EN

Instructions for use

Electronic Motor 21

REF: 2098nou / 2099nou / 2112nou

NOUVAG

- We deliver an unsterile electronic motor. Clean, disinfect, and sterilize the electronic motor before the first application and immediately after each use!
- Do not bend the 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 purpose

The electronic motors 21 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 control unit and corresponding handpiece is used in the following medical indications:

ENT surgery/Orthopaedic foot surgery (REF: 2099nou) Neurosurgery (REF: 2098nou) Plastic and reconstructive surgery (REF: 2112nou)

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 instructions for use of the corresponding device / instrument.

Contraindication / 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 devices. Relevant cases in the literature must be taken into consideration. The electronic motor 21 may only be connected to and operated with Nouvag AG control units. 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.

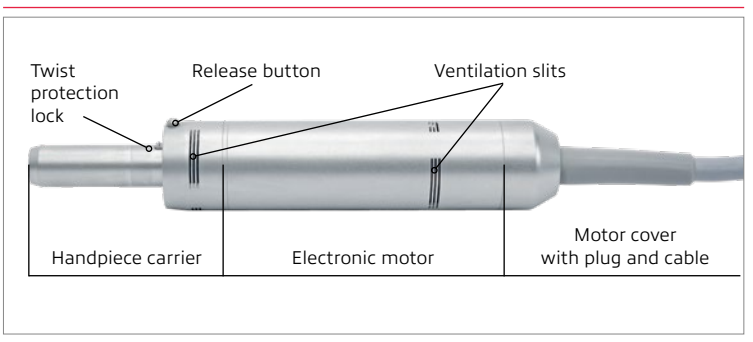
Symbols

	Caution		Manufacturer	LOT	LOT number	134°C	Autoclave at 134°C	REF	Reference number		Application part of type BF
	Caution, hot surfaces		Date of manufacturing		Follow the instructions for use		Suitable for thermal disinfection	SN	Serial number		Note on disposal

Technical Data

		2098nou	2099nou	2112nou
Weight, without cable	g	280	280	280
Torque max.	Ncm	6	6	6
Output max.	VA	120	120	120
Current max.	A	8	8	8
Rated voltage	V	35	35	35
Rated speed	rpm	80000	50000	40000
Coupling		ISO 3964	ISO 3964	ISO 3964
Cable length	m	3,0	3,0	3,0
Pin assignment of the connector		10	10	8

Overview

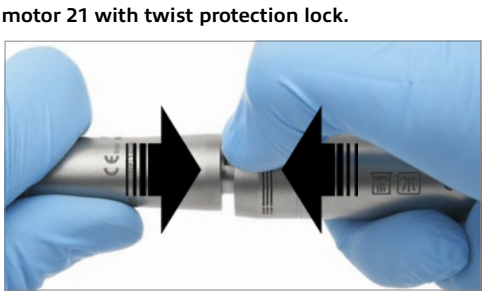


Operation

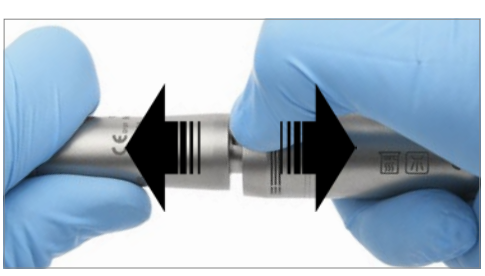
Coupling handpieces with a groove with the electronic motor 21 with twist protection lock.

Twist protection lock with release button

Handpiece coupling with groove for twist protection



Align groove at handpiece with the twist protection and connect the handpiece with the electronic motor while pressing the button. Check for proper seating.



Press the button and decouple the handpiece from the electronic motor.

Possible combinations

Elektronic motor	Device	Intended use
REF: 2098nou	HighSurg 30	Neurosurgery
REF: 2099nou	HighSurg 30 HighSurg 11 OFA-Drill	ENT-Surgery ENT-Surgery Orthopaedic foot surgery
REF: 2112nou	TCM 3000 BL	Reconstructive surgery Rhinoplasty

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.
- The electronic motors 21 may only be connected to Nouvag control units.

Ambient conditions

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

Electromagnetic compatibility (EMV)

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 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.
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	1. 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! 2. The electronic motor should always be treated with utmost care when being transported, cleaned, serviced, sterilised and stored. 3. We recommend the use of mild alkaline and enzymatic cleaners with as low a content of silicate as possible in order to avoid staining (silicatizing) the electronic motor. 4. 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. 5. Follow precisely the operating instructions of the devices and chemicals etcetera, used during preparation. 6. Adhere exactly to the chemical dosages, action times and exposure temperatures during cleaning and disinfection. 7. The end of the product life can be reached before reaching the maximum 250 sterilization cycles in case of excessive wear and damage by use. 8. Do not overload dishwashers. Avoid dead zones. Pay attention to secure storage in the machine. 9. Follow the applicable regulations in your country for reprocessing medical devices. 10. Nouvag AG recommends using a screen basket including a rinse strip from 3mach (Nouvag AG REF: 51401), a re-usable container for 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.
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.

Caution
With regard to patients with Creutzfeldt-Jakob disease or its variant (vCJD), no responsibility can be assumed for the reuse of the electronic motor. The Robert Koch Institute recommends withdrawing used products from circulation to avoid infecting other patients, users and third parties.

Attention
Never clean the motor in an ultrasonic bath.
This will impair the functionality of the motor.

Pre-cleaning for cleaning and disinfection	1. Wipe down the electronic motor with a disposable damp cloth or paper towel to remove all visible impurities. 2. Unscrew the motor cover and remove the cable including the motor cover. 3. Unscrew the handpiece carrier and also remove the O-ring.  4. Clean the plastic parts of the electronic motor and its accompanying parts under running tap water using a soft brush (e.g. Insitumend GmbH, REF: MED100.33). 5. Rinse the outer surface of the electronic motor for 10 seconds with a water pressure gun at a pressure of at least 2.0 bar. (e.g. HEGA Medical, REF: 6010 or 7060)	
Cleaning	**Mechanical cleaning** ⚠ Mechanical cleaning is only successful if the pre-cleaning, described above, is adhered to! 1. Place the electronic motor and accompanying parts in the strainer basket after pre-cleaning. 2. Cleaning is done using the Vario TD programme in the cleaning and disinfection unit (CDU). For the cleaning process it's advisable to use DI water (fully desalinated water). 3. After completing the cleaning programme (incl. thermal disinfection) check the electronic motor, motor cover with cable, handpiece carrier and O-ring for visible contamination in grooves and gaps. Repeat cleaning if necessary.	**Automatic cleaning process (Vario TD programme)** 1. Pre-clean for 4 minutes with cold water < 40°C. 2. Empty 3. Clean for 5 minutes at 55°C with 0.5 % alkaline or at 40°C with 0.5 % enzymatic cleaner. 4. Empty 5. Neutralise for 3 minutes with cold water < 40°C. 6. Empty 7. Inter-rinse for 2 minutes with cold water < 40°C. 8. Empty
Disinfection	**Mechanical disinfection** 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 A0 value (see DIN EN ISO 15883-1). We recommend an A0 value of 3000 for the electronic motor and its accompanying parts. Disinfection must be carried out with DI water.	⚠ **Caution** When inadequately rinsed or exposed to the disinfectant or detergent for too long, the electronic motor and its accompanying parts can corrode. Please see the corresponding detergent and disinfectant's instructions for use for dwell times.
Drying	**Mechanical drying** Dry the electronic motor and accompanying parts using the cleaning/disinfection unit's (CDU) drying cycle. 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.	**Manual drying** 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. After using the cloth, set the electronic motor up in an upright position without motor cover, cable, handpiece carrier, and O-ring. Dry the electronic motor for at least 30 minutes.
Inspection and care  Spray-Adapter REF: 19584	1. Perform a visual check for damage, corrosion and wear. 2. Spray the electronic motor using the care spray "Lubrifluid". Screw the spray adapter (REF: 19584) in place of the cable connector onto the motor and spray with "Lubriflluid" spray for about 3 seconds.  3. Wipe down the electronic motor with a moist cloth. 4. Reassemble the O-ring, the handpiece carrier and the motor cover with the cable back onto the electronic motor.	
Sterilisation	Sterilisation of the electronic motor is performed with a fractionated pre-vacuum steam sterilisation technique (DIN EN 13060/DIN EN 285) giving due consideration to the respective national requirements. Minimum requirements: 1. Pre-vacuum phases: 3 2. Sterilisation temperature: minimum 132°C – maximum 137°C. 3. Hold time: At least 5 minutes (full cycle). 4. Drying time: At least 10 minutes. 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. 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.	
Storage	**Storing the sterile packaging** The sterilised product must be stored away from dust, humidity and contamination. During storage ensure that there is no direct exposure to sunlight. If the expiry date exceeded, the product must be reprocessed again.	**Handling the sterile packaging** Before taking out the product, check that the sterile packing is intact. When taking out the product, follow the respective aseptic procedures.
Information for validating the preparation	The above preparation process has been verified by a validated procedure. The following materials and machines were used: 1. Alkaline cleaner: Neodisher® Mediclean; Chemische Fabrik Dr. Weigert GmbH & Co. KG 2. Enzymatic cleaner: Neodisher® MediZym; Chemische Fabrik Dr. Weigert GmbH & Co. KG 3. Cleaning/disinfection unit: Miele G 7836 CD 4. Rack trolley: Miele E429 5. Screen basket/rince strip: 3mach (Nouvag AG REF: 51401) 6. Autoclave: Selectomat 666-HP (MMM) 7. Sterile packaging: Sterisheet 100; Broemeda Amcor Flexibles GmbH Chemicals and machines other than those mentioned can also be used. In such 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. If you should opt for a different procedure for reprocessing to the one given above, you are required to validate it.	
Note ☞	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!	
Caution ⚠	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.	

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**

Accessories

REF	Description	Units
2128	Lubrifluid	1
19584	Spray adapter for Lubrifluid oil for the care of the electronic motor	1

Spare parts

REF	Description	Units
76067	Motor cable complete, for motor 2098nou	1
76068	Motor cable complete, for motor 2099nou	1
76052	Motor cable complete, for motor 2112nou	1
24119	O-Ring	1

Troubleshooting

Problem	Cause	Solution
Motor is not running.	Plug is not inserted properly.	Insert plug and check fitting.
Motor stops when cable is moved.	Defective cable.	Replace cable.
Motor is running but tool is not turning.	Handpiece is not properly connected to the motor.	Press handpiece firmly to the motor until it clicks in place.

Manufacturer and service centers

Nouvag AG ▪ St. Gallerstrasse 25 ▪ CH-9403 Goldach
Tel. +41 71 846 66 00
info@nouvag.com ▪ www.nouvag.com

Nouvag GmbH ▪ Schulthaissstrasse 15 ▪ DE-78462 Konstanz
Tel. +49 7531 1290-0
info-de@nouvag.com ▪ www.nouvag.com

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

Disposal

☞ When disposing of devices, device components and accessories, local, customary regulations of the legislator must be followed.
Please dispose the electronic motor as electric and electronic waste (WEEE).