EN Operating instructions

Electronic Motor 21 (REF 2090/2097/2116)

NOUVAG

REF 20472EN, V05/18

- 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 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!

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.

Contraindication

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

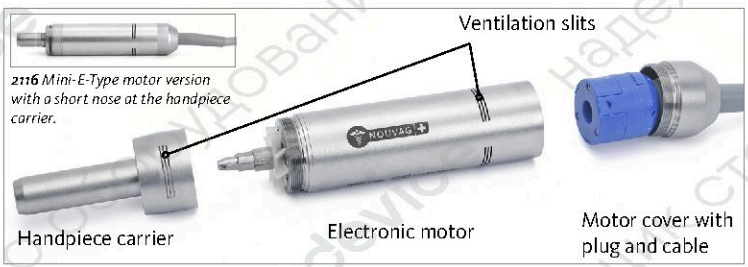
	Warning, hot surfaces	135°C	Autoclave at 135°C		Suitable for thermal disinfection		Date of manufacturing	REF	Order number
	Warning		Manufacturer	CE 0197	CE symbol with notified body	SN	Serial number		Observe instructions for use

Technical data, Electronic motor 21

REF	2090	2097	2116
Weight, without cable	280 g	280 g	275 g
Maximum torque	6 Ncm	6 Ncm	6 Ncm
Maximum output	120 VA	120 VA	120 VA
Maximum current	8 A	8 A	8 A
Rated voltage	35 V	35 V	35 V
Rated speed	40.000 rpm	50.000 rpm	50.000 rpm
Coupling	acc. to ISO 3964	acc. to ISO 3964	acc. to ISO 3964
Cable length	3.0 m	2.0 m	2.0 m

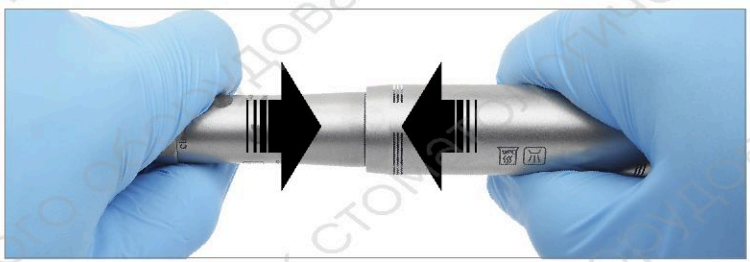
The motors vary by a different number of pins at the motor plug.

Overview

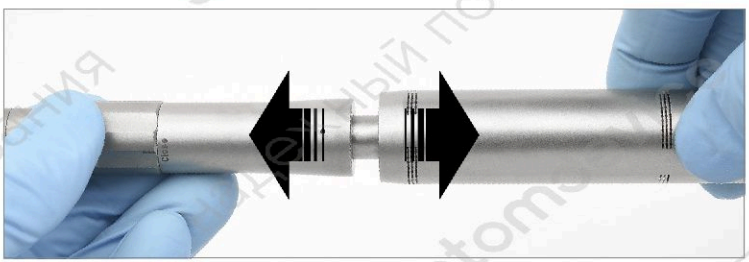


Operation

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



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



Disconnect coupling with a short, strong pull and slide off the handpiece from the handpiece carrier in the direction of the arrow.

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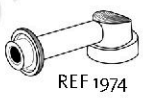
General handling	1. Every electronic motor must be thoroughly cleaned, disinfected and sterilised before initial operation (products straight from the factory) and also immediately following each use. Only a cleaned and disinfected electronic motor permits proper sterilisation! 2. The electronic motor 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 (silicatising) 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 service life is determined by wear and damage through use. The electric motor is designed for 250 sterilisation cycles. 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. The electronic motor must never be subjected to ultrasonic cleaning! This will impair the functionality. 11. Nouvag AG recommends using a screen basket including a rince 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.
Cleaning and disinfection, pre-cleaning	1. Wipe down the electronic motor with a damp disposable cloth/paper towel while removing all visible impurities. 2. Unscrew the motor cover and remove the cable incl. the motor cover. 3. Unscrew the handpiece carrier and also remove.  4. Brush down the plastic parts of the electronic motor under running tap water with a soft brush (Manufacturer Insitumend GmbH, REF MED100.33). 5. Rinse the outer surface of the electronic motor for 10 seconds with a water pistol (at a pressure of at least 2.0 bar). 6. Then spray the electronic motor with NouClean (see the Section „Inspection and care").  REF 1974 

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Cleaning	**Mechanical cleaning** 1. Place the electronic motor in the strainer basket after pre-cleaning. 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 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.	**Automatic cleaning process (Vario TD programme)** 1. Pre-clean for 4 minutes with cold water. 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 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.	**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** 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.	**Manual drying** 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 (see fig. 4).

Inspection and care



1. First unscrew the motor cover and remove the cable incl. the motor cover. Unscrew the handpiece carrier and remove it also.



2. Perform a visual check for damage, corrosion and wear.
3. 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 (fig. 1) in place of the connector onto the motor and spray with NouClean spray for about 3 seconds (fig. 2) until only clear liquid runs off the electronic motor.



4. Then wipe down with a moist cloth (Follow the product's instructions for use).
5. After spraying the electronic motor screw the handpiece carrier and the motor cover with the cable back onto the electronic motor (see figs. 3 – 4).

Sterilisation

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.

Minimum requirements:

1. Pre-vacuum phases: 3
2. Sterilisation temperature: At least 132°C.
3. Hold time: At least 3 minutes (full cycle).
4. Drying time: At least 10 minutes (max. 25 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. 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.

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. After the expiry date has passed, do not use the product any longer.	**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® MediZyme; Chemische Fabrik Dr. Weigert GmbH & Co. KG 3. Cleaning/disinfection unit: Miele G 7836 CD 4. Rack trolley: Miele E429 5. Autoclave: Selectomat 666-HP (MMM) 6. 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.	
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.	

Spare parts

REF	Description	Units
1984	Maintenance and care spray „Nou-Clean"	1
1974	Spray nozzle for Nou-Clean spray	1
76052	Motor cable pre-assembled for (motor 2090) TCM3000BL-Morcellator	1
76066	Motor cable pre-assembled for motor 2097) MD 11, MD 30	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.Gallerstr. 23 – 25 • CH-9403 Goldach
Phone +41 071 846 66 00 • Fax +41 071 845 35 36
info@nouvag.com • www.nouvag.com

A complete list of Nouvag certified service centers are found on the Nouvag website at:

www.nouvag.com/en/service/service-provider

Disposal

Conform strictly to local laws and regulations at the disposal of devices, device parts and accessories.

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