EN

Instructions for use

Electronic Motor 21

REF 2098nou | REF 2099nou | REF 2112nou

NOUVAG

SYMBOLS

General warning sign	Warning! Hot surface	Observe instructions for use	Note
Manufacturer	Date of manufacture	Autoclavable at 134 °C	Suitable for thermal disinfection
LOT Batch code	REF Catalog number	SN Serial number	Type BF applied part
EC REP Authorized representative in the European Community	Separate collection required (WEEE)		

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.

MEDICAL INDICATIONS

The electronic motor 21 in conjunction with a control unit and corresponding handpiece is used in the following medical indications:
// ENT surgery (REF 2098nou | REF 2099nou)
// Neurosurgery (REF 2098nou | REF 2099nou)
// **Orthopaedic hand and foot surgery** (REF 2099nou)
// Rhinoplasty and reconstructive surgery (REF 2112nou)

CONTRA INDICATIONS

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.

INTENDED USERS

Intended users are trained and qualified personnel, in professional settings (e.g. hospital, ambulatory).

AMBIENT CONDITIONS	TRANSPORT AND STORAGE	DURING USE
Relative humidity	max. 90%	max. 80%
Temperature	0 °C – 50 °C	10 °C – 30 °C
Atmospheric pressure	700 hPa – 1'060 hPa	800 hPa – 1'060 hPa

SAFETY INFORMATION

⚠ We deliver an unsterile electronic motor. Clean, disinfect, and sterilize the electronic motor before the first application and immediately after each use!

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.

Improper use or repair of the device, or failure to observe these instructions, relieves NOUVAG from any obligation arising from warranty provisions or other claims.

⚠ The use of the product other than that for which it was designed is not permitted. The responsibility is solely carried by the operator.

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

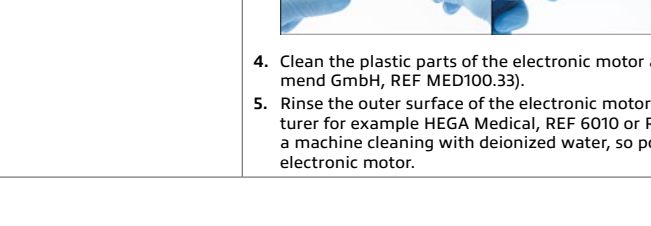
Manipulate the instrument only when the motor is at a standstill.

The device shall only be operated by qualified and trained personnel.

To avoid cable breakage, do not bend the motor cable!

The electronic motor may only be connected with connection sockets marked with the symbol «Type BF» .

OVERVIEW

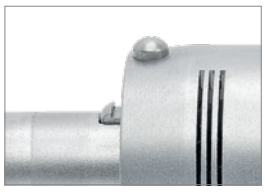


POSSIBLE COMBINATIONS

REF	CONTROL UNIT	INTENDED USE
2098nou	HighSurg 30	Neurosurgery ENT surgery
2099nou	HighSurg 30	Neurosurgery ENT surgery
	HighSurg 11	ENT surgery
	HighSurg 11 OFA-Drill	Orthopaedic hand and foot surgery
2112nou	TCM 3000 BL	Rhinoplasty and reconstructive surgery

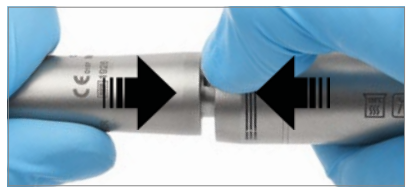
OPERATION

COUPLING HANDPIECES WITH A GROOVE WITH THE ELECTRONIC MOTOR 21 WITH TWIST PROTECTION LOCK

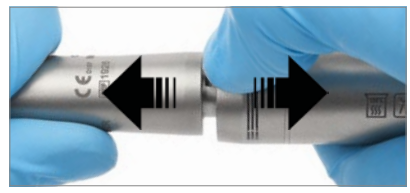


Twist protection lock with release button on the electronic motor.

Handpiece coupling with groove for twist protection.



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



Press the button and decouple handpiece from electronic motor.

REPROCESSING INSTRUCTIONS

⚠ 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.

⚠ Never clean the electronic motor in an ultrasonic bath! This impairs the functionality of the motor.

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 instrument is designed for 250 sterilization cycles.
General handling	**1.** The 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 enables correct 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 mildly alkaline and enzymatic cleaners with as low a silicate content as possible to avoid staining (silicatization) on 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.** Instructions for use for the equipment and chemicals etc. used during reprocessing must be strictly followed. **6.** Dosage of chemicals, exposure times and exposure temperatures for cleaning and disinfection must be strictly followed. **7.** The end of product life may be reached before the 250 sterilization cycles in case of excessive wear and damage from use. **8.** Do not overload the washer. Avoid rinsing blind spots. Ensure secure storage in the machine. **9.** Observe the regulations valid in your country for the reprocessing of medical devices. **10.** NOUVAG recommends the use of a screen basket with rinsing bar from 3mach (NOUVAG REF 51401), a reusable container for convenient preparation and storage (including transport) of the products. The screen basket can be used for safe storage of the products during the rinsing process as well as during and after sterilization until the products are used. The screen basket is suitable for use with sterilization paper or a rigid sterilization container. It does not have a barrier effect on its own to protect sterility.
Preparation 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 the contamination of the environment.
Cleaning and disinfection, pre-cleaning	**1.** Wipe the electronic motor with a damp disposable cloth/paper towel, removing all visible dirt. **2.** Unscrew motor cap and remove cable including motor cap. **3.** Unscrew handpiece carrier and remove 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 (manufacturer for example HEGA Medical, REF 6010 or REF 7060). Local tap water is sufficient for this purpose, since the last step is always a machine cleaning with deionized water, so possibly hard water with lime traces from the pre-cleaning cannot remain on the electronic motor.

Cleaning	**Mechanical cleaning** **1.** After pre-cleaning place the electronic motor and its accessories in the strainer basket. **2.** Mechanical cleaning is only successful if the pre-cleaning, described above, is adhered to! **3.** 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). **4.** After completing the cleaning program (incl. thermal disinfection) check the electronic motor, motor cap with cable, handpiece carrier and O-ring for visible contamination in the grooves and gaps. Repeat cleaning if necessary.	**Automatic cleaning process (Vario TD programme)** **1.** Pre-clean with cold water for 4 minutes. **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 with cold water for 3 minutes. **6.** Empty **7.** Inter-rinse for 2 minutes with cold water. **8.** Empty
Disinfection	**Mechanical disinfection** The cleaning/disinfection unit has a thermal disinfection programme which follows after 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 3.000 for the electronic motor and the attachments. Disinfection must be carried out with DI water.	**Warning** 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.
Drying	**Mechanical drying** Drying of the electronic motor by the drying cycle of the cleaning/disinfection unit's (CDU). If required, manual drying can also be achieved by using a lint-free cloth. Pay particular attention to the grooves and spaces between the electronic motor. Then spray the electronic motor again with Lubrifluid. 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** Set up the electronic motor vertically. Allow the electronic motor and the small parts to dry for at least 30 minutes. Then spray the electronic motor again with Lubrifluid.
Inspection and care	**1.** Perform a visual inspection for damage, corrosion and wear. **2.** Spray the electronic motor for cleaning and care. NOUVAG recommends using Lubrifluid for this purpose. Screw the spray adapter (REF 19584) onto the electric motor instead of the cable plug. Attach the blue spray adapter to the spray can and spray the electronic motor from the coupling side for about 3 seconds until only clear liquid flows out of the electronic motor.  **3.** Then wipe off with a moistened cloth (observe the product's instructions for use). **4.** After spraying the electronic motor, screw the O-ring, handpiece holder and motor cap with cable back onto the electronic motor.	
Sterilisation	Sterilisation of the electronic motor is performed with a fractionated pre-vacuum steam sterilisation process (in accordance with 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 (within the sterile band) **3.** Holding 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 vacuum function. After sterilisation an immaculate sterilisation result must be detected by examining the appropriate 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, it must be labelled with the sterilisation date on the packaging.	
Storage	**Storing the sterile packaging** The sterilised product must be stored away from dust, humidity and contamination. During storage, direct sunlight should be safely avoided. After the expiry date has passed, do not use the product any longer.	**Handling the sterile packaging** Before taking out the product, check for the packaging to be 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® MediZyme; Chemische Fabrik Dr. Weigert GmbH & Co. KG **3.** Cleaning and disinfection unit: Miele G 7836 CD **4.** Rack trolley: Miele E429 **5.** Strainer basket/flush socket bar: 3mach (NOUVAG 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 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. If you should opt for a different procedure for reprocessing to the one given above, you are required to correspondingly establish the suitability.	

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!

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.

MALFUNCTIONS AND 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.

TECHNICAL DATA

REF	2098nou	2099nou	2112nou
Weight, without cable	115 g	115 g	115 g
Torque max.	4 Ncm	7.5 Ncm	7.5 Ncm
Speed max.	80'000 rpm	50'000 rpm	40'000 rpm
Rated voltage	35 V	35 V	35 V
Current max.	8 A	8 A	8 A
Output max.	120 VA	120 VA	120 VA
Coupling	ISO 3964	ISO 3964	ISO 3964
Cable length	3.0 m	3.0 m	3.0 m
Pin assignment of the connector	10	10	8

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.

ACCESSORIES AND SPARE PARTS

REF	DESCRIPTION	QUANTITY
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

INFORMATION ON DISPOSAL

When disposing of the device, device components and accessories, the regulations issued by the legislator must be followed.
Used electrical and electronic equipment is hazardous waste and must not be disposed of with household waste.

MANUFACTURER AND SERVICE POINTS

Switzerland
NOUVAG AG
St. Gallerstrasse 25
9403 Goldach

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

Germany
NOUVAG GmbH
Schulthaissstrasse 15
78462 Konstanz

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

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