**Intended use / indication**

The motors are equipped with handpiece carriers according to ISO 564, which enable the attachment of handpieces and contra angles and ensure secure hold. The electronic motor is in conjunction with a drive system and corresponding handpiece is used in the following medical areas:

- Plastic surgery
- Spine surgery
- ENT surgery
- Facial and cranial surgery
- Traumatology
- Orthopaedics/Arthroscopy
- Gyroscopy
- Urology and laparoscopy
- Dental/dental implantology

The electronic motor 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 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 may only be connected and operated with NOUGAV AG motor systems. The use of handpieces & contra angles by other manufacturers in conjunction with the electronic motor is the responsibility of the user. Switching on the electronic motor 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>2090nou</th>
<th>2097nou</th>
<th>2116nou</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voltage, without cable</td>
<td>220 V</td>
<td>220 V</td>
<td>220 V</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>Maximum current</td>
<td>8 A</td>
<td>5 A</td>
<td>5 A</td>
</tr>
<tr>
<td>Rated voltage</td>
<td>35 V</td>
<td>35 V</td>
<td>35 V</td>
</tr>
<tr>
<td>Rated speed</td>
<td>400/min to 1500/min</td>
<td>400/min to 1500/min</td>
<td>400/min to 1500/min</td>
</tr>
<tr>
<td>Coupling</td>
<td>acc. to ISO 1594b</td>
<td>acc. to ISO 1594b</td>
<td>acc. to ISO 1594b</td>
</tr>
<tr>
<td>Cable length</td>
<td>2.0 m</td>
<td>2.0 m</td>
<td>2.0 m</td>
</tr>
</tbody>
</table>

The motors may differ in a different number of pins at the motor plug.

**Possible combinations**

Electronic motor 21, REF 2090nou, 2097nou, 2116nou

**Ambient conditions**

- Transport and storage: Operation:
  - Relative humidity: Max. 90 %
  - Max. 80 %
- Temperature: 10 – 30°C
- Atmospheric pressure: 700 – 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 to be avoided.

The product is suitable for use in established facilities of the industrial sector and hospitals. When used in the domestic environment, 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**

- Frequent reprocessing has only a limited impact on the electronic motor. The end of the product’s service life is normally determined by war and damage through use. The electronic motor 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, stored, 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)
4. Only commercial grade DGHI-VAHR-listed agents may be used for cleaning and disinfection. See these agent manufacturer’s specifications for the method of use, action time and suitability of disinfecting and cleaning substances
5. Follow precisely the operating instructions of the devices and chemicals 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 sterilisation 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. NOUGAV AG recommends using a screen basket including a ring stripe from smajx (NOUGAV REF 5043/1), a reusable container for comfortable storage and transportation (incl. transport of products). The screen basket can be used to transport both parts of the motor carrier during the storage 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.
12. Further observe the EMC manufacturers declaration of conformity.

**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 the use of the products combined.

**Cleaning and disinfection, pre-cleaning**

1. Wipe down the electronic motor with a damp disposable cloth/paper towel while removing all visible impurities.
2. Remove the handpiece carrier and remove the cable (incl. the motor cover).
Cleaning
1. Mechanical cleaning
   - Place the electronic motor in the strainer basket after pre-cleaning.
   - Mechanical cleaning is only successful if the pre-cleaning described above is adhered to!
2. 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)
3. 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 % or 40°C with 0.5 % enzymatic cleaner.
4. Empty
5. Neutralise with cold water for 5 minutes.
6. Empty
7. Rinse with clear water for 3 minutes.
8. Empty

Disinfection
1. 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 AUC value (DIN EN ISO 17665-1).
2. Expiration date has passed, do not use the product any longer.

Warning
If the electronic motor is not used immediately after sterilisation, the material/packaging must be labelled with the sterilisation date.

Drying
1. 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 and a lint-free cloth.
2. Enzymatic cleaner: Neodisher® MediZyme; Chemische Fabrik Dr. Weigert GmbH & Co. KG
3. Alkaline cleaner: Neodisher® Mediclean; Chemische Fabrik Dr. Weigert GmbH & Co. KG
4. Screen basket/rinse strip: 3mach (NOUVAG REF 51401)
5. Sterilisation temperature: At least 132°C.
6. Drying time: At least 10 minutes (max. 25 minutes).
7. 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.

Sterilisation
1. Sterilisation of the electronic motor is performed with a fractional pre-vacuum steam sterilisation technique (in accordance with DIN EN 1565/1- DIN EN ISO 17665-1) giving due consideration to the respective national requirements.
2. Sterilisation must be stored away from dust, humidity and sunlight. After the expiry date has passed, do not use the product any longer.

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: Maile G 3860 CD
4. Rack tray: Maille E 990
5. Screen basket/rinse strip: 3mach (NOUVAG REF 51401)
6. Autolavage: Selectomat 666-HP (INIMA)
7. Sterile packaging: Stinech noks Bienenwerk Amorflex GmbH
8. 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 can achieve 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 procedures, etc.

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

Troubleshooting

Manufacturing and service centers
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www.nouvag.com

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www.nouvag.com

Nouvag USA, LLC
4201 Airport Freeway, Suite 200
Haltom City, Texas 76117 USA
Fax +1 817 887 9817
Tel: +1 817 887 9814
Toll free no. (800) 673 7427

A complete list of Novug certified service centers are found on the Novug 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 equipment may be returned to the distributor or manufacturer.

Spare parts

<table>
<thead>
<tr>
<th>REF</th>
<th>Description</th>
<th>Units</th>
<th>REF</th>
<th>Description</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>1984</td>
<td>Maintenance and care spray &quot;Nou-Clean&quot;</td>
<td>56052</td>
<td>2090nou</td>
<td>Motor cable pre-assembled for motor</td>
<td>1</td>
</tr>
</tbody>
</table>

Handling the sterile packaging
Before taking out the product, check that the sterile pack is intact.

Note
Users bear full responsibility if they use a procedure which differs from the validated sterilisation procedure described.

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. Then wipe down with a moist cloth (Follow the product manufacturer’s directions and operating instructions).
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. Then wipe down with a moist cloth (Follow the product manufacturer’s directions and operating instructions).
6. Then spray the electronic motor with NouClean (see the Section “Inspection and care”).
7. After spraying the electronic motor screw the handpiece carrier and the motor cover with the cable back onto the electronic motor.