

Electronic Motor 31 ESS



©NOUVAG AG • 20473 • V20220906 • All rights reserved.



- 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 the 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 purpose

The electronic motors 31 ESS 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 31 ESS in conjunction with a control unit and corresponding handpiece is used in the following medical indications:

Plastic surgery Spine surgery Traumatology Facial and cranial surgery

ENT surgery

Instructions for use

Orthopedics/Arthroscopy

Gynecology Urology and laparoscopy

Oral/maxillary surgery, dental implantology

The electronic motor 31 ESS may only be operated by qualified and trained personnel. Improper operation can lead to malfunctions. The intended use is clearly described in the instructions for use of the corresponding device/instrument.

Contraindication/Limitations

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 devices. Relevant cases in the literature must be taken into consideration. The electronic motor 31 ESS 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 31 ESS is the responsibility of the user. Switching on the electronic motor 31 ESS without holding it, or correctly placing it in the handpiece holder leads to uncontrolled movements of the motor.

Symbols

	20.5											
\wedge	Caution	~	Manufacturer	LOT	LOT number	134°C ∭	Autoclave at 134°C	REF	Reference number	<u> </u>	Note on disposal	
	Caution, hot surfaces	\sim	Date of manufacturing	③	Follow the instruc- tions for use	凶	Suitable for thermal disinfection	SN	Serial number			

Technical Data

		2063nou	2064nou	2058nou
Weight, without cable	g	310	310	310
Torque max.	Ncm	6	6	6
Output max.	VA	120	120	120
Current max.	А	6	6	6
Rated voltage	V	35	35	35
Rated speed	rpm	40 000	40 000	40000
Coupling		ISO 3964	ISO 3964	ISO 3964
Cable length	m	2,0	3,0	4,0

Overview



Operation

Coupling handpieces with the electronic motor 31 ESS.



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.

Reprocessing instructions



Caution

With regard to patients with Creutzfeldt-Jakob disease or its variant (vCJD), no responsibility can be assumed for the reuse of the electronic motor. The Robert Koch Institute recommends withdrawing used products from circulation to avoid infecting other patients, users and third parties.



Attention

Never clean the motor in an ultrasonic bath. This will impair the functionality of the motor.

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 (silicatizing) 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 used during preparation.
- 6. The end of the product life can be reached before reaching the maximum 250 sterilization cycles in case of excessive wear and damage by use.
- Do not overload dishwashers. Avoid dead zones. Pay attention to secure storage in the machine.
- Follow the applicable regulations in your country for reprocessing medical devices.
 Nouvag AG recommends using a screen basket including a rinse strip from 3mach (Nouvag AG REF: 51401), a re-usable container for 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

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

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

- 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 including the motor cover.

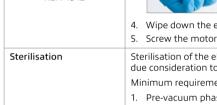
container. It has no barrier effect itself in order to maintain sterility.



- Brush down the plastic parts of the electronic motor under running tap water with a soft brush (manufacturer Insitumed GmbH, REF MED100.33).
- Rinse the outer surface of the electronic motor for 10 seconds with a water pistol (at a pressure of at least 2.0 bar).
 Then spray the electronic motor with Lubrifluid (see the Section "Inspection and care").



Cleaning Mechanical cleaning Automatic cleaning process (Vario TD programme) 1. Pre-clean for 4 minutes with cold water < 40°C. Mechanical cleaning is only successful if the pre-cleaning, 2. described above, is adhered to! Clean for 5 minutes at 55°C with 0.5 % alkaline or at 40°C with 3. 0.5 % enzymatic cleaner. Place the electronic motor and accompanying parts in the strainer basket after pre-cleaning. 4. Empty Cleaning is done using the Vario TD programme in the cleaning 5. Neutralise for 3 minutes with cold water < 40°C. and disinfection unit (CDU). For the cleaning process it's advisable 6. Empty to use DI water (fully desalinated water). 7. Inter-rinse for 2 minutes with cold water < 40°C. After completing the cleaning programme (incl. thermal disinfec-8. Empty tion) check the electronic motor, motor cover with cable, handpiece carrier and O-ring for visible contamination in grooves and gaps. Repeat cleaning if necessary. Disinfection Mechanical disinfection Caution The cleaning/disinfection unit has a thermal disinfection programme When inadequately rinsed or exposed to the disinfectant which follows the cleaning. When performing mechanical thermal disinfection, give due consideration to the national requirements relating or detergent for too long, the electronic motor and its accompanying parts can corrode. Please see the correspondto the A0 value (see DIN EN ISO 15883-1). We recommend an A0 value ing detergent and disinfectant's instructions for use for of 3000 for the electronic motor and its accompanying parts. Disinfecdwell times. tion must be carried out with DI water. Drying Manual drying Dry the electronic motor and accompanying parts using the clean-If required, manual drying can also be achieved by using a lint-free ing/disinfection unit's (CDU) drying cycle. Then spray the electronic cloth. motor again with Lubrifluid. When drying manually, take particular care with the grooves and gaps Every CDU must provide a corresponding drying procedure through the of the electronic motor. manufacturer (see ISO 15883-1). Please follow the corresponding CDU-After using the cloth, set the electronic motor up in an upright position manufacturer's directions and operating instructions. without motor cover and cable. Dry the electronic motor for at least 30 minutes. Inspection and care 1. First unscrew the motor cover and remove the cable including the motor cover. 2. Perform a visual check for damage, corrosion and wear. Spray the electronic motor for cleaning and care. Nouvag AG recommends using Lubrifluid for this purpose. Spray the electronic motor from the front with the spray adapter (REF 1942) in place for about 3 seconds (fig. 4) until only clear liquid runs out of the electronic motor. REF: 1942 Wipe down the electronic motor with a moist cloth. Screw the motor cover with the cable back onto the electronic motor. Sterilisation Sterilisation of the electronic motor is performed with a fractionated pre-vacuum steam sterilisation technique (DIN EN 13060/DIN EN 285) giving due consideration to the respective national requirements. Minimum requirements: 1. Pre-vacuum phases: 3



- 2. Sterilisation temperature: minimum 132°C maximum 137°C.
- 3. Hold time: At least 5 minutes (full cycle). 4. Drying time: At least 10 minutes.

Storing the sterile packaging

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. Sterilisation result needs to be checked using corre-

sponding 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.

Information for validat-

ing the preparation

Storage

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.

The above preparation process has been verified by a validated procedure.

Before taking out the product, check that the sterile packing is intact. When taking out the product, follow the respective aseptic procedures.

Handling the sterile packaging

The following materials and machines were used:

- 1. Alkaline cleaner: Neodisher® Mediclean; Chemische Fabrik Dr. Weigert GmbH & Co. KG
- Enzymatic cleaner: Neodisher® MediZym; Chemische Fabrik Dr. Weigert GmbH & Co. KG
- 3. Cleaning/disinfection unit: Miele G 7836 CD
- 4. Rack trolley: Miele E429
- 5. Screen basket/rince strip: 3mach (Nouvag AG REF: 51401)
- 6. Autoclave: Selectomat 666-HP (MMM)
- Sterile packaging: Sterisheet 100; Broemeda Amcor Flexibles GmbH

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 validate it.

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

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/media/attachments/2022/05/19/for_8-308.pdf as a PDF to this address: complaint@nouvag.com

Accessories

REF	Description	Units
2128	Lubrifluid	1

Spare parts

	•	
REF	Description	Units
76061	Motor cable complete, for motor 2063nou (MD 10)	1
76062	Motor cable complete, for motor 2064nou (MD 20)	1
76063	Motor cable complete, for motor 2058nou (Vacuson 60 LP)	1

Troubleshooting

- Toubleshooting					
Problem	Cause	Solution Insert plug and check fitting.			
Motor is not run- ning.	Plug is not inserted 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

Nouvag AG • St.Gallerstrasse 25 • CH-9403 Goldach Tel. +41 71 846 66 00 info@nouvag.com • www.nouvag.com



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

Disposal

