Electronic motor 21 (REF 2100nou/2101nou)

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 is in conjunction with a drive system and corresponding handpiece is used in the following medical areas:

- Plastic surgery
- Plastic general surgery
- Traumatology
- Orthopedics/Arthroscopy
- Gynecology
- Urology/Intracorporal lithotripsy
- Ophthalmology/Surgery
- Dental implantology

The electronic motor 21 can only be connected with connection sockets marked with the symbol “Type BF”.

Contra indications / Limitations

Relative or absolute contra indications 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 Nouvag AG 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 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>Model</th>
<th>Weight with cable</th>
<th>Maximum torque</th>
<th>Maximum current</th>
<th>Rated speed</th>
<th>Motor coupling</th>
</tr>
</thead>
<tbody>
<tr>
<td>2100nou</td>
<td>118 g</td>
<td>128 Nm</td>
<td>8 A</td>
<td>30,000 rpm</td>
<td>according to ISO 5944</td>
</tr>
<tr>
<td>2101nou</td>
<td>118 g</td>
<td>122 Nm</td>
<td>8 A</td>
<td>30,000 rpm</td>
<td>according to ISO 5944</td>
</tr>
</tbody>
</table>

Operation

Coupling handpieces with the electronic motor

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

Possible combinations

- Electronic motor 21, REF 2100nou/2101nou

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

Reprocessing instructions

- 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 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).
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 a low content of silicate as possible in order to avoid staining (pickling) 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. 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.
6. Do not overload dishwashers. Avoid dead zones. Pay attention to secure storage in the machine.
7. Do not use it beyond its specification. 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 Cereallo® (Ibid. device in its variant (B) and 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 of 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.

Ambient conditions

- Temperature: 5 – 40 °C
- Relative humidity: 40 – 90 %
- Atmospheric pressure: 860 – 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 not 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 representation of the product.

Ordering information

- Order number Type BF applied part is the electronic motor
- Manufacturer NUVAG
- Date of manufacture
- Serial number
- Date of manufacturing
- CS symbol with modified body
- Suitable for thermal disinfection
- Manufacturer declaration of conformity
- Warning for hot surfaces
- Temperature: 5 – 40 °C
- Puncture (of the housing) before 1060 hPa
- Motor coupling with the electronic motor

Manufacturer CE symbol with
• Orthopedics/Arthroscopy
• ENT surgery
• Oral/maxillary surgery, dental implantology
• Plastic surgery
• Plastic general surgery
• Traumatology
• Spine surgery
• Gynecology
• Urology/Intracorporal lithotripsy
• Ophthalmology/Surgery
• Dental implantology
• Oral/maxillary surgery, dental implantology
Cleaning and disinfection, pre-cleaning

1. Wipe down the electronic motor with a damp disposable cloth/paper towel while removing all visible impurities.
2. Unmount the motor cover and remove the cable incl. the motor cover.
3. Unmount the handpiece carrier and also remove.

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 % alkaline or at 40°C with 0.5 % enzymatic cleaner.
4. Empty.
5. Neutralise with cold water for 5 minutes.
6. Empty.
7. Rinse for 2 minutes with cold water.
8. Empty.

Motor interruption during cable movements

Motor is not properly coupled to the handle-piece

Motor must be not handled under running tap water with a soft brush (manufacturer Insitumed 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 bar).

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. Observe the national regulations for the disposal of infectious waste.

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.

Cleaning

1. Place the electronic motor in the strainetaker before 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 programmes (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.

Information for validating the preparation

The above-described procedure has been approved by a validated procedure. The following materials and machines were used:

1. Alkaline cleaner: Neodisher® Medikalis®
2. Enzymatic cleaner: Neodisher® Medizyme®
3. Sterilisation/cleaning unit: Medisafe® CD
4. Rack rinses: Medisafe® CD
5. Screen basket/mini strip-pouch: NUVAG REF 1980
6. Autolavette: Selectomat 1666-IP (MWMS)

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 15883-1) during 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.

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.

Drying

1. Perform a visual check for damage, corrosion and wear.
2. 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 in place of the connector onto the motor and spray with NouClean spray for about 3 seconds until only lightly sprayed off the electronic motor.

Disposal

For a complete list of all services providers, authorized by Nouvag AG, please visit www.nouvag.com/de/service/service provider

Cleaning

1. Motor cable complete, pre assembled for motor 2100nou ............................1 LipoSurg ...1
2. Rotary motion of the motor does not trans-...
3. Motor is not properly coupled to the handle-piece
4. Brush-down the plastic parts of the electronic motor under running tap water with a soft brush (manufacturer Insitumed GmbH, REF MED100.33).

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. Observe the national regulations for the disposal of infectious waste.

Notes

There is no replacement available for other existing sterilisation procedures such as plasma sterilisation, heat temperature sterilisation procedure, etc. Users bear full responsibility if they use a procedure which differs from the validated sterilisation procedure described.

Note

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.

Cleaning

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