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 / Limitations
Relative or absolute contraindications can arise from the general medical diagnosis, 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 not permissible. 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.

Technical data, Electronic motor 21

<table>
<thead>
<tr>
<th>REF</th>
<th>2098nou</th>
<th>2099nou</th>
<th>2112nou</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight, without cable</td>
<td>280 g</td>
<td>280 g</td>
<td>280 g</td>
</tr>
<tr>
<td>Maximum torque</td>
<td>6 Ncm</td>
<td>6 Ncm</td>
<td>6 Ncm</td>
</tr>
<tr>
<td>Maximum output</td>
<td>120 VA</td>
<td>120 VA</td>
<td>120 VA</td>
</tr>
<tr>
<td>Rated voltage</td>
<td>230 V</td>
<td>230 V</td>
<td>230 V</td>
</tr>
<tr>
<td>Rated speed</td>
<td>80,000 rpm</td>
<td>50,000 rpm</td>
<td>40,000 rpm</td>
</tr>
<tr>
<td>Motor cover with plug and cable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cable length</td>
<td>5 m</td>
<td>5 m</td>
<td>5 m</td>
</tr>
</tbody>
</table>

WARNING!
- Do not bend motor cable, to prevent cable break!

Possible combinations

Electronic motor 21 with twist protection lock, REF 2098nou, 2099nou, 2112nou

- The electronic motor may only be connected with connection sockets marked with the symbol “Type BF”
- Do not dispose of the electronic motor with household waste.

Ambient conditions

<table>
<thead>
<tr>
<th>Condition</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>-40°C – 60°C</td>
</tr>
<tr>
<td>Relative humidity</td>
<td>Max. 90 %</td>
</tr>
<tr>
<td>Atmospheric pressure</td>
<td>20 – 100 mbar</td>
</tr>
</tbody>
</table>

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
- 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.
- The electronic motor is only prepared for metal treatment by the use of metal-alkaline and enzymatic cleaners with as low a content of silicate as possible in order to avoid staining (sili-cating) the electronic motor.
- 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.

Electromagnetic compatibility (EMC)

The use of (BT) 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 unrequested or adverse operation. The connection or the placing of other devices in close vicinity is or allowed.

WARNING!
- The electronic motor must never be subjected to ultrasonic cleaning! This will impair the functionality.
- Nougag AG recommends using a screen basket with a rinse strip from 3mach (NOUVAG REF 51401), a re-usable container for comfortable and transport.
- The electronic motor is recommended for use with sterilisation paper or a rigid sterilisation container. It has no barrier effect itself in order to maintain sterility.
- In relation to patients with Cochloïf Jakob disease or its variant (CJD) 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 prior to the use of the product
- 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.

Warning, hot surfaces

Manufacturer at 95°C

Suitable for thermal disinfection

Symbol with unsterilized body

SN

Observe instructions for use

Type B applied part is the electronic motor

Order number

Electromotor

Handpiece carrier

Twist protection lock

Release button

Ventilation slots

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.

Attention!
- In relation to patients with Cochloïf Jakob disease or its variant (CJD) 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.

Operating instructions

Electronic Motor 21 (REF 2098nou/2099nou/2112nou)

- We deliver an umbrella motor. Clean, disinfect, and sterilize the electronic motor before the first application and immediately after each use!
- Do not bend motor cable, to prevent cable break!
- 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”!
Clearing and disinfection before pre-cleaning
1. Wipe down the electronic motor with a damp disposable cloth/paper towel while removing all visible impurities.
2. Uncover the motor cover and remove the cable incl. the motor cover.
3. Unpack the handpiece carrier and also remove the motor cover.
4. Brush down the plastic parts of the electronic motor under running tap water with a soft brush (manufacturer Insitumed GmbH, REF MED100.33).
5. Rinse the outer surface of the electronic motor for about 3 seconds with a water pistol (at a pressure of at least 2 bar).
6. Then spray the electronic motor with NouClean (see the Section “Inspection and care”).

Automatic cleaning process (Vario TD programme)
1. Pre-clean for 4 minutes with cold water.
2. Empty
3. Clean for 5 minutes at 50°C with 0.5 % enzymatic cleaner.
4. Empty
5. Neutralise with cold water for 5 minutes.
6. Empty
7. Inter-rinse for 4 minutes with cold water.
8. Empty

Clearing
Mechanical clearing
1. Place the electronic motor in the strainer basket after pre-cleaning.
2. Mechanical clearing 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 allowing unit (CDU). For the cleaning process it is advisable to use DI water (fully deaerated 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 clearing if necessary.

Disinfection
Mechanical disinfection
The clearing/disinfection unit has a thermal disinfection programme which follows the cleaning. When performing mechanical thermal disinfection, due consideration to the national requirements relating to the Ao value (see DIN EN ISO 11140-1). We recommend an Ao value of 1,000 for the electronic motor. Disinfection must be carried out with DI water.

Drying
Mechanical drying
Dry the electronic motor using the cleaning/disinfection unit’s (CDU) drying cycle. If required, manual drying may also be achieved by using a low speed air blower. 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 11140-1). 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 40 minutes. Then spray with NouClean spray. Afterwards screw the handpiece carrier and the motor cover with cable back onto the electronic motor.

Inspection and care
1. First uncover the motor cover and remove the cable incl. the motor cover. Unpack 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. Spray the screw attachment in place of the connector onto the motor and spray with NouClean spray for about 4 seconds until only clear liquid runs off the electronic motor.
4. 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 cable back onto the electronic motor.

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. Minimum vacuum degree: At least 132°C
3. Hold time: At least 10 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 autoloops without a post sterilisation function. After sterilisation the perfect sterilisation result need 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 sterilisation procedure must be labelled with the sterilisation date.

Storage
Storing the sterile packaging
The sterilised product must be stored away from dust, humidity andcontamination. Storage during ensure that there is no direct exposition 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 packaging is intact. When taking out the product, follow the respective aseptic processes.

Information for validating the preparation
The above preparation process has been verified by a validated procedure. The following machines and machines were used:
1. Autoclave: Selectomat 666-HP (MMM)
2. Enzymatic cleaner: Neoderh®-Medizyme; Chemiche Fabrik Dr. Weigert GmbH & Co. KG
3. Cleaning/disinfection unit: Miele G 7836 CD
4. Rack trolley: Miele Rac 2
5. Jet BioSonics 500
6. Screwdriver/narrow strip rongue (NOVAG UF 3501-4)
7. Sterilisation: Selectemp 666-HP (MAMM)

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.

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 comply with the applicable legislation in your country and the medical practice or hospital’s bygones. This rules especially to the varying requirements for an effective inactivation of prions.

Manufacturer and service centers
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Haltom City, Texas 76177 USA
Phone +1 817 887-9104 Fax +1 817 887-9107 Toll free no. (US) 877 747 2443

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 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. When discarding the device components and accessories, please comply with the issued statutory regulations. With regard to the preservation of the environment old equipment may be returned to the distributor or manufacturer.