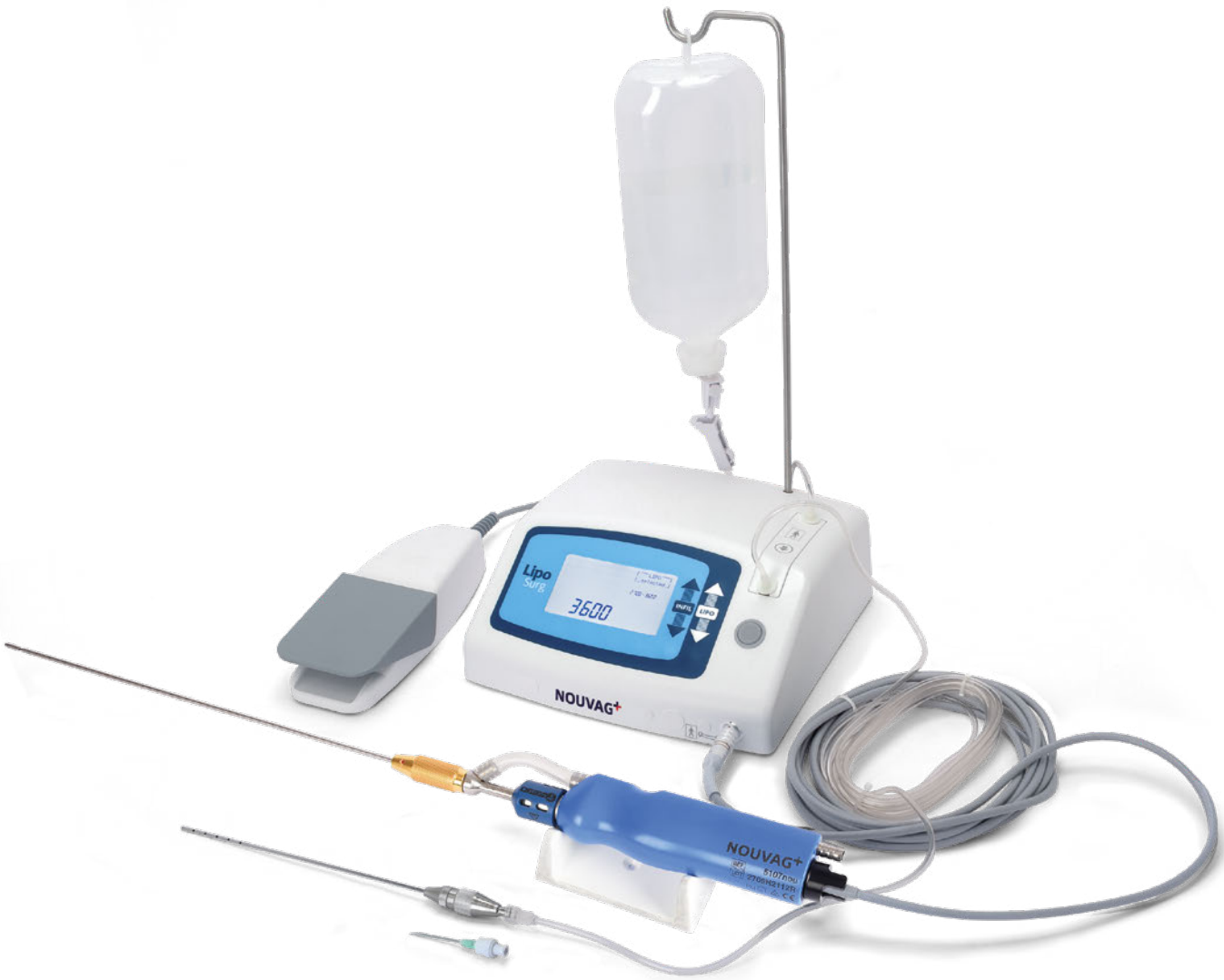
EN

Instructions for use

LipoSurg

NOUVAG+



CONGRATULATIONS ON YOUR PURCHASE OF A PRODUCT FROM NOUVAG.

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

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

SYMBOLS

 General warning sign	 General mandatory action	 Refer to instructions for use
 Manufacturer	 Date of manufacture	 Distributor
 Use-by date	 Separate collection required (WEEE)	 Biological hazard
 Do not use if package is damaged	 Not for reuse	 Contains or presence of Phthalate
LOT Batch code	REF Catalog number	SN Serial number
MD Medical device	EC REP Authorized representative in the European Community	STERILE EO Sterilized using ethylene oxide
 Type BF applied parts are the instruments used	 Autoclavable at 134°C	 For thermal disinfection
 Indication of pump flow direction	 Equipotentiality	 Foot switch
 Protective ground	 Socket for Motor	IPX8 Water resistance
CE 0197 European Conformity mark	 Certified by the TÜV Rheinland North America Group	

CONTENT

INTENDED PURPOSE

MEDICAL INDICATIONS

LipoSurg is a control unit including a motor drive and a peristaltic pump, which is used in combination with an electronic motor, a handpiece, sterile single use tubing sets, and a vacuum pump, for the following medical indications:

// **Infiltration of tumescent solution**
// **Liposuction**

CONTRAINDICATIONS

Infectious wounds Liposuction may only be performed after the treatment of the infection and necrotic tissue.
In principle, generally poor health of the patient.
Liposuction shortly after a strict diet of the patient.
Morbid obesity (obesity) Large suction volumes increase the risk of death due to fluid shifts.
Intravascular infusion of liquids.
Adverse reactions to pharmaceutical components in the tumescent solution.

SIDE EFFECTS

In general, side effects are transient and not frequent. Side effects of infiltration and liposuction include:

¬ Contour irregularities
¬ Seromas
¬ Haematoma
¬ Oedema
¬ Infection
¬ Perforation of abdominal wall
¬ Pulmonary embolism
¬ Fat embolism
¬ Sepsis

INTENDED USERS

The device is designed to be used by professional and trained users only, in professional contexts (e.g., hospital, clinic). The device is not to be used by patients or by untrained users.

TARGET POPULATION

Adult patients, in good health status.

AMBIENT CONDITIONS

	TRANSPORT AND STORAGE	DURING USE
Relative humidity	max. 90 %	max. 80 %
Temperature	0 °C – 60 °C	10 °C – 30 °C
Atmospheric pressure	700 – 1'060 hPa	800 – 1'060 hPa

SAFETY INFORMATION

Every use of the LipoSurg different to the [INTENDED PURPOSE >4] 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 from the place of treatment. Avoid any connection or close adjacency to other devices.

INDICATIONS

The use of the devices outside of the intended purpose is prohibited.
Non intended modifications to the control unit and accessories are not allowed.
Use of third party's devices and accessories not indicated by NOUVAG is not allowed.
Repairs must only be performed by authorized NOUVAG service centres.
Devices and accessories must be perfectly operational before use.
Ensure that the operating voltage settings correspond to the local main voltage.
Before use, read thoroughly all instructions for use of the devices and accessories.

WARNINGS

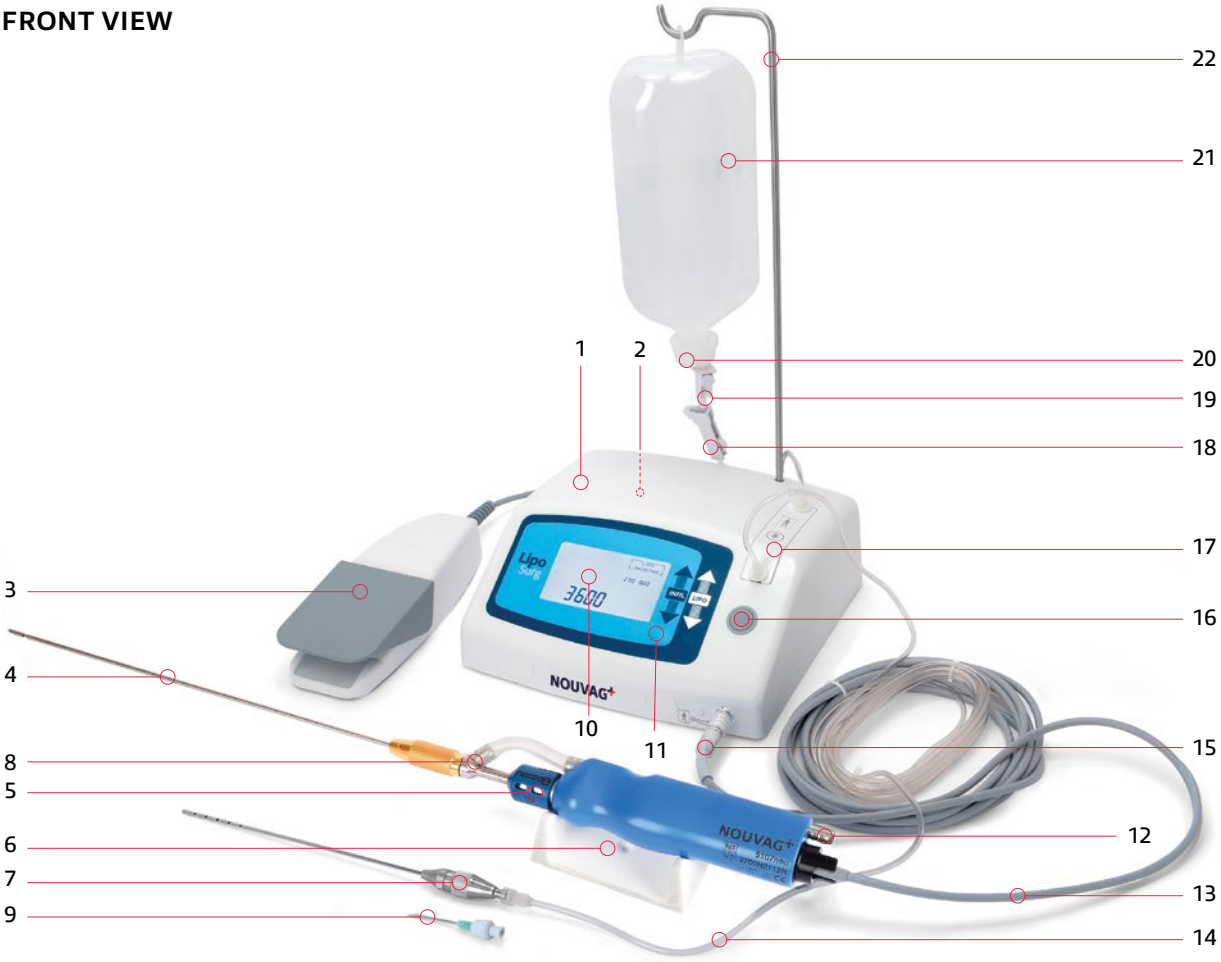
Do not use the device if the shipping box has holes/cracks on the flat surfaces, and/or if the Styrofoam protective packaging is broken.
NOUVAG recommends the use of Klein tumescent anesthesia solution. The use of other solutions is on the responsibility of the surgeon. When infiltrating tumescent anesthesia solution, do not exceed 0.05% w/w anesthetic concentration.
The reprocessing instructions must be followed to the letter. Deviations can cause malfunctions of the devices and hazard to patients' health, users, and third party.
Devices must be cleaned and disinfected before and after each use.
All sterilizable parts and accessories must be sterilized before use.
Devices must be operated outside the danger zone of explosives and flammable mixtures, or gases.
In extreme cases the handpiece may heat up excessively.
The device may only be operated under constant supervision of medical personnel. The absence of a warning buzz to indicate malfunctions of the device requires the permanent control of the volumetric displacement of the pump.
The device may only be operated by qualified and trained personnel.

SCOPE OF DELIVERY

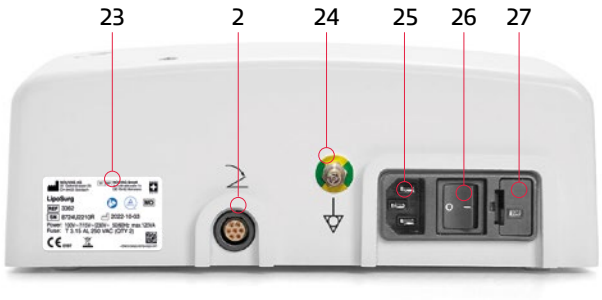
REF	DESCRIPTION	QUANTITY
3392	LipoSurg – Set	1
3362	LipoSurg control unit	1
1511nou	VARIO foot switch	1
2101nou	Electronic motor 21, 12'000 rpm	1
5077nou	Conform cannula handpiece	1
5107	Handle complete	1
29061	Clip set, for tube set attachment to motor cable, PU 5 pcs.	1
1770	Stand for irrigation fluid bottle	1
1170	Handpiece tray	1
19584	Spray adapter with thread, for lubricant spray (REF 2128)	1
31648	LipoSurg instructions for use	1

DEVICE OVERVIEW

FRONT VIEW



REAR VIEW



1 Control unit LipoSurg **2** Socket for VARIO pedal **3** VARIO pedal **4** Liposuction cannula (optional) **5** Handle with Conform cannula handpiece **6** Handpiece cradle **7** Cannula adapter with Luer-Lock (optional) **8** Cannula adapter **9** Infiltration needle (optional) **10** Display **11** Control panel **12** Connection for suction tube **13** Cable of electronic motor **14** Tubing set **15** Connection socket, electronic motor **16** Peristaltic pump release button **17** Swivel arm with tubing set mount **18** Roller clamp **19** Vent valve **20** Bottle cap with rubber membrane **21** Container with tumescent solution **22** Bottle holder **23** Type plate with type designation, reference number, serial number, information on power supply and device fuse **24** Connection for potential equalization **25** Power plug socket **26** Main switch **27** Fuse compartment **28** Spray nozzle for maintenance of Conform cannula handpiece

SETUP

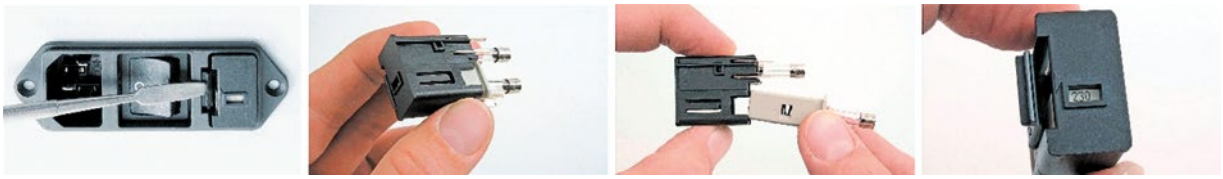
DEVICE AND ACCESSORIES SETUP

- ¬ Place the LipoSurg 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 near other devices is prohibited due to EMC.
- ¬ Do not allow the operating range of the device and accessories to be compromised by limiting factors.
- ¬ The system display must be always fully visible.
- ¬ The 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 always accessible.
- ¬ The motor ventilation slots must be kept clear to prevent the motor from overheating.

CONNECTION TO THE POWER SUPPLY

⚠ Before plugging the power cable into the power socket for the first time, you must check the supply voltage setting next to the power switch!

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



1 **Unplug the power cable.**

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

3 **Remove the fuse holder.**

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

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

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

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

⚠ To prevent of risks of an electric shock, the device may only be connected to a power network with a PE protective ground conductor.

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

SETUP

DEVICE PREPARATION

PREPARING THE ELECTRONIC MOTOR

Sterilize the electronic motor that drives the Conform cannula handpiece (the motor is not sterile on delivery). If the motor has already been sterilized: when removing the motor from the sterile packaging, ensure that the sterile packaging is not damaged and that the sterility indicator confirms sterility (if no sterility indicator is provided, the sterile packaging must at least show the date on which the shelf life of the sterile item is due to expire).

PREPARING THE BOTTLE HOLDER

Insert the bottle holder stand for the suspension of the tumescent solution container into the stand holder at the control unit and hang the container on it. The maximum load on the hook is limited at 2 kg.

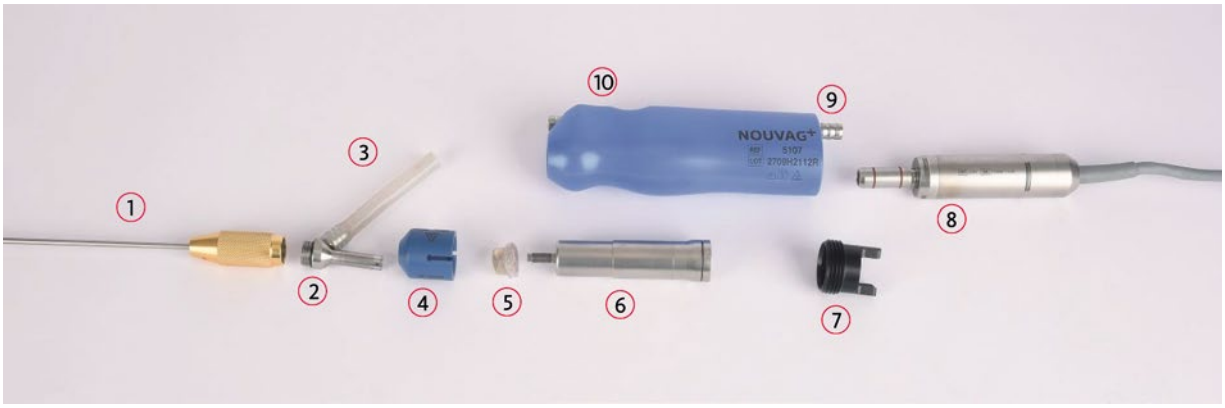
⚠ Heavier loads than allowed (2 kg) on the bottle holder stand may cause the unit to tip over.

PREPARING THE PEDAL

Connect the pedal plug with the pedal socket at the rear of the control unit.

PREPARING THE HANDLE WITH CONFORM CANNULA HANDPIECE

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



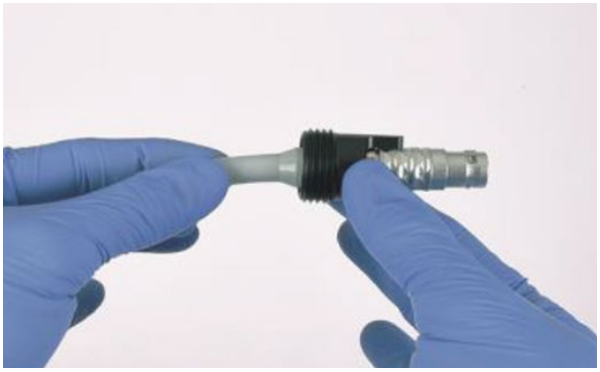
1 Liposuction cannula (optional) **2** Cannula adapter with suction channel (REF 75705) **3** Connection tube (REF 29063) **4** Protective cap (REF 40376) **5** Silicone sealing (REF 40377) **6** Conform cannula handpiece (REF 5107) **7** Closure 8 Electronic motor (REF 2101nou) **9** Suction pipe integrated in handle **10** Handle

SETUP

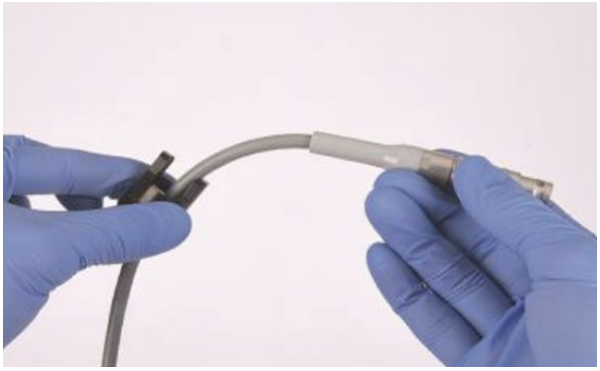
ASSEMBLING THE HANDLE WITH CONFORM CANNULA HANDPIECE

1 **Have the electronic motor ready.**

2 **Attach the Conform cannula handpiece onto the motor and check that it is firmly seated.**



3 **First slide the closure over the motor connector plug.**



4 **Guide the closure, thread first, over the cable of the electronic motor until just before the electronic motor.**

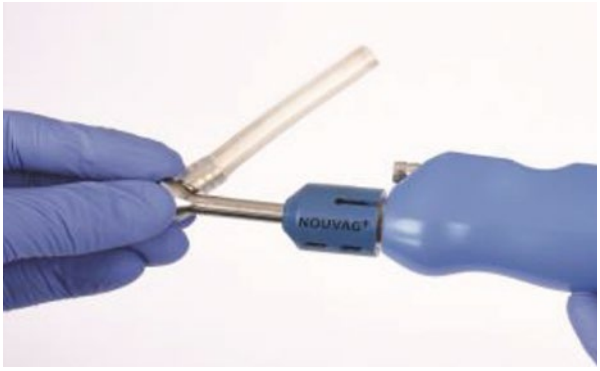
5 **Insert the electronic motor with attached Conform cannula handpiece into the opening of the handle. Make sure that the Conform cannula handpiece with motor are completely inserted.**

6 **Now screw the cap past the cable into the opening of the Conform cannula handpiece.**

7 **Seat the silicone sealing via the tread onto the Conform cannula handpiece.**

SETUP

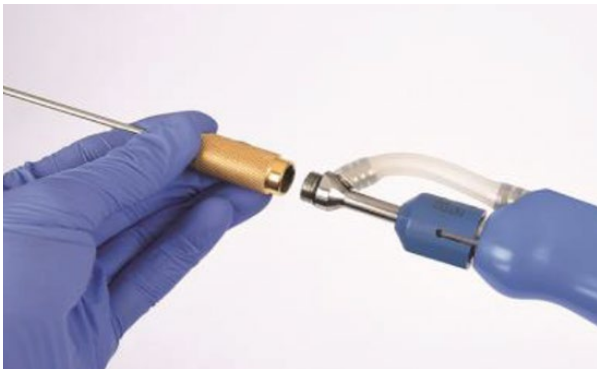
8 **Also place the protective sleeve over the thread on the Conform cannula handpiece.**



9 **Screw the cannula adapter through the opening of the protective cap onto the thread of the Conform cannula handpiece.**

10 **Connect the connection tube to the suction pipe.**

11 **Adjust the alignment of the hose by loosening the closure on the back of the handpiece.**



12 **Screw the cannula onto the cannula adapter.**

SETUP

PREPARING THE TUBING SET

Use only NOUVAG tube set REF 6022a/b for infiltration, otherwise the correct function cannot be guaranteed.

Check the expiry date of the tubing set and ensure that the packaging is not damaged. Using non-sterile tubing sets can result in serious infections and worst case can be fatal.

When inserting the tubing set, observe the arrow on the cover of the pump compartment. It indicates the flow direction of the infiltration solution.

The integrated peristaltic pump is used for the infiltration of the tumescent solution.

Do not regulate the amount of irrigation fluid using the roller clamp on the tubing set; with the LipoSurg, this is regulated instead using the integrated pump. For this reason, make sure to open the roller clamp as far as it will go (refer also to [Overview: Control elements >13]).

1 **Press release key for tubing set bracket (on top of the control unit) to open the pump.**

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

3 **Place the tubing set into the tubing bracket provided in such a way that the part of the tubing set with the spike exits the pump towards the rear of the device. Make sure the tubing is secure.**

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

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

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

7 **Open the bleed valve beneath the drip chamber.**

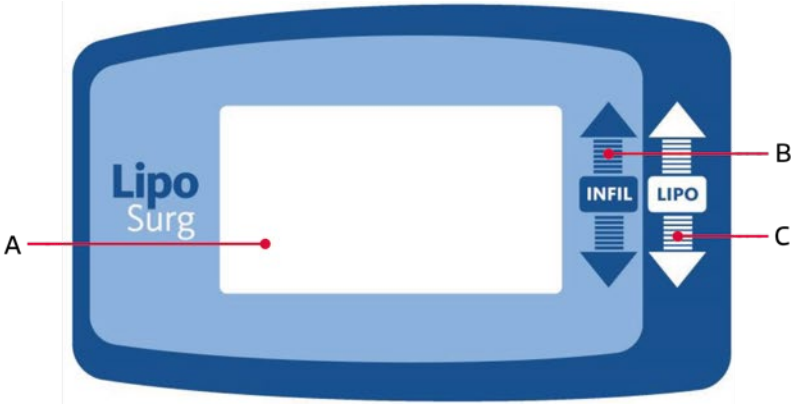
8 **Connect the control unit to the power socket.**

OPERATION

SWITCHING THE DEVICE ON AND OFF

The power switch «I/O» (at the rear) is used to switch the control unit on and off. The device can be switched off at any time irrespective of any procedure for switching off the device.

OVERVIEW: CONTROL ELEMENTS



A **Display** — *Display of various parameters.*
[Infiltration «INFIL» >14], [Liposuction «LIPO» >14], [«COMBI-MODE» >14]

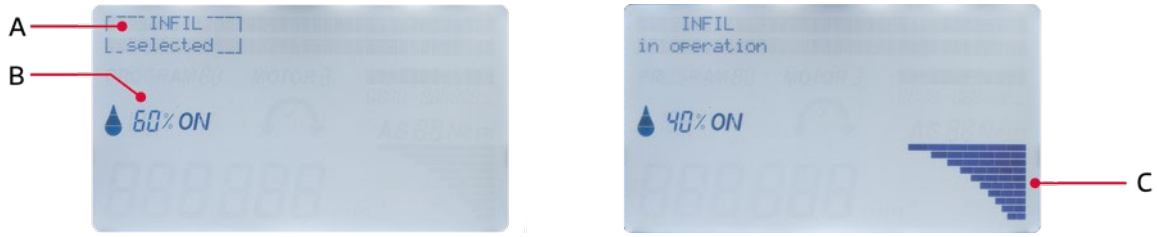
B **«INFIL» key** — *Selection of the function «Infiltration».*
By pressing the «INFIL ▲» key, the volumetric displacement is increased.
By pressing the «INFIL ▼» key, the volumetric displacement is reduced.

C **«LIPO» key** — *Selection of the function «Liposuction».*
By pressing the «LIPO ▲» key, the number of cannula strokes is increased.
By pressing the «LIPO ▼» key, the number of cannula strokes is reduced.

By pressing both «INFIL» and «LIPO» keys simultaneously, the «COMBI-MODE» is activated. In this case INFIL and LIPO are both active at the same time.

OPERATION

INFILTRATION «INFIL»



A **Selected function «INFIL»**
By pressing the «INFIL» key, the «INFIL function» (Infiltration) is displayed up left.
By pressing the pedal, the display shows «INFIL in operation» up right.

B **Setting the maximal by pedal retrievable volumetric displacement of the peristaltic pump.**
The output limit of the tumescent solution can be regulated in 10% steps, beginning with 10%.

C **Real-time display of the pump delivery rate, which is retrieved by pedal.**
Bar graph shows the percentage of flow rate of the peristaltic pump, retrieved by pedal.

> The pump does not begin to operate until the motor has been activated by pressing the pedal.

LIPOSUCTION «LIPO»

A **Selected function «LIPO»**
By pressing the «LIPO» key, the LIPO function (Liposuction) is displayed up left.
By pressing the pedal, the display shows «LIPO in operation» up right.

B **Setting range of the number of cannula strokes.**
Display of the range of possible cannula strokes.

C **Regulating the cannula strokes.**
By pressing the pedal the Conform cannula handpiece is running with the preset value.

«COMBI-MODE»

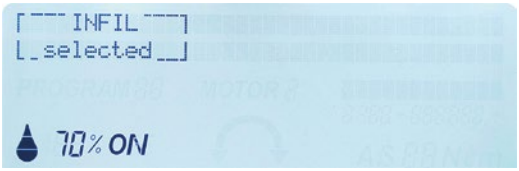
Selected function «INFIL & LIPO»
By pressing both «INFIL» and «LIPO» keys simultaneously, the «COMBI-MODE» (Infiltration & Liposuction) is displayed. Set values for both functions just as mentioned above.

OPERATION

OPERATION WITH VARIO PEDAL

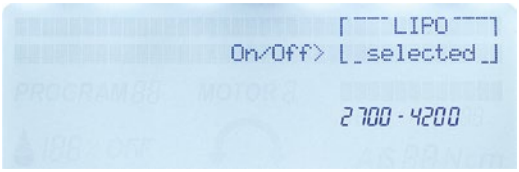
The pedal can be used in two different modes for not having to press the pedal permanently during infiltration or liposuction.

In **«Normal» Pedal Mode (variable)** it is required to press or move the pedal permanently to vary the infiltration up to the preset maximum value, while at liposuction the stroke of the cannula works always with the preset stroke rate.



Infiltration in «Normal» Pedal Mode

In **«ON/OFF» Pedal Mode** the pedal behaves like a switch. By shortly pressing the pedal, infiltration and liposuction is carried out with the preset values. It is not necessary to keep pressing the pedal. If the pedal is pressed shortly again, the device stops immediately.



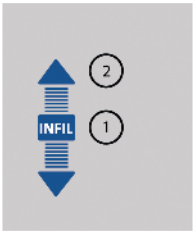
Liposuction in «ON/OFF» Pedal Mode

PEDAL MODE SELECTION

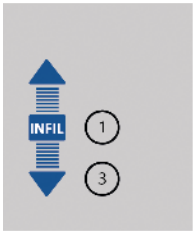
The pedal mode is set on the operation panel.

1 **Press keys «(1)» and «(2)» simultaneously.**
Pedal Mode «ON/OFF» is active in function «INFIL».

2 **Press keys «(1)» and «(3)» simultaneously.**
Pedal Mode «Normal» is active in function «INFIL».



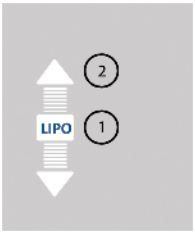
Pedal Mode «ON/OFF»



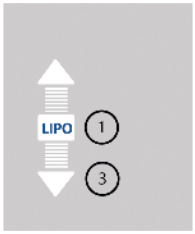
Pedal Mode «Normal»

1 **Press keys «(1)» and «(2)» simultaneously.**
Pedal Mode «ON/OFF» is active in function «LIPO».

2 **Press keys «(1)» and «(3)» simultaneously.**
Pedal Mode «Normal» is active in function «LIPO».



Pedal Mode «ON/OFF»



Pedal Mode «Normal»

«NORMAL» PEDAL MODE (VARIABLE)

STEP PLATE...	CANNULA STROKE	PERISTALTIC PUMP
not pressed	No cannula stroke	Pump off
pressed gently	Cannula works with maximal speed	Pump runs with the speed shown by the bar graph

«ON/OFF» PEDAL MODE

STEP PLATE...	CANNULA STROKE	PERISTALTIC PUMP
not pressed	No cannula stroke	Pump off
pressed shortly	Cannula works with preset value	Pump runs with preset value

OPERATION

FUNCTIONAL CHECK

Prior to every startup of the LipoSurg, or the use of accessory equipment, the user must always ensure that each individual component is in good working order, free from defects, and is clean, sterile and operational. All inscriptions on the device and its accessories must be readable and there must be no loose parts in the device. Once the device is switched on, the most recent settings entered appear on the display.

ELECTRONIC MOTOR

The functional check of the electronic motor is carried out without the Conform cannula handpiece attached.

1 **To activate the liposuction mode, press the key «LIPO».**

2 **Press the «LIPO ▲» key to increase the speed to its maximum value.**

3 **Press the pedal.**
The electronic motor starts running and accelerates up to its maximum speed. When releasing the pedal, the electronic motor decelerates and finally comes to a stop.

The motor ventilation slots must be kept clear, to prevent the motor temperature from becoming excessive. When the electronic motor is placed in the handle, built in channels ensure sufficient cooling of the motor.

PERISTALTIC PUMP

1 **Activate the infiltration mode by pressing the «INFIL» key.**

2 **Press the «INFIL ▲» key to select the maximum speed of the pump (100%).**

3 **Press the pedal all the way down.**
The pump starts working and quickly speeds up to its maximum speed. At the outlet of the tube respectively at the infiltration needle or at the infiltration cannula the liquid is spurting out.

CLEANING AND STERILIZATION

The instructions described here are intended for the parts supplied in the set. The cleaning, disinfection and sterilization instructions for extensions and accessories are described in their respective operating instructions.
The following points are important regarding the caring for the material:

Perform cleaning, disinfection and sterilization after every treatment!
Always autoclave the material in sterilization packaging.
Make sure that the sterilization packaging is not more than 80% filled.
Autoclave material for at least 5 minutes at 134°C.
If sterilized material is not used immediately, the sterilization packaging must be labeled with the sterilization date.
NOUVAG recommends including a sterility indicator.

CONTROL UNIT AND PEDAL

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

HANDPIECE CRADLE

Soiled handpiece cradles are cleaned using a neutral cleaning agent and then sterilized in accordance with the same instructions as for electronic motor 21.

HANDLE WITH CONFORM CANNULA HANDPIECE

For the reprocessing instructions of the Handle with Conform cannula handpiece, please refer to the instructions for use supplied with the Conform cannula handpiece.

ELECTRONIC MOTOR 21

For the reprocessing instructions of the electronic motor 21, please refer to the instructions for use supplied with the electronic motor.

TUBING SET REF 6022a/b AND REF 6026E

Single-use tubing sets may not be reused!
Used tubing sets must be disposed of properly.
Don’t use tube set when packaging is already opened or damaged!
Do not use tubing set if expired.
Use only NOUVAG tubing sets with REF 6022a/b and REF 6026E.
Sterility cannot be guaranteed by reusing and re-sterilization of tubing sets. The characteristics of the material may change resulting in serious infections or, in worst case, the death of the patient.

MAINTENANCE

REPLACING THE CONTROL UNIT FUSES

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

1 **Switch off device.**

2 **Unplug the power plug.**

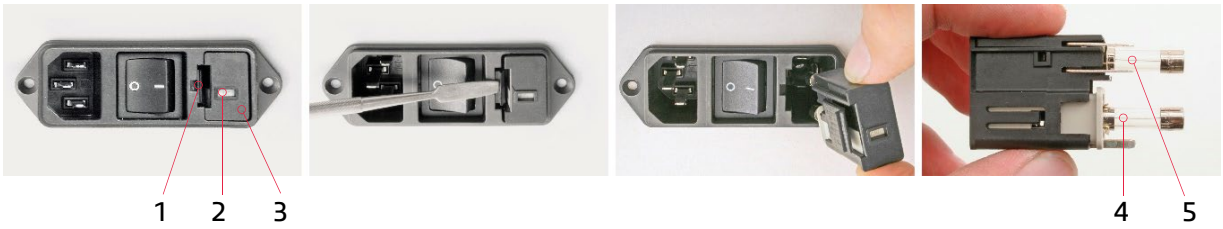
3 **Open the fuse slot using a screwdriver.**

4 **Replace the faulty fuse T 3,15A, 250V AC.**

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

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

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



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

SAFETY INSPECTIONS

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

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

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

NOUVAG offers a safety inspection service for its customers. Addresses can be found in the appendix of this instructions for use under [Service points >23]. For further information please contact our technical service department.

MALFUNCTIONS AND TROUBLESHOOTING

MALFUNCTION	CAUSE	SOLUTION	REFER TO INSTRUCTIONS FOR USE
Device is not functional (Indicator light is off)	Control unit not switched on	Set the power switch «I/O» to «I»	[SWITCHING THE DEVICE ON AND OFF >13]
	Power connection not established	Connect the control unit to the mains power supply	[CONNECTION TO THE POWER SUPPLY >8]
	Incorrect operating voltage	Check the mains voltage	[CONNECTION TO THE POWER SUPPLY >8]
	Faulty fuse	Replace fuse	[REPLACING THE CONTROL UNIT FUSES >18]
	Processor error	Set the power switch to «O», wait 10 seconds and switch back to position «I»	[SWITCHING THE DEVICE ON AND OFF >13]
No stroke movement at the Conform cannula handpiece	«LIPO» function is not selected	Select function «LIPO»	[OVERVIEW: CONTROL ELEMENTS >13]
	Motor to drive cannula not activated	Activate motor to drive cannula by pressing pedal	[OPERATION WITH VARIO PEDAL >15]
	Motor to drive cannula not connected	Insert motor plug into the socket at the devices front	[DEVICE OVERVIEW >7] [PREPARING THE HANDLE WITH CONFORM CANNULA HANDPIECE >9]
	Conform cannula handpiece is not connected properly to the motor	Press the Conform cannula handpiece firmly to the motor until it engages	[PREPARING THE HANDLE WITH CONFORM CANNULA HANDPIECE >9]
No delivery of infiltration solution at the cannula	«INFIL» is not selected	Select function «INFIL»	[OVERVIEW: CONTROL ELEMENTS >13]
	Peristaltic pump is not switched on	Activate peristaltic pump by pressing the pedal	[OPERATION WITH VARIO PEDAL >15]
	Tube set not properly inserted	Insert tube set correctly	[PREPARING THE TUBING SET >12]
	Tube set is blocked	Replace the tubing set	[PREPARING THE TUBING SET >12]
	Infiltration container is not ventilated	Open air bleed valve at tube set	[PREPARING THE TUBING SET >12]
	Tube set is dripping	Replace tube set	[PREPARING THE TUBING SET >12]
	Roller clamp is closed	Open the roller clamp all the way	[PREPARING THE TUBING SET >12]
Pedal is not functional	Pedal not connected	Insert the pedal plug into the socket at the devices back	[PREPARING THE PEDAL >9] [DEVICE OVERVIEW >7]
	Control unit is not switched on	Use mains switch, in the back of the device, to switch on	[SWITCHING THE DEVICE ON AND OFF >13]
	Incorrect operation	Check operating instructions	[OPERATION WITH VARIO PEDAL >15]

If the problem cannot be solved please contact your supplier or an authorized service center. Addresses can be found in the appendix of this instructions for use under [SERVICE POINTS >23].

MALFUNCTIONS AND TROUBLESHOOTING

ERROR-MESSAGES ON DISPLAY

ERROR-MESSAGE / ERROR CODE	CAUSE	SOLUTION
Storing factory settings/ 08, User configuration & Program	Message while the factory settings of the parameters and the programs are being saved with the LipoSurg dongle.	
Storing factory settings/ 09, Program	Message while the factory settings of the programs are being saved.	
Pedal not connected/ E10	Pedal is not connected.	Plug in the pedal power cable
	Connector or cable defective.	Send control unit and pedal to the service point.
No motor connected/ E13	There is no motor connected.	Plug in the motor power cable.
	Motor, motor cable, motor plug or control unit is defective.	Send control unit and pedal to the service point.
Unknown motor/ E16	Motor connection selected but an unauthorized motor was plugged in.	Plug in the authorized motor.
	A permitted motor is plugged in to the motor socket, but the motor, motor cable, motor plug or control unit is defective.	Send control unit and pedal to the service point.
Pump is open/ E20	When the pump is open, the motor does not turn so there is no risk of injury.	Close the pump.
Pedal locked/ W26, pedal let go	If the pedal was pressed while the control unit was switched on, the pedal is locked.	Release the pedal for a second.
Handpiece XX is faulty/ E29	The handpiece absorbed too much torque during calibration or testing.	Clean the handpiece. For lubrication spray with Lubrifluid.
		If the message still appears during the subsequent test, the handpiece / con-tra angle handpiece must be sent to the service point.
Handpiece XX is Ok! 30	The tested handpiece is OK.	
Testing the handpiece XX 32	Handpiece is testing.	
Motor Error E35, Pedal let go	Message appears when the pedal is pressed but the motor cable is defective.	Probably broken cable.
Disturbed, Pedal locked E36, Pedal let go	Pressing the pedal triggered an error.	Briefly release the pedal and press it again.
Nou-Dongle is plugged in 37	This message is displayed for one second when the Nou dongle is plugged in.	
Fatal error! E38, Wrong hardware		
System Message XX Send unit to service point		

ACCESSORIES

ACCESSORIES

DESCRIPTION	REF
Disposable tubing set with spike and Luer-Lock connection, sterile, 4 m	6022a/b
Disposable tubing set Ø 6.5 x 9 mm, sterile, 4 m	6026E
Clip set, for tube set attachment to motor cable, PU 5 pcs.	29061
Lubricant spray LUBRIFLUID	2128
Spray adapter with thread, for lubricant spray (REF 2128)	19584
Connection tube between handle and tube adapter, non-sterile, 5 x 2 x 79 mm	29063
Cannula adapter for Conform cannula handpiece, incl. connection tube 5 x 2 x 79 mm	75705
Luer-Lock adapter for Luer-Lock liposuccion cannulas	28557
Cannula handle with opening for false air ventilation, Luer-Lock connection, sterilizable	4391
Cannula handle without opening, Luer-Lock connection, sterilizable	4390
Stand for irrigation fluid bottle	1770

SUCTION CANNULAS FOR LIPOSUCTION (STERILIZABLE)

DESCRIPTION	REF
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 CANNULAS

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

POWER CORDS

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

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

ACCESSORIES

INFORMATION ON DISPOSAL

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. Prevailing national and local disposal regulations apply.

When disposing of the device, device components and accessories, the requirements specified in legislation must be followed. To ensure environmental protection, old devices can be returned to the dealer or manufacturer.

TECHNICAL DATA

LIPOSURG

Voltage, switchable	100 V~ / 115 V~ / 230 V~, 50/60 Hz
Fuse power supply	2 fuses, T 3,15 A, 250 V AC
Power consumption	max. 120 VA
Type of applied part	Type BF*
Protection class	Class I
Pedal	IPX8
Dimensions (W x D x H)	260 x 250 x 110 mm
Net weight control unit	3,4 kg

* Applied parts are the instruments used with the LipoSurg.

ELECTRONIC MOTOR TO DRIVE THE CANNULA

Motor coupling	INTRA coupling, ISO 3964
Speed	max. 12'000 rpm
Torque	max. 7,5 Ncm
Weight (without cable)	120 g
Cable length	4,0 m

HANDLE WITH CONFORM CANNULA HANDPIECE

Strokes	max. 4'200 strokes / min.

PERISTALTIC PUMP

Flow rate	0 – 450 ml/min**
Pressure	max. 2,0 bar**

** The mentioned volumetric displacement is only valid for aqueous solutions without any instrument attached.

WARRANTY COVERAGE

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

POST MARKET SURVEILLANCE

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

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

SERVICE POINTS

Switzerland
NOUVAG AG
St. Gallerstrasse 25
9403 Goldach

Phone +41 71 846 66 00
info@nouvag.com
www.nouvag.com

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NOUVAG GmbH
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78462 Konstanz

Phone +49 7531 1290-0
info-de@nouvag.com
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CE 0197

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

APPENDIX

Electromagnetic compatibility (EMC)

Remark:
The **Product** subsequently referred to herein always denotes the LipoSurg.

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

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

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

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

Essential Performance
The essential performance is that the infiltration of tumescent solution in the fat tissue and peel off the fat cells with CHP handpiece taking into account the infiltration flow rate, pressure and handpiece speed is maintained. The maximum speed deviation is ± 15%, the infiltration flowrate is between 100 and 480ml/min and the maximum pressure is 2.5bar.

Compliant Cables and Accessories

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

Description	Length max.
Power supply cord REF 22261 / 22262 / 22264 / 22266	3.0m
Electronic motor REF 2101nou	4.0m
Foot pedal IPX8 REF 1511nou	2.9m

Guidance and manufacturer's declaration – electromagnetic emissions		
The Product is intended for use in the electromagnetic environment specified below. The customer or the user of the Product should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Product is intended for use in the electromagnetic environment specified below. The customer or the user of the Product should assure that it is used in such an environment.			
Immunity tests	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	+/- 2 kV with 100kHz for power supply lines +/- 1 kV with 100kHz for input/output lines	+/- 2 kV with 100kHz for power supply lines +/- 1 kV with 100kHz for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.

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Surge IEC 61000-4-5	+/- 0.5 kV, +/- 1 kV differential mode +/- 0.5 kV, +/- 1 kV, +/- 2 kV common mode	+/- 0.5 kV, +/- 1 kV differential mode +/- 0.5 kV, +/- 1 kV, +/- 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines	0 % U_T; for 0,5 cycle with 0, 45, 90, 135, 180, 225, 270, 315 degree 0 % U_T; for 1 cycle	0 % U_T; for 0,5 cycle with 0, 45, 90, 135, 180, 225, 270, 315 degree 0 % U_T; for 1 cycle	Mains power quality should bet hat of a typical commercial or hospital environment. If the user of the Product requires continued operation during power mains interruptions, it
IEC 61000-4-11	70 % U_T; for 25/30 cycles 0 % U_T; for 5 sec	70 % U_T; for 25/30 cycles 0 % U_T; for 5 sec	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	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

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

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

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

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Fixed strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the Product is used exceeds the applicable RF compliance level above, the Product should b observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Product.

b over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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

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

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

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

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

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

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