


- Warning, hot surfaces
- Do not bend motor cable, to prevent of cable brake!

- Any guarantees on our part or other claims against us become void in the case of inappropriate use of the electronic motor or failure to comply with our instructions!
- The electronic motor may only be connected with connection sockets marked with the symbol "Type BF 

Intended use / indication

The motors are equipped with handpiece carriers according to ISO 3964, which enable the attachment of handpieces and contra angles and ensure secure hold. The electronic motor 21 in conjunction with a drive system and corresponding handpiece is used in the following medical areas:

- Plastic surgery
- Spine surgery
- Traumatology
- Facial and cranial surgery
- ENT surgery
- Orthopedics/Arthroscopy
- Gynecology
- Urology and laparoscopy
- Oral/maxillary surgery, dental implantology

The electronic motor 21 may only be operated by qualified and trained personnel. Improper operation can lead to malfunctions. The intended use is clearly described in the operation instruction manual of the corresponding device/instrument and is obvious to the trained user.

Contra indications / Limitations

Relative or absolute contra indications can arise from the general medical diagnose, or in special cases by a significantly increased risk to the patient through the use of motor-driven systems. Relevant cases in the literature must be taken into consideration. The electronic motor 21 may only be connected to and operated with Nouvag AG motor systems. The use of handpieces & contra angles by other manufacturers in conjunction with the electronic motor 21 is the responsibility of the user. Switching on the electronic motor 21 without holding it or correctly placing it in the handpiece holder leads to uncontrolled movements of the motor.

Symbols

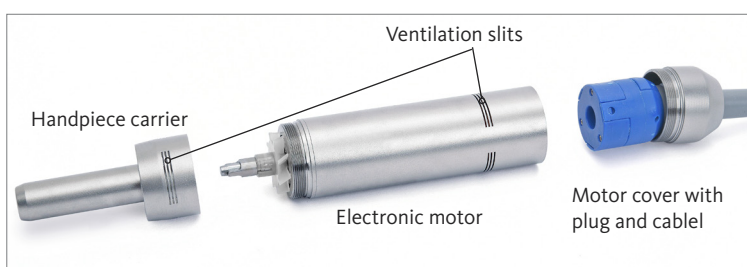
	Warning, hot surfaces		Autoclave at 135°C		Suitable for thermal disinfection		Date of manufacturing		Order number		Type BF applied part is the electronic motor
	Warning		Manufacturer		CE symbol with notified body		Serial number		Observe instructions for use		Do not dispose of electronic motor with household waste

Technical data, Electronic motor 21

REF	2100nou	2101nou
Weight, without cable	280 g	280 g
Maximum torque	6 Ncm	6 Ncm
Maximum output	120 VA	120 VA
Maximum current	8 A	8 A
Rated voltage	35 V	35 V
Rated speed	50'000 rpm	50'000 rpm
Motor coupling	according to ISO 3964	according to ISO 3964
Cable length	4,0 m	4,0 m

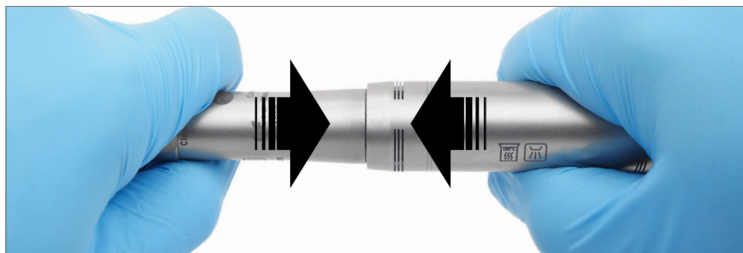
The motors differ by a different number of pins at the plug.

Overview

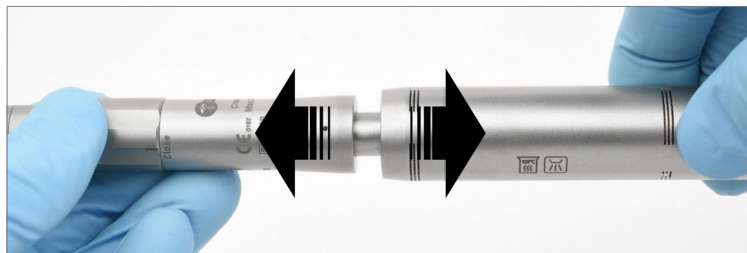


Operation

Coupling handpieces with the electronic motor



Slide Handpiece over the handpiece carrier and press at the stop until it engages. Check for good seating with a counter movement.



Disconnect coupling with a short, strong pull and slide off the handpiece from the handpiece carrier of the electronic motor.

Possible combinations

Electronic motor 21, REF 2100nou, 2101nou

REF 2100nou is used in conjunction with the Vacuson 60 LP liposuction vacuum pump as control unit and the Conform cannula handpiece driven by the electronic motor.

REF 2101nou is used in conjunction with the LipoSurg engine control unit, which also separately controls the tumescent infiltration, and the Conform cannula handpiece, which is driven by the electronic motor and loosens the fatty tissue through lifting movements of the cannula and makes it more absorbent.

Warning! Wrong combination of products

Damage to the product and injury to the patient, user or third parties are possible.

- Only apply the different products together if the purpose and the relevant technical data, such as working lengths, diameters, etc. match.
- Always follow the instructions for use of the products used in combination.

Ambient conditions

	Transport and storage:	Operation:
Relative humidity:	Max. 90 %	Max. 80 %
Temperature:	0 – 60°C	10 – 30°C
Atmospheric pressure:	700 – 1060 hPa	800 – 1060 hPa


Electromagnetic compatibility (EMC)

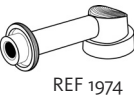

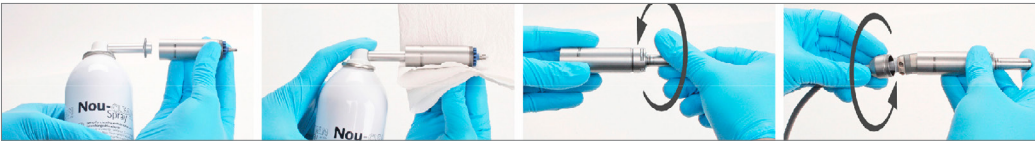

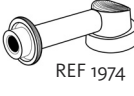

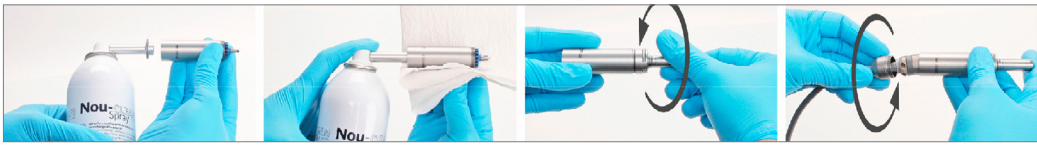

The use of (RF) Radio Frequency emitting devices and equipment as well as the occurrence of negative environmental factors in the close area of the electronic motor may cause unexpected or adverse operation. The connection or the placing of other devices in close vicinity is or allowed.

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.

Further observe the EMC manufacturers declaration of conformity.

Reprocessing instructions

Reprocessing restrictions	Frequent reprocessing has only a limited impact on the electronic motor. The end of the products service life is normally determined by wear and damage through use. The electronic motor 21 is designed for 250 sterilization cycles.
General handling	<ol style="list-style-type: none"> Every electronic motor must be thoroughly cleaned, disinfected and sterilised before initial operation (products straight from the factory) and also immediately following each use. Only a cleaned and disinfected electronic motor permits proper sterilisation! The electronic motor should always be treated with utmost care when being transported, cleaned, serviced, sterilised and stored. We recommend the use of mild alkaline and enzymatic cleaners with as low a content of silicate as possible in order to avoid staining (sili-catising) the electronic motor. Only commercial grade DGHM-/VAH-listed agents may be used for cleaning and disinfection. See these agent manufacturers' specifications for the method of use, action time and suitability of disinfection and cleaning substances. Follow precisely the operating instructions of the devices and chemicals etcetera, used during preparation. Adhere exactly to the chemical dosages, action times and exposure temperatures during cleaning and disinfection. The end of the product life can be reached even before reaching the maximum 250 sterilization cycles in case of excessive wear and damage by use. Do not overload dishwashers. Avoid dead zones. Pay attention to secure storage in the machine. Follow the applicable regulations in your country for reprocessing medical devices. The electronic motor must never be subjected to ultrasonic cleaning! This will impair the functionality. Nouvag AG recommends using a screen basket with a rinse strip from 3mach (NOUVAG REF 51401), a re-usable container for comfortable preparation and storage (incl. transport) of products. The screen basket can be used to keep products safe both during the rinsing cycle and also during and after sterilisation until the products are used. The screen basket is suitable for use with sterilisation paper or a rigid sterilisation container. It has no barrier effect itself in order to maintain sterility.
Attention!	 In relation to patients with Creutzfeldt Jakob disease or its variant (vCJK) no responsibility can be assumed for re-use of the electronic motor. The Robert-Koch Institute recommends removing used products from circulation after use in order to avoid infecting other patients, users and third parties.
Preparation preliminaries at the point of use	After surgery immediately remove blood, secretion, tissue and bone residue with a disposable cloth/paper towel, do not allow to dry! Dried residues cause corrosion.
Safe-keeping and transport	Contaminated products must be stored and transported to the preparation site in a closed container to avoid damaging the products and contaminating the environment.

<p>Cleaning and disinfection, pre-cleaning</p> 	<ol style="list-style-type: none"> Wipe down the electronic motor with a damp disposable cloth/paper towel while removing all visible impurities. Unscrew the motor cover and remove the cable incl. the motor cover. Unscrew the handpiece carrier and also remove.  <ol style="list-style-type: none"> Brush down the plastic parts of the electronic motor under running tap water with a soft brush (manufacturer Insitumed GmbH, REF MED100.33). Rinse the outer surface of the electronic motor for 10 seconds with a water pistol (at a pressure of at least 2.0 bar). Then spray the electronic motor with NouClean (see the Section "Inspection and care"). 	
<p>Cleaning</p>	<p>Mechanical cleaning</p> <ol style="list-style-type: none"> Place the electronic motor in the strainer basket after pre-cleaning. Mechanical cleaning is only successful if the pre-cleaning described above is adhered to! Cleaning is done using the Vario TD programme in the cleaning and disinfection unit (CDU). For the cleaning process it is advisable to use DI water (fully desalinated water). After completing the cleaning programme (incl. thermal disinfection) check the electronic motor, motor cover with cable and handpiece carrier for visible contamination in the grooves and gaps. Repeat the cleaning if necessary. 	<p>Automatic cleaning process (Vario TD programme)</p> <ol style="list-style-type: none"> Pre-clean for 4 minutes with cold water. Empty Clean for 5 minutes at 55°C with 0.5 % alkaline or at 40°C with 0.5 % enzymatic cleaner. Empty Neutralise with cold water for 3 minutes. Empty Inter-rinse for 2 minutes with cold water. Empty
<p>Disinfection</p>	<p>Mechanical disinfection</p> <p>The cleaning/disinfection unit has a thermal disinfection programme which follows the cleaning. When performing mechanical thermal disinfection, give due consideration to the national requirements relating to the Ao value (see DIN EN ISO 15883-1). We recommend an Ao value of 3,000 for the electronic motor. Disinfection must be carried out with DI water.</p>	<p>Warning </p> <p>When inadequately rinsed or exposed to the disinfectant or detergent for too long, the electronic motor can corrode. Please see the corresponding detergent and disinfectant's package insert for dwell times.</p>
<p>Drying</p>	<p>Mechanical drying</p> <p>Dry the electronic motor using the cleaning/disinfection unit's (CDU) drying cycle. If required, manual drying can also be achieved by using a lint-free cloth. When drying manually, take particular care with the grooves and gaps of the electronic motor. Then spray the electronic motor again with NouClean spray (see the Chapter "Inspection and care") . Every CDU must provide a corresponding drying procedure through the manufacturer (see ISO 15883-1). Please follow the corresponding CDU-manufacturer's directions and operating instructions.</p>	<p>Manual drying</p> <p>Set the electronic motor up in an upright position without motor cover and cable and without handpiece carrier. Dry the electronic motor for at least 30 minutes. Then spray with NouClean spray. Afterwards screw the handpiece carrier and the motor cover with cable back onto the electronic motor.</p>
<p>Inspection and care</p> 	<ol style="list-style-type: none"> First unscrew the motor cover and remove the cable incl. the motor cover. Unscrew the handpiece carrier and remove it also.  <ol style="list-style-type: none"> Perform a visual check for damage, corrosion and wear. In the next step spray the electronic motor for cleaning and care. Nouvag AG recommends using NouClean spray for this purpose. Screw the spray attachment in place of the connector onto the motor and spray with NouClean spray for about 3 seconds until only clear liquid runs off the electronic motor.  <ol style="list-style-type: none"> Then wipe down with a moist cloth (Follow the product's instructions for use). After spraying the electronic motor screw the handpiece carrier and the motor cover with the cable back onto the electronic motor. 	
<p>Sterilisation</p>	<p>Sterilisation of the electronic motor is performed with a fractionated pre-vacuum steam sterilisation technique (in accordance with DIN EN 556-1/ DIN EN ISO 17665-1) giving due consideration to the respective national requirements.</p> <p>Minimum requirements:</p> <ol style="list-style-type: none"> Pre-vacuum phases: 3 Sterilisation temperature: At least 132°C. Hold time: At least 3 minutes (full cycle). Drying time: At least 10 minutes (max. 25 minutes). <p>When sterilising several products during one sterilisation cycle, do not exceed the maximum steriliser load. (see manufacturer's details). A drying cycle must be added in the case of autoclaves without a post-vacuum function. After sterilisation the perfect sterilisation result needs to be checked using corresponding indications. According to the Robert-Koch Institute preparation ends with the documented release for use of the medical device. If the sterilised electronic motor is not used immediately after sterilisation, the material packaging must be labelled with the sterilisation date.</p>	
<p>Storage</p>	<p>Storing the sterile packaging</p> <p>The sterilised product must be stored away from dust, humidity and contamination. During storage ensure that there is no direct exposure to sunlight. After the expiry date has passed, do not use the product any longer.</p>	<p>Handling the sterile packaging</p> <p>Before taking out the product, check that the sterile packing is intact. When taking out the product, follow the respective aseptic procedures.</p>
<p>Information for validating the preparation</p>	<p>The above preparation process has been verified by a validated procedure. The following materials and machines were used:</p> <ol style="list-style-type: none"> Alkaline cleaner: Neodisher® Mediclean; Chemische Fabrik Dr. Weigert GmbH & Co. KG Enzymatic cleaner: Neodisher® MediZyme; Chemische Fabrik Dr. Weigert GmbH & Co. KG Cleaning/disinfection unit: Miele G 7836 CD Rack trolley: Miele E429 Screen basket/rinse strip: 3mach (NOUVAG REF 51401) Autoclave: Selectomat 666-HP (MMM) Sterile packaging: Sterisheet 100; Broemeda Amcor Flexibles GmbH <p>Chemicals and machines other than those mentioned can also be used. In such a case consult the manufacturers or suppliers to find out whether their products confer the same performance as the products that the procedure was validated with.</p> <p>If you should opt for a different procedure for reprocessing to the one given above, you are required to correspondingly establish the suitability.</p>	
<p>Note</p>	<p>There is no experience available from conducting other sterilisation procedures such as plasma sterilisation, low temperature sterilisation procedure, etc. Users bear full responsibility if they use a procedure which differs from the validated sterilisation procedure described!</p>	
<p>Caution! </p>	<p>Please also comply with the applicable legislation in your country and the medical practice or hospital's hygiene rules. This especially applies to the varying requirements for an effective inactivation of prions.</p>	

Spare parts

REF	Description	Units	REF	Description	Units
1984	Maintenance and care spray „NouClean“	1	76072	Motor cable complete, pre assembled motor 2101nou	1
1974	Spray nozzle for NouClean spray; for maintenance of electronic motor	1	5077	Conform cannula handpiece for liposuction	1
76069	Motor cable complete, pre assembled for motor 2100nou	1			

Errors and causes

Problem	Cause	Solution
Motor is not running	Plug is not properly plugged in	Connect the motor plug with the motor socket at the device.
Motor interruption during cable movements	Cable break	Replace faulty cable
Rotary motion of the motor does not translate to handpiece	Motor is not properly coupled to the handpiece	Press electronic motor firmly against handpiece until it snaps into place. Check seat with counter-movement.

Manufacturer and service providers

	Nouvag AG • St.Gallerstr. 23 – 25 • CH-9403 Goldach Tel. +41 071 846 66 00 info@nouvag.com • www.nouvag.com
	Nouvag GmbH • Schulthaißstr. 15 • D-78462 Konstanz Tel. +49 (0)7531 1290-0 • Fax +49 (0)7531 1290-12 info-de@nouvag.com • www.nouvag.com
	Nouvag USA, LLC • 6201 Airport Freeway • Suite 200 Haltom City, Texas 76117 • USA Phone +1 817 887-9814 • Fax +1 817 887-9817 • Toll free no. (800) 673 7427

For a complete list of all services providers, authorized by Nouvag AG, please visit our website: www.nouvag.com/de/service/service_provider

Disposal

When disposing of the device, parts and accessories, the regulations prescribed by law must be observed. To ensure environmental protection, old devices can be returned to the dealer or manufacturer. Observe the national regulations for the disposal of infectious waste.

