pump may only be operated under constant supervision of qualified and trained personnel!

Repairs may only be performed by authorized NOUVAG service technicians.

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

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!

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.

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 60 LP suction pump must be at least one meter above ground.

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

The surgeon is responsible for the choice of the infiltration tumescent solution.

In extreme cases the handle of the Conform Cannula Handpiece may be heated up excessively.

4 Scope of delivery

REF	Description	Quantity
	Vacuson 60 LP, 115 V model, REF for complete set 4179-115	
4285-115	Control unit Vacuson 60 LP	1
	Vacuson 60 LP, 230 V model, REF for complete set 4179-230	
4285-230	Control unit Vacuson 60 LP	1
	Common equipment features for the 115 V and 230 V model:	
1861nou	VARIO foot switch with pedal, IPX8	1
4052	Secretion jar, 2 liter, polysulfone, sterilizable, including operation manual	2
4058	Jar lid for 2 and 5 liter secretion jars with overflow protection, sterilizable	2
4246	Disposable bacteria filter, Ø 64 mm, PTFE, hydrophobic	10
4155	Connecting tube between bacteria filter and secretion char, 8 x 3 x 400 mm, sterilizable	1
4190	Connecting tube between bacteria filter and secretion char, 8 x 3 x 500 mm, sterilizable	1
6026	Disposable suction tube 9 x 6.5 x 4000 mm, sterile	1
6022	Disposable tubing set for infiltration, sterile, 4 m	1
2101nou	Electronic motor 21; 4 m cord, sterilizable	1
5107	Handle for Conform Cannula Handpiece, sterilizable	1
5077nou	Conform Cannula Handpiece, sterilizable	1
1170	Handpiece cradle, white, sterilizable	1
28535	Angled connector for mounting the suction tube at the VACUUM connection of the secretion jar lid	1
29061	Clip set to attach suction tube to motor cable of the Conform Cannula Handpiece	5
4043	Rinsing goblet, 30 cm length, including suspention module, sterilizable	1
2127	NouvaClean-Spray for the care (cleaning) of handpieces	1
2128	NouvaOil-Spray for the care (lubrication) of handpieces and electronic motor 21	1
1770	Bottle holder for Infiltration liquid	1
31793	Operating instructions for Vacuson 60 LP on CD-ROM	1

In line with regulations pertaining to hazardous materials, the article **2127, NouvaClean-Spray** and **2128, NouvaOil-Spray,** is not delivered with the control unit but can be ordered separately from any official Nouvag service center.

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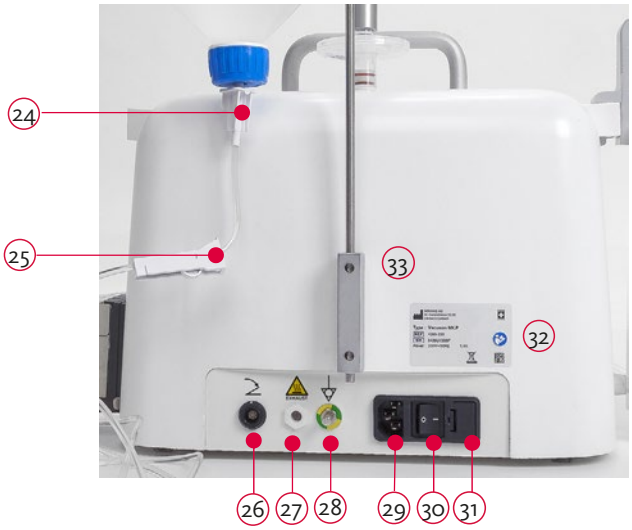
5 Device overview

Front view

1. Conform Cannula Handpiece
2. Suction cannula (option)
3. Infiltration cannula (option)
4. Handpiece cradle
5. Cannula adapter with Luer Lock connection (option)
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 (option, REF 4130)
15. Bacteria filter
16. Carrying handle
17. Vacuum control (VACUUM)
18. Indicator light, LED (POWER)
19. Vacuum manometer, mm/Hg
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
28. Connection for potential equalization
29. Mains connection

Rear view



30. Power switch ON/OFF (O/I)
31. Fuse compartment
32. Type plate with device name, reference number, serial number, voltage information, fuse specification
33. Stand holder for infiltration bottle

6 Startup

6.1 Device setup

- Installations-Layout

- Place the Vacuson 60 LP 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 instrument to be compromised by limiting factors.
- The manometer must be fully visible at all times.
- The foot switch with 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 of the Vacuson 60 LP must be kept clear in order to prevent temperature from becoming excessive.
- While in operation the device 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 60 LP pump 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.

Use only a certified power cord to connect the device to the power supply.

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

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6.3 Preparation of secretion jars

1. Hold sterile, open jar available (2 or 5 liter), or the jars (2 liter) of the FLOVAC system.

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).

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.

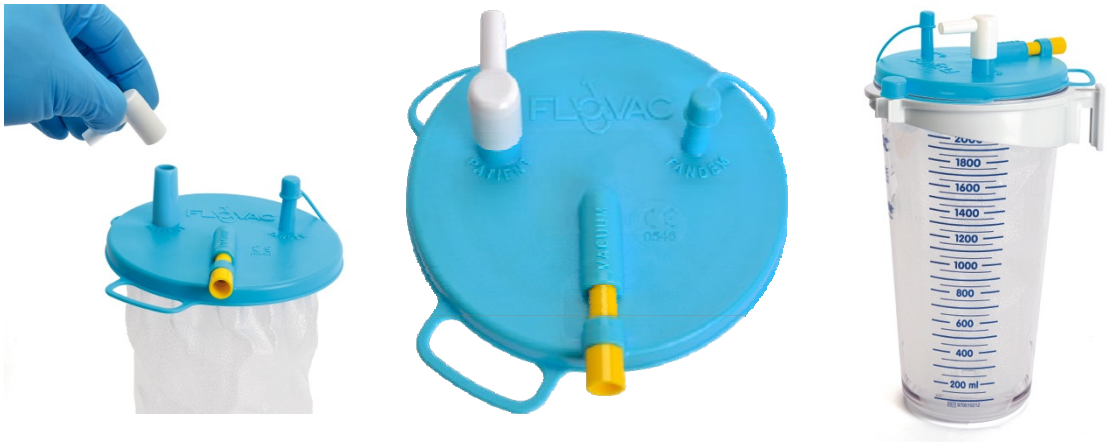
4. Flap down Turn and Tilting Lever into the designated groove.

Turn and Tilting Lever locked
and secured.

6.4 Preparing the FLOVAC secretion jar system

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

2. Attach the angled tube connector to the FLOVAC lid (PATIENT) and insert the disposable inlay pouch into the FLOVAC collection container and close the container with sustained pressure on the lid.



3. Place bottle holder ring into the bracket of the Vacuson pump and suspend the collection container in it.

4. Graft the connection tube over the tube adapter (4019F) to the VACUUM port and graft the suction tube to the PATIENT port.

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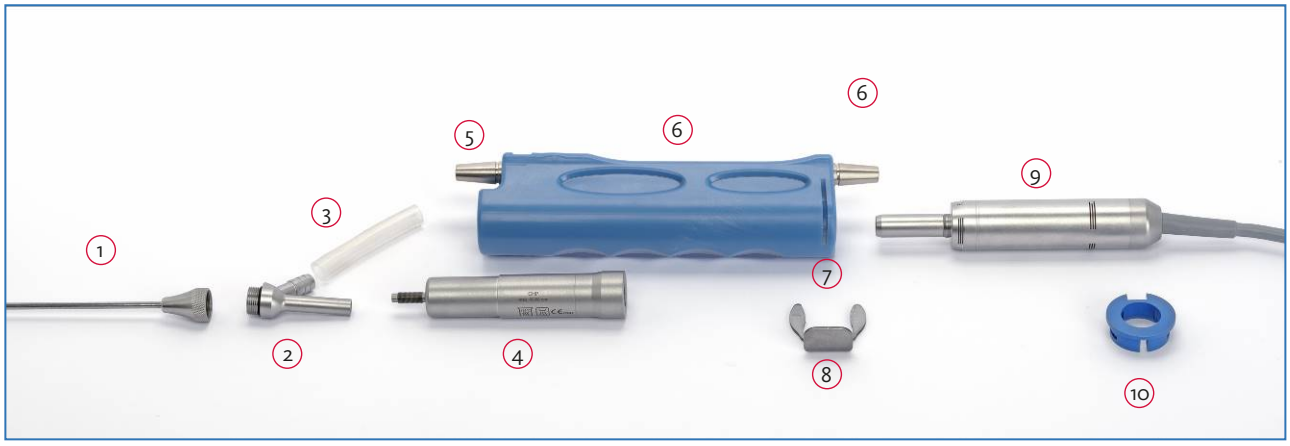
6.5 Preparing Conform Cannula Handpiece

Assemble the sterilized Conform Cannula Handpiece, electronic motor and all the accessories according to the following instruction.



1. Liposuction cannula (optional)
2. Cannula adapter (REF 75705)
3. Connecting piece of suction tube (REF 28987)
4. Transmission capsule (REF 75700)
5. Suction pipe integrated in handle
6. Handle (REF 5107)
7. Slot opening for locking clamp
8. Locking clamp for blocking ring (REF 28556)
9. Electronic motor (REF 2101)
10. Blocking ring (REF 28554)

Remove locking clamp.

Remove blocking ring.

Unscrew tube adapter ...

... from cannula adapter.

Pull the motor cable plug thru the blocking ring until the blocking ring is on the rear of the motor.

Engage transmission capsule with the electronic motor, press until it clicks.

Insert transmission-motor-unit into the handle.

... all the way to the stop.

Slide blocking ring over the cable...

...and insert it into the opening.

Slip locking clamp into the slot ...

... and lock it flush to the housing.

Screw cannula adapter onto the transmission capsule.

Align tube adapter by twisting the transmission capsule

Graft tube piece onto the suction pipe of the handle bar.

Screw liposuction cannula onto the cannula adapter.

Insert plug of electronic motor into the socket at the control unit.

Full assembled Conform Cannula Handpiece, ready to use. (Connect suction tube with Conform Cannula Handpiece and your vacuum pump system).

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6.6 Device preparation

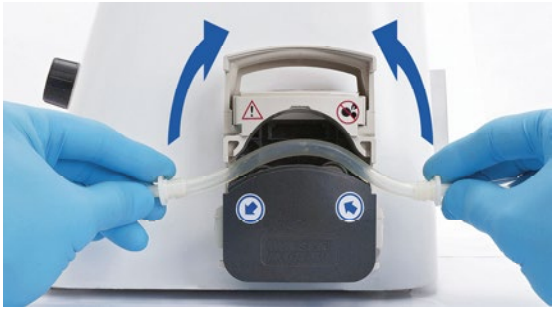
1. Prior to use, all sterilizable parts (e.g. Silicone tubes, Cannulas, Conform cannula handpiece, handlebar, char lid and bottles) must be sterilized.

134 °C

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

3. Lay the VARIO foot switch with pedal on the floor and connect the power plug with the foot switch socket.

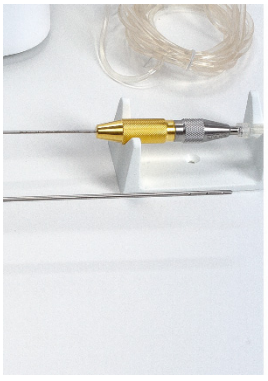
4. Open the hood of the tube compartment and insert the tubing set. Make sure the flow direction corresponds with the arrows on the tube compartment.



5. Adjust the clamps at the left and at the right of the infiltration pump to fix the tube set in place. Therefore close the tube compartment and gently adjust the clamps by twisting the knurled wheels into the appropriate position.

6. Hang bottle with infiltration solution on the stand and insert the spike through the diaphragm at the bottle top. Open the bleed valve.

7. Attach infiltration cannula to the to the cannula adapter. Open the roller clamp all the way. The amount of infiltration liquid is adjusted by the pump (INFILTRATION).



8. Attach the short connection tube (40 cm) on one end with the bacteria filter and the other end with the narrow connector (VACUUM) of the jar lid.

9. Attach the suction tube on one end with the angled connector (REF 28535) and the other end of the tube with the Conform Cannula Handpiece.

10. 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).

11. Graft the angled connector (REF 28535) of the suction tube (400 cm) onto the wider nozle (PATIENT) of the secretion jar. Place the other end of the filling tube with the Conform Cannula Handpiece on the handpiece cradle.

12. 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!

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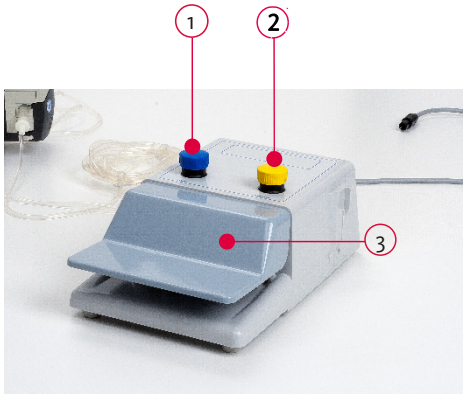
7 Operation

7.1 Switching device on and off

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 the front of the device.
The device can be switched off at any time, irrespective of any procedure for device switch-off.

7.2 Operation of the VARIO footswitch with pedal



1. Foot switch **“Vacuum”** (blue) starts the vacuum pump.
2. Foot switch **“Motor”** (yellow) starts the electronic motor to conduct the lifting movement of the cannula at the Conform Cannula Handpiece.
3. Pedal for starting the infiltration pump and regulating the amount of infiltration liquid delivery up to the preset maximum value.

7.3 Regulation of suction performance

The suction performance is regulated by the Vacuum Controller at the front side of the device.

Turning clockwise:	*Vacuum increases, suction performance is enhanced.*
Turning counterclockwise:	*Vacuum decreases, suction performance is reduced.*

Establishing airtightness of the suction system and checking for leaks:

1. Turn Vacuum Controller counter clockwise all the way to the stop (equivalent to vacuum minimum).
2. Switch on device (I/O) and press the foot switch **“Vacuum”** at the VARIO pedal. Pump is running and vacuum is building up.
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 (relative)).
6. Now by turning the Vacuum Controller the suction performance can be regulated steplessly from 0 to – 0.9 bar (relative).

The vacuum pump is always running at maximum speed. The reduction of the suction performance is achieved by forced ventilation.

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.

7.4 Regulation of infiltration performance

The Infiltration Controller is used to preset the maximum infiltration performance that can be retrieved by using the pedal. By pressing the pedal infiltration can be started, regulated and halted.

Turning clockwise:	*Delivery of maximal infiltration liquid is increased.*
Turning counterclockwise:	*Delivery of maximal infiltration liquid is reduced.*

7.5 Operation of Conform Cannula Handpiece

By pressing the foot switch **"Motor",** the stroke movement of the Conform Cannula Handpiece is actuated. The motor is running with a constant speed of 10,000 rpm.

7.6 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.

1. Swich off suction pump.
2. Disconnect tubes including connectors 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.

7.7 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, indicator light, **LED,** is illuminated.
2. Neither the Infiltration pump nor the suction pump or the motor of the Conform Cannula Handpiece may be actuated without the pedal being pressed.

Suction pump:

1. Press foot switch **"Vacuum"** (blue) at the VARIO pedal to activiate the suction pump.
2. Hold hand in front of the **"Exhaust"** (Rear of the device). Airflow is perceptible.
3. Turn Vacuum Controller (Vacuum) clockwise, equivalent to vacuum maximum.
4. Control vacuum performance at the openings of the cannula. Suction performance is high.
5. Turn Vacuum Controller anticlockwise all the way to the stop, equivalent to vacuum minimum.
6. Control vacuum intensity at the openings of the cannula. Suction performance is low.
7. Use the power switch **"I/O"**, at the rear of the device, to switch off device, indicator light, **LED**, goes off.

Infiltration pump:

1. Turn Infiltration Controller, **"Infiltration"**, clockwise, all the way it goes, equivalent to maximal flow rate.
2. Press pedal on the VARIO Pedal, infiltration pump starts.
3. Turn Infiltration Controller couterclockwise, all the way it goes, equivalent to minimum flow rate.
4. Infiltration performance is reduced down to a stand still.
5. Once the maximum infiltration amount is set, the delivery of infiltration liquid can be regulated by pedal.

Conform Cannula Handpiece with Electronicmotor:

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.

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.

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8.1 Control unit and VARIO Pedal

Control unit and VARIO 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 (REF 31732).

8.3 FLOVAC collection container with disposable inlay pouches

The disposable FLOVAC inlay pouches are not to be reprocessed. They have to be discarded off expertly.
For reprocessing the reusable collection containers please refer to the operation instructions 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 Quiver (Extension)

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.*

8.6 Silicone tube

REF 4155, filling tube 8 x 3 x 400 mm, from bacteria filter to secretion jar, silicone, sterilizable.
REF 4190, filling tube 8 x 3 x 500 mm, from bacteria filter to secretion jar. 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 water 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 a 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 disposable tube set, REF 6026, 4 meters of legth, 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!

8.7 Cannulas

The optional cannulas 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 cannulas.

8.8 Conform Cannula Handpiece with Grasp

The Conform cannula handpiece comes into contact with the patient via the screwed-on cannula and the integrated suction channel and must therefore be reprocessed accordingly.
For reprocessing instructions, please refer to the instructions for use supplied with the Conform cannula handpiece.

8.9 Electronicmotor 21, reprocessing instruction

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

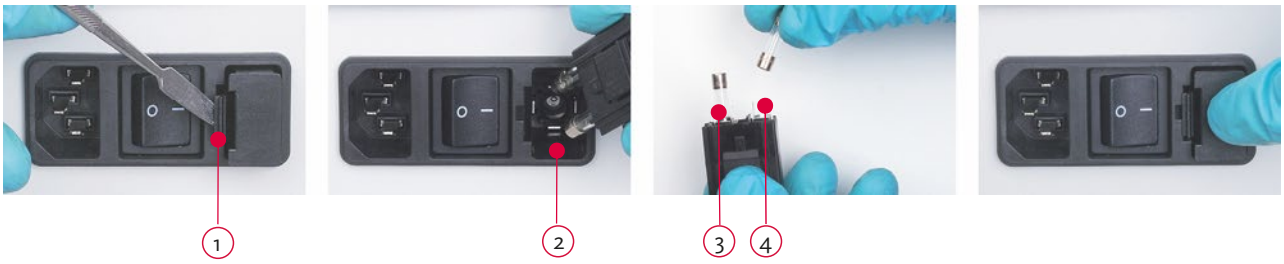
9 Maintenance

Maintenance work on the device may only be carried out if no operation on the patient is performed.

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 2 AL 250 VAC** for the 230 V version and **T4 AL 250 VAC** for the 115 V version.
- 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 60 LP 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

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.

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9.4 Collection container

The influxing mixture of air and secretion fluids into the collection container 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 collection container 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 foot switch to start the pump 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 (relative)).

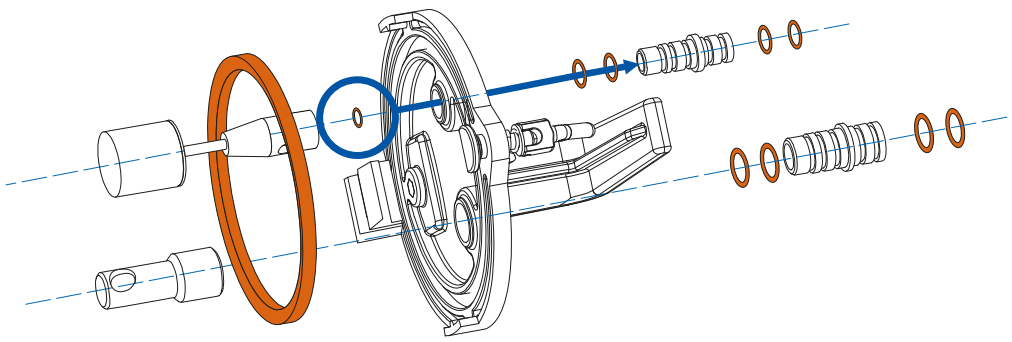
If the manometer doesn't show maximal vacuum (> – 0.9 bar (relative)), the overflow protection system has to be disassembled, cleaned and the seals have to be replaced.

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.

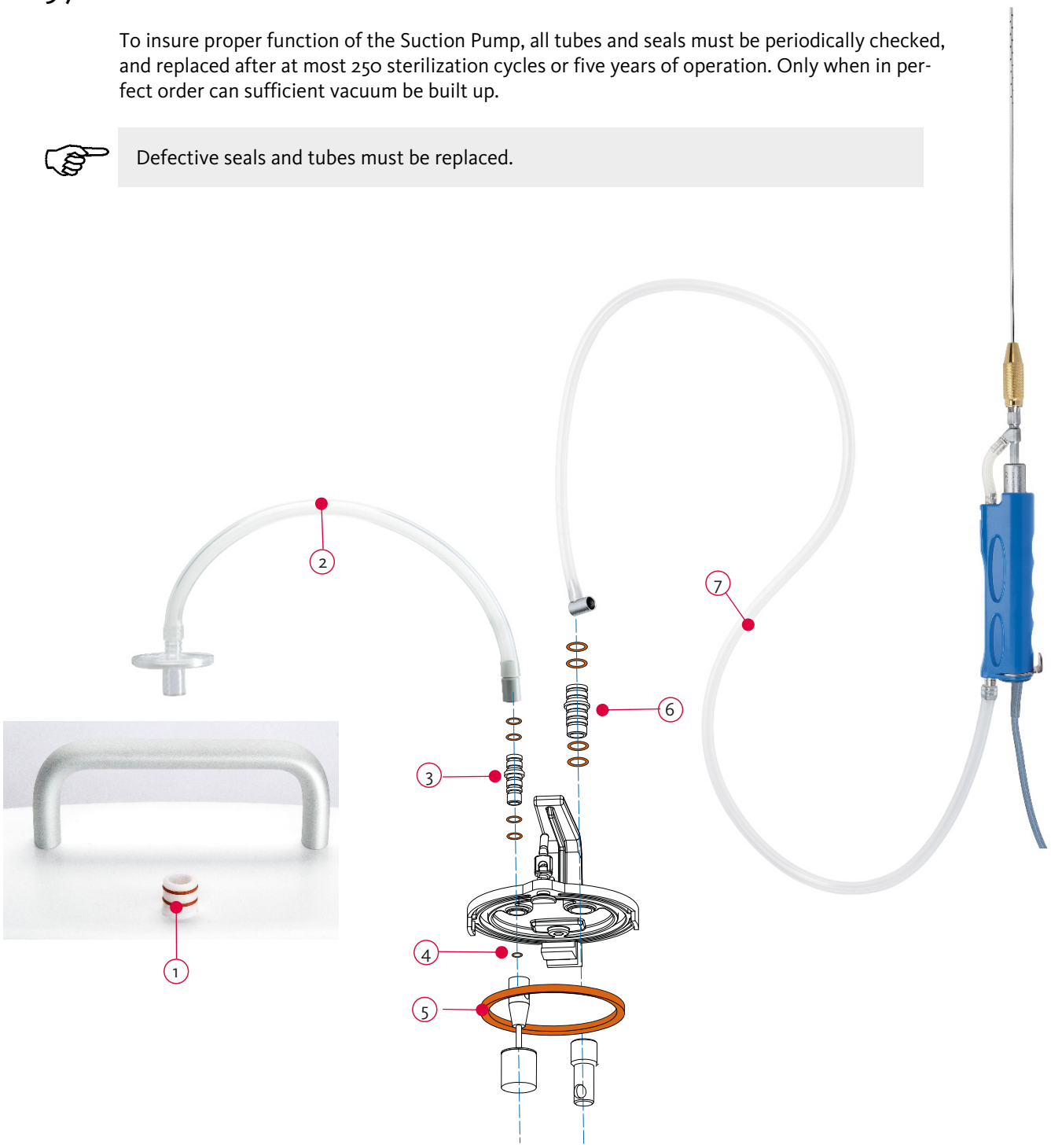


If the float gauge doesn't fall back in place by itself the cleaning procedure has to be repeated and the sitting of the O-Ring seal has to be checked and corrected.

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. Suction tube between connection nozzle (PATIENT) and cannula ----------1 unit ---------- REF 6026

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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	6.6 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	VARIO pedal is not connected	Connect VARIO pedal with device at rear	6.6 Device preparation
	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	Press connected VARIO pedal	7.2 Operation of the VARIO footswitch with 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 6.6 Device preparation 9.7 Seals and tubes
	Air inlet port (for VARIO-Air-Pedal) at rear of the device is open	Close air inlet port with its cap.	6.6 Device preparation
	Tubes are wrong connected	Connect tubes correctly	6.6 Device preparation
	Jar is full and Overflow protection has locked down	Replace full jar by a fresh, empty jar	7.6 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	7.3 Regulating suction process
	Vacuum-system is not air tight	Check all seals and tubes. Make sure char lid is properly closed.	6.3 Preparation of secretion jar 6.6 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)	

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

Tubing elements	REF
Connecting tubing, Silicone, bacteria filter to jar lid, (Outer-Ø x inner-Ø x length) 8 x 3 x 400 mm	4155
Connecting tubing, Silicone, bacteria filter to jar lid, (Outer-Ø x inner-Ø x length) 8 x 3 x 500 mm	4190
Suction tube, PVC, disposable, sterile, (Outer-Ø x inner-Ø x length) 9 x 6.5 x 4000 mm	6026
Tubing set for infiltration, Disposable, sterile	6022

Accessories	REF
Secretion jar, polysulfone, autoclavable, 2 liter volume, sterilisable	4052
Secretion jar, polysulfone, autoclavable, 5 liter volume, sterilisable	4245
FLOVAC, disposable secretion jar system with receptable for 2 liter pouches, with suspension device	4030F
FLOVAC, 2 liter disposable pouches including lid, 50 units per packaging unit	4035F
FLOVAC, 2 liter inlay jar, sterilizable	4036F
FLOVAC, bottle holder for suspending the FLOVAC-System	4037F
Bacteria filter for all NOUVAG Vacuson suction pumps, disposable, hydrophobe, Ø 64 mm, PTFE	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
2 way tap for switchin the secretion jar	4130

Suction Cannulas for Liposuction (sterilisable)	REF
Cannula handlebar with opening for false air ventilation	4391
Cannula handlebar without opening	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 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

Infiltration cannula	REF
Straight cannula, Ø 3 mm, length 250 mm	4350
Cannula adapter for the connection of infiltration cannulas with Luer-Lock connection	4398

Power cord	
Power cord CH with deivice socket, 3 m	22261
Power cord D with deivice socket, 3 m	22262
power cord GB with deivice socket, 3 m	22264
power cord USA with deivice socket, 3 m	22266

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

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12 Information on disposal

When disposing of the device, device parts and accessories, the regulations prescribed by law must be observed.
Lithium batteries (rechargeable batteries) and aerosol sprays are dangerous goods that must be declared accordingly when they are sent on to the end user. Nouvag AG / Nouvag GmbH is not liable if this regulation is not observed. Defective or even damaged batteries must not be sent back to Nouvag AG / Nouvag GmbH, but must be properly disposed of locally.

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

Appendix

Appendice

Appendice

Apéndice

Appendix

додаток

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.

NOUVAG

Service center

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CE 0197

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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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