




- The electronic motor 21 is supplied by us non-sterile! Before first use and immediately after each use, the motor must be cleaned, disinfected and sterilized!
- To avoid cable breakage, do not kink the motor cable!



- 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 ".

Use and intended purpose

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 control unit and corresponding handpiece is used in the following medical areas:

Laparoscopic hysterectomy (electronic motor 21; REF: 2090nou) Dental implantology (electronic motor 21; REF: 2097nou) Dental implantology (electronic motor 21; REF: 2116nou)

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 / Restrictions

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 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.

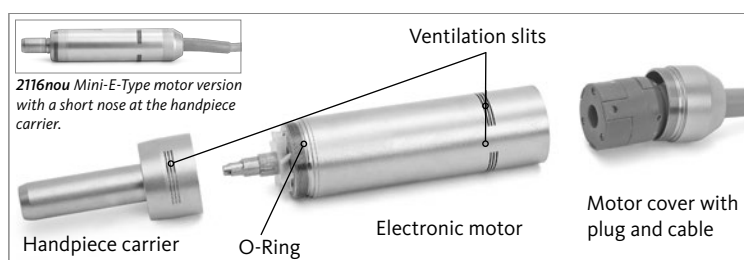
Symbols

	Warning, hot surfaces		Manufacturer		Follow the instructions for use		Autoclave at 134°C		Reference number		Application part of type BF is the electronic motor
	Warning		Date of manufacturing		European authorised Representative		Suitable for thermal disinfection		Serial number		Note on disposal
									LOT number		CE symbol with notified body

Technical data

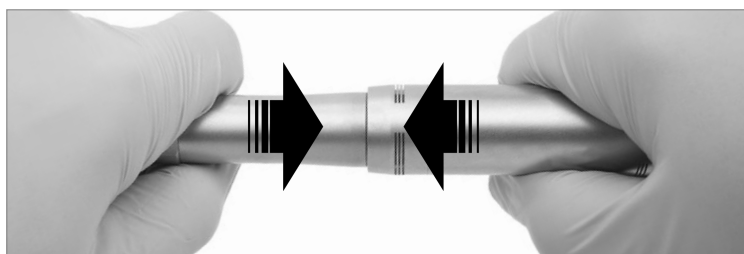
REF	2090nou	2097nou	2116nou
Weight, with cable	325 g	310 g	300 g
Maximum torque	6 Ncm	6 Ncm	6 Ncm
Maximum output	120 VA	120 VA	120 VA
Maximum current	8 A	8 A	8 A
Rated voltage	35 V	35 V	35 V
Rated speed	40'000 rpm	50'000 rpm	50'000 rpm
Coupling	acc. ISO 3964	acc. ISO 3964	acc. ISO 3964
Cable length	3,0 m	2,0 m	2,0 m
Pin assignment of the connector			

Overview

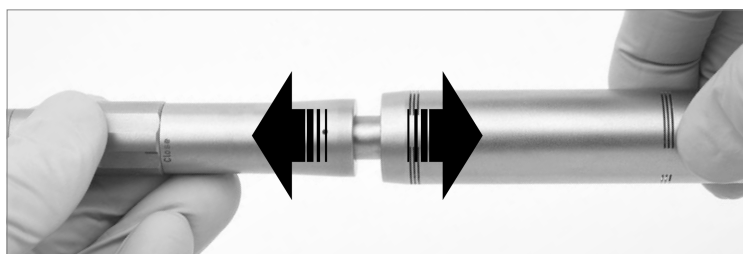


Operation

Coupling handpieces to the electronic motor 21



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 2090nou, 2097nou, 2116nou Mini-E-Type

REF 2090nou is used together with the TCM 3000 BL control unit and the corresponding handpiece in dermabrasion and reconstructive surgery. Together with the TCM 3000 BL morcellator, the motor is used in laparoscopic hysterectomy.

REF 2097nou is exclusively used in dental implantology in connection with the implantology control units MD 11 and MD 30, which control this electronic motor and provide settings for speed and torque according to the contra-angle/handpiece used.

REF 2116nou, Mini E-Type is used in dental implantology in conjunction with the MD 11 implantology control unit, which controls this electronic motor and provides settings for speed and torque according to the contra-angle/handpiece used.



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 motor control units.

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"> 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 (silicating) 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 even 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. 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 rinse strip from 3mach (Nouvag AG 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.

Pre-cleaning for Cleaning and disinfection	<ol style="list-style-type: none"> Wipe down the electronic motor with a damp disposable cloth or paper towel while removing all visible impurities. Unscrew the motor cover and remove the cable including the motor cover. Unscrew the handpiece carrier and also remove the O-ring.  <ol style="list-style-type: none"> Clean the plastic parts of the electronic motor and its accompanying parts under running tap water using a soft brush (Manufacturer e.g. Insitumend GmbH, REF MED100.33). 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 e.g. HEGA Medical, REF 6010 oder 7060) 	
Cleaning	Mechanical cleaning <ol style="list-style-type: none"> Place the electronic motor and accompanying parts 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's advisable to use DI water (fully desalinated water). 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) <ol style="list-style-type: none"> Pre-clean for 4 minutes with cold water < 40°C. Empty Clean for 5 minutes at 55°C with 0.5 % alkaline or at 40°C with 0.5 % enzymatic cleaner. Empty Neutralise for 3 minutes with cold water < 40°C. Empty Inter-rinse for 2 minutes with cold water < 40°C. Empty
Disinfection	Mechanical disinfection <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 and its accompanying parts. Disinfection must be carried out with DI water.</p>	Warning  <p>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 package insert for dwell times.</p>
Drying	Mechanical drying <p>Dry the electronic motor and accompanying parts 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. 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>	Manual drying <p>Set the electronic motor up in an upright position without motor cover and cable and without handpiece carrier and O-ring. Dry the electronic motor for at least 30 minutes. Afterwards reassemble the</p>
Inspection and care	<ol style="list-style-type: none"> Perform a visual check for damage, corrosion and wear. In the next step spray the electronic motor using the care spray "Lubrifiuid". Screw the spray adapter (REF: 19584) in place of the cable connector onto the motor and spray with "Lubrifiuid" spray for about 3 seconds.  <ol style="list-style-type: none"> Then wipe down the electronic motor with a moist cloth. After spraying the electronic motor reassemble the O-ring, the handpiece carrier and the motor cover with the cable back onto the electronic motor. 	
Sterilisation	<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: minimum 132°C – maximum 137°C. Hold time: At least 5 minutes (full cycle). Drying time: At least 10 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>	
Storage	Storing the sterile packaging <p>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.</p>	Handling the sterile packaging <p>Before taking out the product, check that the sterile packing is intact. When taking out the product, follow the respective aseptic procedures.</p>
Information for validating the preparation	<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 AG 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 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.</p>	
Note		<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>
Caution!		<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>

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/en/contact-us/incident-questionnaire>) as a PDF to this address: complaint@nouvag.com

Spare parts

REF	Description	Units	REF	Description	Units
2128	"Lubrifiuid" spray	1	24119	O-Ring	1
19584	Spray adapter for the lubrication of the electronic motor	1	76052	Motor cable pre-assembled for motor 2090nou	1
			76066	Motor cable pre-assembled for motor 2097nou and 2116nou	1

Troubleshooting

Problem	Cause	Solution
Motor is not running	Plug is not inserted properly	Insert plug and check fitting properly
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

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

Disposal

 When disposing of devices, device components and accessories, local, customary regulations of the legislator must be followed.