

HighSurg 11 OFA-Drill

for Orthopaedic Foot Surgery



Vorwort

Herzlichen Glückwunsch zum Kauf eines Produktes der Firma NOUVAG AG. Wir freuen uns, dass Sie sich für ein NOUVAG Erzeugnis entschieden haben und danken Ihnen für Ihr entgegengebrachtes Vertrauen. Diese Bedienungsanleitung wird Sie mit dem Gerät und seinen Eigenschaften vertraut machen, damit eine möglichst lange und problemlose Funktion gewährleistet werden kann. Im Anhang finden Sie die Konformitätserklärung und unsere autorisierten Servicestellen.

- **Bitte lesen Sie diese Anleitung vor Inbetriebnahme aufmerksam durch!**

Foreword

Congratulations on your purchase of a NOUVAG AG product. Thank you for the confidence shown in our products. Please consult the instruction manual for the use and maintenance of the device in order to ensure that it will function properly and efficiently for many years. You will find the conformity statement and list of authorized service representatives attached.

- **Please read instructions carefully before operating!**

Préface

Félicitations vous venez d'acheter un produit NOUVAG AG. Merci de la confiance que vous montrez en nos produits.

Merci de consulter le mode d'emploi pour l'utilisation et l'entretien de cet appareil de manière à vous assurer qu'il fonctionnera correctement et efficacement pendant de nombreuses années.

Vous trouverez ci-joint les déclarations de conformité et la liste des agents agréés pour l'entretien.

- **Lire soigneusement les instructions avant utilisation!**

Prefazione

Ci congratuliamo con Lei per l'acquisto di un prodotto NOUVAG AG e le auguriamo un susseguirsi di successi professionali.

Questo manuale l'aiuterà a conoscere meglio l'apparecchiatura e le sue caratteristiche. Contiene indicazioni utili che le assicureranno un funzionamento efficiente ed una lunga durata.

Qui allegato troverete la dichiarazione di conformità e la lista dei rivenditori autorizzati.

- **Prego leggere attentamente le istruzioni per l'uso prima di mettere in funzionamento!**

Preposición

Muchas gracias por la compra de un producto NOUVAG AG.

Felicidades por la elección y la confianza depositada en nuestros productos.

Para garantizar una función duradera y eficiente del aparato, por favor consultar el manual de instrucciones.

El Certificado de Conformidad y la lista de Centros de Servicio se encuentran en el apéndice.

- **Por favor leer las instrucciones detenidamente antes de poner en marcha el aparato!**

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1 Product description

1.1 Intended use and operation

The motor system OFA-Drill is used in the percutaneous foot surgery for drilling, milling and sawing, as well as for applying K-wire. With the integrated peristaltic pump tissue is cooled to prevent of necrotization.

The OFA-Drill may only be operated by qualified and trained personnel.

1.2 Contraindications

Not known.

1.3 Technical data, OFA-Drill

Voltage: -----variable: 100 V~/ 115 V~/ 230 V~, 50 – 60 Hz
 Fuse, power supply: ----- 2 fuses, T 3.15 AL 250 V AC
 Power consumption: ----- 120 VA
 Applied part: ----- Type B*
 Protection class: ----- Class I
 Dimensions (W x D x H): ----- 260 x 250 x 110 mm
 Net weight control unit: ----- 3.3 kg

Motor:

Motor coupling:----- Intra coupling ISO3964
 Motor speed:----- 300 - 50,000 rpm
 Max. Motor torque: ----- 6 Ncm
 Motor weight: ----- 0.280 kg
 Motor cable length----- 3 m

Pedal:

IP code (pedal) ----- IPX8

**Applied part of Type B is the instrument used with the OFA-Drill.*
























1.4 Ambient conditions

| | Transport and storage: | Operation: |
|------------------------------|------------------------|--------------------|
| Relative humidity: | Max. 90% | Max. 80% |
| Temperature: | 0°C – 60°C | 10°C – 30°C |
| Atmospheric pressure: | 700 hPa – 1060 hPa | 800 hPa – 1060 hPa |

1.5 Warranty coverage

Purchasing the OFA-Drill entitles you to a **1-year** warranty. If you return the warranty card for registration within four weeks of the date of purchase, warranty coverage will be extended for a further **6 months**. Consumable parts are not covered by the warranty. Improper use or repair, or failure to observe these instructions, relieve us from any obligation arising from warranty provisions or other claims.

2 Explanation of symbols

| | | | |
|---|--|---|--|
|  | Important information |  | Autoclavable at 135°C |
|  | Do not use if the packaging is damaged |  | Suitable for thermal disinfection |
|  | Warning |  | Sterilized using ethylene oxide |
|  | Manufacturer |  | Observe the instructions for use |
| 1 min. on/ 3 min. off | The device is designed for intermittent duty operation at "1 min ON/3 min OFF". "1 min. on/3 min. off" at 4 cycles, after 15 min. brake. |  | Electrical and electronic devices that have reached the end of their service life comprise hazardous waste and may not be disposed of together with household waste. Valid local disposal regulations apply. |
|  | Type B applied part Applied parts is the instrument |  | Symbol indicating the serial number with the date of manufacture (year/month). |
|  | Do not reuse |  | Symbol indicating the order number. |
|  | Biohazard |  | Symbol indicating the lot number. |
|  | Motor |  | CE symbol with notified body |
|  | Pedal |  | Containing phthalate (DEHP) |
| IPX8 | Protection against continual submerging. |  | Certified by the Canadian Standards Association (CSA) |
|  | Date of manufacture |  | Date of expiry |
|  | European authorized representative | | |

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3 Safety information

Your safety, the safety of your team, and of course that of your patients is very important to us. It is therefore essential to bear the following information in mind.

3.1 EMC Manufacturer's Declaration of Conformity

Please observe the information on electromagnetic compatibility provided with these instructions.

3.2 Integrated peristaltic tube pump

The integrated peristaltic pump is used to cool tissue in order to prevent damage to the tissue. It may only be operated with watery solutions, such as 0.9% Sodium Chloride irrigation solution (Ref. 1707) or "Ringer" solution. Supplying medication using the integrated pump is expressly prohibited.

3.3 Modification and misuse



If modifications are made by the user/operator or a third party to the OFA-Drill and the accessory equipment provided, or if these items are used by these individuals for a purpose other than that for which the items were designed (according to chapter 1.1 Intended use and operation), the manufacturer assumes no responsibility and the guarantee is void.

3.4 Essential requirements



The OFA-Drill may only be operated by qualified and trained personnel.



Repairs may only be performed by authorized NOUVAG service technicians.



The use of third-party products is the responsibility of the operator. Functionality and patient safety cannot be guaranteed with third-party accessories.



Prior to using the device, before startup, and before operation, the user must always ensure that the device and accessories are in good working order and are clean, sterile and operational.



Improper use or repair of the device and failure to observe these instructions relieve us from any obligation arising from warranty provisions or other claims.



Use Nou-Clean spray for maintenance and care of the motor, handpieces and contra angles. Using other care products can result in malfunctions and/or cause the warranty to be revoked.

3.5 During use



The device is not sterile on delivery. All sterilizable parts must be sterilized before use (see Chapter 8 Cleaning, disinfection and sterilization).



At the choosing of the instrument the operator has to make sure it's biocompatible, according to EN ISO 10993.



Handpieces and Shaver blades may only be attached when the electronic motor is at a stand still.



Never operate the clamping mechanism of the handpieces or contra angles while the system is running. This could result in instrument damage.



To prevent injury, never touch drill bits or burrs while they are still running.



Do not use device in the vicinity of flammable mixtures!



The user must ensure that as little friction heat as possible is generated during a procedure on a patient. High speeds and high application pressure may cause thermal necrosis of tissue.

4 Scope of delivery

Ref. 3393, OFA-Drill motor system set with control unit, pedal, electronic motor, tubing set, cooling liquid, spray nozzles and operation instructions:

| Ref. | Description | Quantity |
|---------|--|----------|
| 3363 | OFA-Drill control unit ----- | 1 unit |
| 1866nou | Vario pedal; IPX8; electronic----- | 1 unit |
| 2099 | Electronic motor 21 incl. 3 m motor cable, up to 50,000 rpm ----- | 1 unit |
| 6024 | Tube set, sterile, 3 m, single-use ----- | 1 unit |
| 1873 | Clip set (10 pieces) for tube set attachment at motor cable ----- | 1 unit |
| 1707 | Irrigation fluid; 0.9% sodium chloride/water solution, 1 liter----- | 1 unit |
| 1770 | Stand for irrigation fluid ----- | 1 unit |
| 1170 | Handpiece cradle ----- | 1 unit |
| 1974 | Spray nozzle for Nou-Clean spray; for care and maintenance of electronic motor ----- | 1 unit |
| 1958 | Spray nozzle for Nou-Clean spray; for care and maintenance of instruments ----- | 1 unit |
| 31595 | User Manual OFA-Drill on CD-ROM----- | 1 unit |

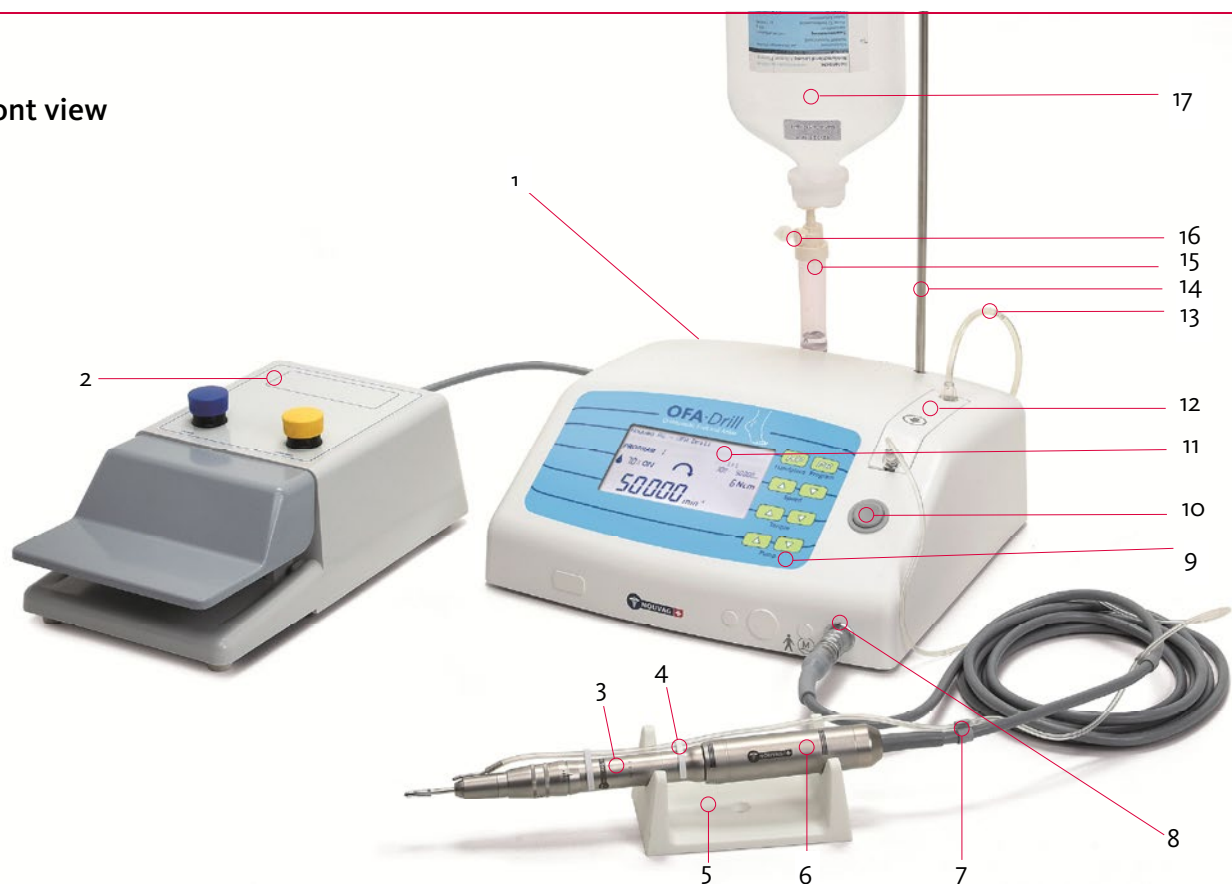


In line with regulations pertaining to hazardous materials, the following items are not delivered with the control unit and must be ordered separately:

| | | |
|------|--|--------|
| 1984 | Nou-Clean maintenance and care spray ----- | 1 unit |
|------|--|--------|

5 Device overview

Front view



- | | |
|--|---|
| 1. Pedal socket, device rear | 14. Stand for irrigation fluid bottle |
| 2. Vario pedal | 15. Drip chamber |
| 3. Handpiece (not included in delivery) | 16. Bleed valve |
| 4. Clip for tubing set attachment at handpieces | 17. Bottle with irrigation fluid |
| 5. Handpiece cradle | 18. Type plate with type designation, reference number, serial number, information on power supply and device fuse. |
| 6. Electronic motor (delivery includes 1 motor) | 19. Potential equalization |
| 7. Clip for tubing set attachment at motor cable | 20. Power plug socket |
| 8. Motor socket | 21. Main switch |
| 9. Operating panel | 22. Fuse compartment |
| 10. Release key for tubing set bracket | 23. Spray nozzle for maintenance of electronic motor |
| 11. Display | 24. Spray nozzle for handpiece maintenance |
| 12. Peristaltic pump | |
| 13. Tubing set | |

Rear view



6 Startup

6.1 Device setup

- Place the OFA-Drill and all required accessories and instruments on an even, non-slip surface and make sure you have good access to all controls.
- Do not allow the operating range of the device (including the cable and contra angle) to be compromised by limiting factors.
- The system display must be fully visible at all times.
- The pedal must be placed within stepping distance between the patient and the surgeon.
- It must be explicitly ensured that no objects can fall on the pedal.
- The power plug at the rear of the device must be accessible at all times.
- The motor ventilation slots must be kept clear in order to prevent the motor temperature from becoming excessive.

6.2 Connection to the power supply



Before plugging the power cable into the power socket for the first time, you must check the supply voltage setting next to the power switch.

If the voltage shown does not correspond to the local mains voltage, the grey fuse holder must be set to the correct voltage:



- Unplug the power cable.
- Use a screwdriver to open the fuse slot.
- Remove the fuse holder.
- Remove the grey fuse holder and reinsert it so that the local mains voltage setting is shown in the small window.
- Slide fuse holder back in and close the fuse slot.
- Check the mains voltage shown on the fuse slot.
- Plug the power cable back into the device.



In order to prevent the risk of electric shock, the device may only be connected to a power network with a PE protective ground conductor.

6.3 Device preparation

1. Sterilize the motor (the motor is not sterile on delivery). If the motor has already been sterilized: when removing the motor from the sterile packaging, ensure that the sterile packaging is not damaged and that the sterility indicator confirms sterility (if no sterility indicator is provided, the sterile packaging must at least show the date on which the shelf life of the sterile item is due to expire).
2. Insert the stand for the irrigation fluid into the stand holder.
3. Plug the motor plug of the electronic motor into the motor sockets.
4. Plug the pedal plug into the pedal socket at the rear of the control unit.
5. Attach the sterilized handpiece to the electronic motor. Press the handpiece firmly onto the electronic motor until it clicks into position and make sure it is secure by moving it slightly in the opposite direction.
6. Assemble the tubing set: For the cooling of the Handpiece fix the tube set Ref. 6024 in the tube compartment according to the following instructions.



Use only Nouvag tube sets Ref. 6024, otherwise the correct function cannot be guaranteed.



Check the expiry date of the tubing set and ensure that the packaging is not damaged. Using non-sterile tubing sets can result in serious infection and, in extreme cases, can be fatal.



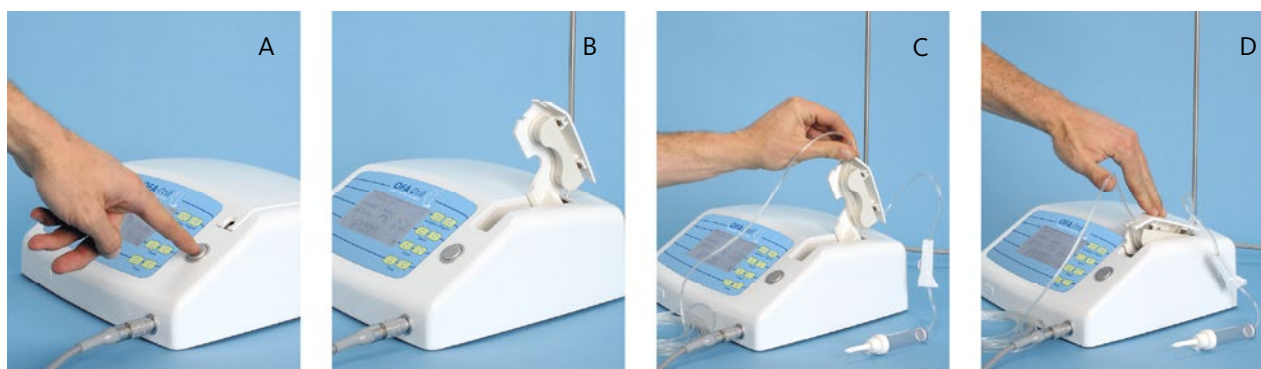
When inserting the tubing set, watch the arrow on the cover of the pump compartment. It indicates the flow direction of the cooling liquid.



The integrated peristaltic pump is used to cool tissue in order to prevent damage to the tissue. It may only be operated with watery solutions, such as 0.9 % Sodium Chloride irrigation solution (Ref. 1707) or "Ringer" solution. Supplying medication using the integrated pump is expressly prohibited.



Do not regulate the amount of irrigation fluid using the roller clamp on the tubing set; with the OFA-Drill, this is regulated instead using the integrated pump. For this reason, make sure to open the roller clamp as far as it will go (please refer to 7.4.5 Setting the pump supply quantity).



- A) Press release key for tubing set bracket (on top of the control unit) to open the pump.
- B) The compartment with the integrated tubing bracket opens.
- C) Place the tubing set into the tubing bracket provided in such a way that the part of the tubing set with the spike exits the pump towards the rear of the device. Make sure the tubing is secure.
- D) With the tubing set inserted, press the compartment downwards until it clicks into place.



7. Insert the spike at the end of the tubing set into the irrigation fluid bottle and hang the bottle onto the stand.
8. Open the roller clamp on the tubing set as far as it will go.
9. Open the bleed valve beneath the drip chamber.
10. Connect the control unit to the power socket.

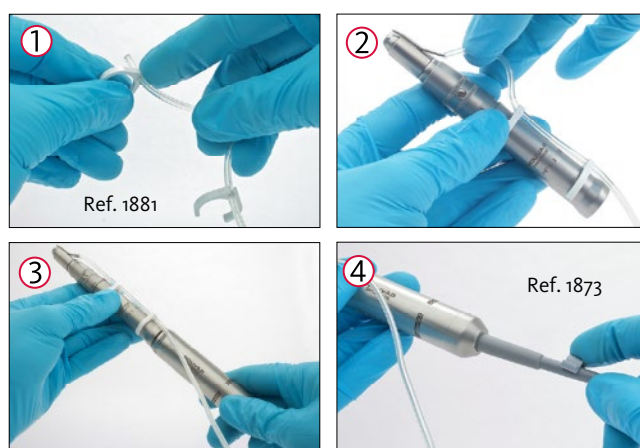


At the choosing of the instrument the operator has to make sure it's biocompatible, according to EN ISO 10993.



Ensure that the operating voltage setting corresponds to the local mains voltage.

6.4 Assembly of external irrigation system



1. Attach clip to irrigation tubing.
2. Connect tubing with cooling nozzle and attach clips to the handpiece.
3. Attach motor (not included in delivery) to the coupling flange.
4. Attach cable clip to the cable of the motor and suspend tubing.

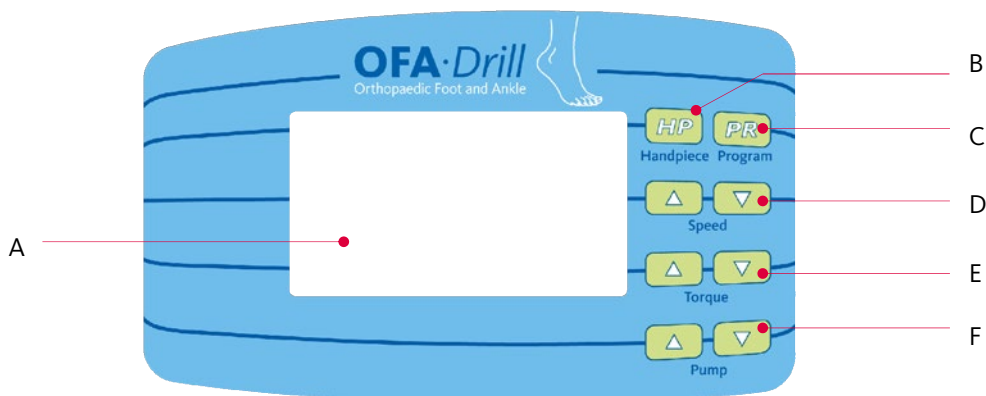
7 Operation

7.1 Switching the device on and off

The power switch “I/O” (at the rear) is used to switch the control unit on and off.
The device can be switched off at any time irrespective of any procedure for switching off the device.

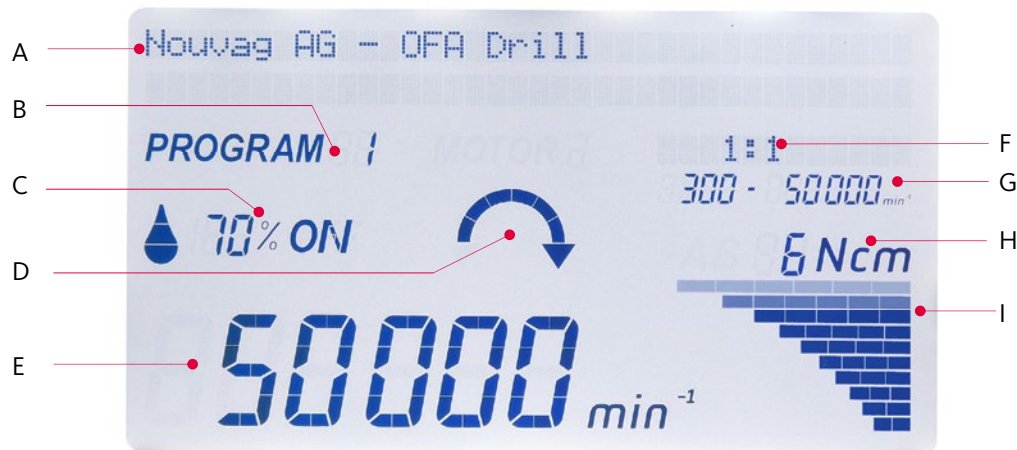
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7.2 Overview: Control elements on the operation panel



- A) **Display:** Shows the operating values (See chapter “7.3 Overview: Standard display”).
- B) **“Handpiece” key:** Selection of the required handpiece with the corresponding settings.
 - The factory default settings contain the handpieces 1 : 1, 4 : 1, K-Wire as well as micro saws.
- C) **“Program” key:** Saving individual settings.
 - 4 memory slots are available for individual settings.
 - By pressing both „HP + PR“ keys at the same time the programs can be reset to the factory default settings.
- D) **“Speed” keys:**
 - Restrict the maximum speed that can be selected using the pedal.
 “▲”: increases the maximum speed “▼”: reduces the maximum speed
 - By pressing both “Speed” keys at the same time “Speed ▲ + ▼” the handpiece testing procedure will be started. (refer to “7.4.2 Handpiece testing”).
- E) **“Torque” keys:**
 - Restricts the maximum torque.
 “▲”: increases the maximum torque “▼”: reduces the maximum torque
 - With the use of the micro saws and the K-Wire handpiece the torque is fix and cannot be altered.
- F) **“Pump” keys:**
 - Adjusting the maximal pump flow rate, recalled by the pedal.
 “▲”: increases the maximum supply quantity “▼”: reduces the maximum supply quantity
 - By pressing both “Pump” keys at the same time “Pump ▲ + ▼” the pump will be put on call, pressing again will switch it off.

7.3 Overview: Standard display



- A) **Information Line**
Information and error messages are displayed here. Display is illuminated red when error messages are displayed.
- B) **Program**
Shows the selected program number.
- C) **Pump**
The numerical value shows the pump flow rate in percent and the drop symbol together with the on/off indication shows if the pump is in stand-by mode or switched off.
- D) **Rotational direction of the motor**
The arrow indicates the rotational direction set for the motor. The rotation direction can be changed by pressing the button **"FOR/REV"** on the pedal. When using a micro saw no rotation direction is indicated.
- E) **Current speed**
At stand still of the motor the set maximum speed is displayed. As the motor starts running by pressing the pedal, the evolving speed is shown in real-time.
- F) **Name of the handpiece or corresponding transmission ratio**
Shows name of the handpiece used or the selected transmission ratio. (See also 7.4.1, "Selecting handpiece or transmission ratio")
- G) **Speed range**
Shows speed range of the handpiece used when motor is standing still. With running motor the speed range display is blinded out.
- H) **Maximum torque**
Shows maximum torque setting of the used handpiece.
- I) **Current torque**
Bar graph providing a graphical representation of the current torque. All bars active means max. torque reached.



The pump does not begin to operate until the motor has been activated by pressing the pedal.

7.4 Adjusting the programs

Values for operation settings depend on the connected handpiece as well as the task to be performed.

7.4.1 Step 1: Selecting handpiece or transmission ratio



Depending on the handpiece attached to the motor, the corresponding handpiece (transmission ratio) has to be selected by using the “HP” key. Make sure the display shows the correct handpiece.



Press «HP» key to select the handpiece.

Parameter of handpieces

| Name of handpiece/ transmission ratio | Handpiece name on Display | Speed min. rpm | Speed max. rpm | Torque min. Ncm | Torque max. Ncm |
|--|------------------------------|-------------------|-------------------|--------------------|--------------------|
| Handpiece, 1 : 1 | 1 : 1 | 300 | 50,000 | 1 | 6 |
| Handpiece 4 : 1 | 4 : 1 | 200 | 12,000 | 1 | 18 |
| Micro oscillating saw Micro sagittal saw Micro compass saw | Micro saw | fix 15,000 | | fix 6 | |
| K-Wire handpiece | Kirschner Hp | 500 | 2,800 | fix 48 | |

7.4.2 Step 2: Testing the handpieces

To make sure the displayed parameters correspond with the actual, measurable parameters of the handpiece, it is recommended to test each handpiece on a regular basis.

It's a procedure as simple as it is important to guarantee safety and precision for each handpiece being used.

After taking care of all prior preparations such as sterilization, maintenance and care of handpieces, device preparation and the selection of the handpiece of use, the calibration procedure can be performed.



The testing of handpieces guarantees for accurate torque. Due to wear as well as varying lubrication of the handpieces and lack of maintenance and care, the distribution of torque can widely vary.

1. Press the "Handpiece" -key to select the correct handpiece, corresponding to the one mounted on the motor, and double check on the display for correct selection.
2. Hold motor with mounted handpiece in your hand, in safe distance to your body.
3. Press both "Speed" keys at the same time (Speed ▲ + ▼). "Testing the handpiece XX" is displayed.



4. Motor and handpiece start running and pass several speed cycles up to maximum speed.
5. After a tone is emitted the test is finished. The display shows "Handpiece XX is OK".



If the Handpiece is not working according to the values of the look up chart, the device produces an error message and the display is illuminated red and shows the message "Handpice XX is faulty".

This indicates soiling, wearout or a technical defect. These Handpieces must be cleaned, repaired or exchanged.

7.4.3 Step 3: Setting the speed

The possible speed range depends on the attached handpiece. The maximum speed within this speed range can be restricted to the required value.

Using the pedal, the speed can be varied from the minimum speed up to the maximum speed as set.

The micro saws work with a fixed speed of 15,000 rpm and cannot be altered.

Setting the speed:

Press the "Speed" keys "▲" to increase or "▼" to decrease the maximum speed. When key is pressed continuously the speeds will be shown in fast forward mode.



7.4.4 Step 4: Setting the torque

Once the speed has been selected, the torque can be determined from the corresponding torque range.

Press the “Torque/Frequency” keys “▲” to increase or “▼” to decrease the maximum torque. By pressing the key continuously the torques are shown in fast forward mode.



The build up of torque is displayed as a bar graph. When maximum torque is reached all elements of the bar graph are full displayed.



The following handpieces run on a fixed torque.

- K-Wire (Kirschner)
- all micro saws

7.4.5 Step 5: Setting the pump supply quantity

Press the “Pump” keys “▲” to increase or “▼” to decrease the pump supply quantity. By pressing the key continuously the values are fast forwarded.



To activate or deactivate the pump, press both “Pump” keys at the same time, “Pump ▲ + ▼”, or press “PUMP” on the pedal.

7.4.6 Step 6: Saving individual settings

By pressing the “Program”-key, 4 different settings can be saved for further use.

1. Select the desired memory slot by pressing the „Program“-key (e.g. Program 1).
2. Perform **step 1 to step 5** for setting up the device.
3. Repeat this procedure until all the memory slots are programmed.
4. At switch-off, the settings made by the user are automatically saved.



For the micro saws only the amount of coolant liquid can be altered.



By pressing both „HP + PR“-keys at the same time the memory slots can be reset to the factory default settings.

7.5 Torque limiter

This device comes with a built in torque limiter that works just like a torque wrench.

If the attached instrument detects increasing drag the torque is raised and the speed is reducing, if necessary up to a stand still. The torque at the instrument persists. If the load on the instrument decreases the speed picks up again up to its maximal output setting.

The procedure can be followed at, watching the bar graph in the lower right of the display. The segments of the bar graph are filling up the more drag is building up on the instrument. When maximum torque is reached, means all segments of the bar graph are visible, the speed is declining. As soon as the load on the instrument is reduced, the torque decreases and the motor speeds up again.

7.6 Switching device off

At switch-off, the settings made by the user are automatically saved. This includes the following parameters:

- Handpiece
- Max. speed
- Max. torque
- Pump On/Off
- Pump performance
- Rotational direction of the motor

To change a program go to the specific parameter and change it. When the device is switched off, all parameters are saved in that program.

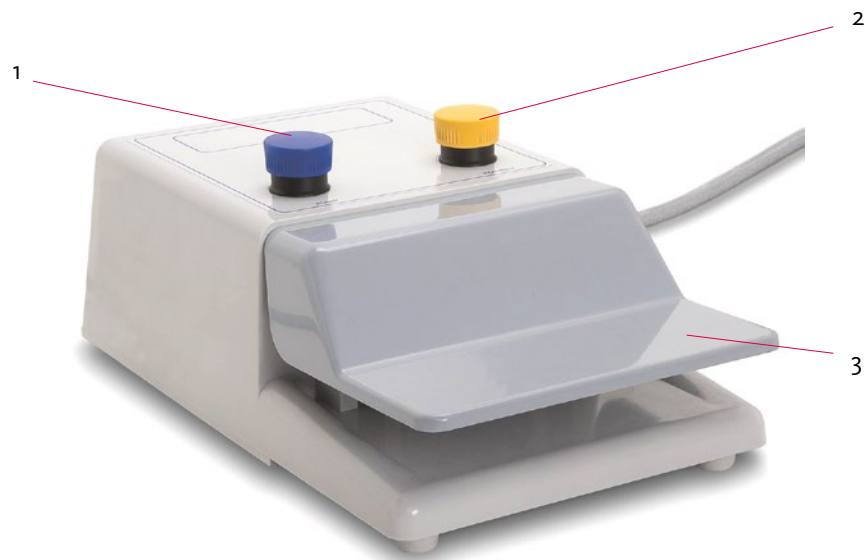


When the OFA-Drill device is switched on, the display shows always the last used settings.



By pressing both „HP + PR“-keys at the same time the memory slots can be reset to the factory default settings.

7.7 Operation using the Vario pedal



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1. **“PUMP” key:**
Pressing the key briefly: switches the pump on or off (check display).
Pressing the key longer: increases the pump speed (check display).
2. **“FOR/REV” key:**
Changing the rotational direction of the motor (check arrow on the display).
3. **Treadplate**
With the treadplate pedal the motor speed is variably adjusted and the pump is activated.

| Treadplate... | Motor: | Pump: |
|------------------------------|---|---|
| ... not pressed | Motor off | Pump off |
| ... pressed gently | Motor runs slowly | Pump on, if pump “On” displayed (speed as set on the control unit) |
| ... pressed all the way down | Motor runs at maximum speed (speed as set on the control unit) | Pump on, if pump “On” displayed (speed as set on the control unit) |



For safety reasons, the unit can only be operated by pedal.

7.8 Functional check

Prior to every startup of the OFA-Drill, or the use of accessory equipment, the user must always ensure that each individual component is in good working order, free from defects, and is clean, sterile and operational. All inscriptions on the device and its accessories must be readable and there must be no loose parts in the device. Once the device is switched on, the most recent settings entered appear on the display.

7.8.1 Electronic motor

The functional check of the electronic motor is carried out without a handpiece being attached. Nevertheless the 1:1 Handpiece must be selected to test the max. speed of the motor. Use the “**Speed**” selection keys to set the speed of the electronic motor to **50,000 rpm**. Press the pedal treadplate; the electronic motor starts and accelerates to up to 50,000 rpm. When the treadplate is released, the electronic motor slows down again and comes to a stop.



- The electronic motor is designed for intermittent duty operation at maximum speed of “**1 min ON/3 min OFF**” at 4 cycles. After 15 min brake.
- Disregarding these directives (1 min ON/3 min OFF/4 cycles/ 15 min brake) can cause serious burns when touching the handpiece or the hull of the motor
- The motor ventilation slots must be kept clear in order to prevent the motor temperature from becoming excessive.

7.8.2 Pump

Press the “**PUMP**” key on the pedal briefly; the peristaltic pump is switched on, which is shown on the display by the symbol of a drop. Press the pedal treadplate; the peristaltic pump and the electronic motor start up. Water sprays from the irrigation needle on the handpiece.

7.8.3 Rotational direction of the electronic motor

Press the “**FOR/REV**” key on the pedal briefly; the rotational direction of the electronic motor changes. Press the pedal treadplate; the electronic motor rotates to the left and a continuous tone is emitted. Release the treadplate; the electronic motor ceases to operate and the tone is no longer emitted. By pressing the key again, the rotational direction is switched back to right rotation, which is shown on the display by the symbol of a changing arrow.

8 Cleaning, disinfection and sterilization

The herein described reprocessing instructions are intended for the parts delivered within the set of the OFA-Drill. Extension or accessory parts come with their own reprocessing instructions.

The following points in particular are important with regard to caring for the material:

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- Perform cleaning, disinfection and sterilization after every treatment.
- Always autoclave the material in sterilization packaging.
- Make sure that sterilization packaging is no more than 80 % filled.



- Always autoclave the material at 135°C for at least 5 minutes.
- If sterilized material is not used immediately, the material packaging must be labeled with the sterilization date.
- Nouvag AG recommends including a sterility indicator.

8.1 Control unit and pedal


The control unit and pedal do not come into contact with the patient.

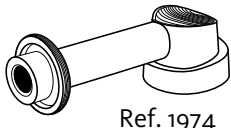
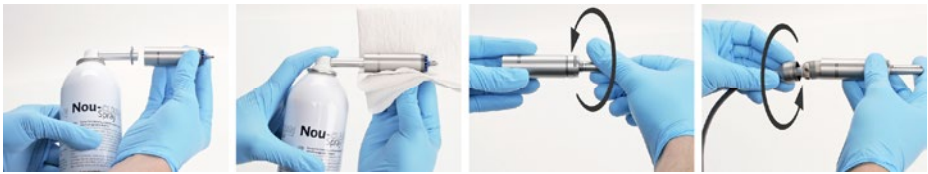

Wipe the outside using micro-biologically tested surface disinfectant or a 70 % isopropyl alcohol solution.

The front plate of the control unit is sealed for this purpose and can be wiped clean.

8.2 Electronic motor 21

| | |
|---------------------------|---|
| Reprocessing restrictions | Frequent reprocessing has only a limited impact on the electronic motor. The end of the product service life is normally determined by wear and damage through use. The electronic motor 21 is designed for 250 sterilization cycles. |
|---------------------------|---|

| INSTRUCTIONS | |
|-------------------------------------|--|
| At the location of use | Remove surface soiling with a disposable cloth/paper towel. |
| Storage and transport | No special requirements. Due to the risk of drying and corrosion, reprocessing must be performed without undue delay. |
| Preparation for cleaning | <p>Remove soiling from the electronic motor with a disposable cloth/paper towel. Unscrew the motor cap, remove the cable and unscrew the handpiece carrier.</p>  |
| Automatic cleaning and disinfection | <p>Equipment: Washer-disinfector with a special load carrier that ensures motors are connected to the washer-disinfector and channels are rinsed. Rinse the motor from the front. Use a neutral or alkaline cleaning agent for this purpose.</p> <p>Place the electronic motor in the load carrier (ensure that the channels can be rinsed). Place the motor cap and cable, and handpiece holder, in the basket.</p> <p>Set a cleaning cycle that offers sufficient cleaning and rinsing. Perform the final rinse with fully deionized water.</p> <p>Perform a 10-minute rinse cycle at 93°C to facilitate thermal disinfection.</p> <p>When removing the electronic motor, check the motor cap and cable, and handpiece holder, to verify whether soiling is still visible in the gaps and the grooves. If necessary, repeat the cycle or clean manually.</p> |
| Manual cleaning | <p>Equipment: Neutral or alkaline cleaning agent, soft brush, running demineralized water (< 38°C)</p> <p>Procedure:</p> <p>Rinse off and brush away surface soiling on the electronic motor, motor cap and cable, and handpiece holder.</p> <p>Use a brush to apply cleaning agent to all surfaces and gaps.</p> <p>Rinse the electronic motor, motor cap and cable, and handpiece holder thoroughly under running water.</p> |
| Manual disinfection | For manual disinfection, wipe the electronic motor, the motor cap and the plug and cable underneath it, and the handpiece holder, with a certified non-chlorine disinfectant. |
| Drying | If a drying program is not provided by the washer-disinfector, the electronic motor must be dried manually or in a drying cabinet. The handpiece holder must then be screwed back onto the motor. |

| | |
|---|---|
| Inspection and maintenance  Ref. 1974 | <p>Perform a visual inspection to check for damage, corrosion and wear. Connect Motor with the spray nozzle (Ref. 1974) by screwing it on and spray motor for about 3 seconds and briefly wipe with a moist cloth (see instructions on spray can). Once thorough spraying has been completed, screw the cable and motor cap back onto the electronic motor.</p>  |
| Packaging | <p>Individual: Pack the electronic motor in individual packaging for sterile items. The bag must be large enough to ensure that the seal is not subject to strain. Nouvag AG recommends including a sterility indicator.</p> <p>Sets: Sort electronic motors on trays intended for this purpose or place them on all-purpose sterilization trays.</p> |
| Sterilization  | <p>Autoclave in the vacuum autoclave (Class B or S as per EN 13060 with fractionated pre-vacuum) at 135°C for at least 5 minutes*. When sterilizing several instruments during one sterilization cycle, do not exceed the maximum sterilizer load. A drying cycle must be added in the case of autoclaves without a post-vacuum function. Allow the electronic motor to dry in the bag for at least 1 hour at room temperature with the paper side facing upwards.</p> <p>* Temperature exposure times are based on country-specific guidelines and standards. Maximum exposure time: 25 minutes.</p> |
| Storage | <p>If the sterilized electronic motor is not used immediately after sterilization, the material packaging must be labeled with the sterilization date. Including a sterility indicator is recommended.</p> |

The effectiveness of the sterilization instructions provided above for electronic motor 21 and the handpiece has been validated by Nouvag AG. The user is responsible for ensuring that the sterilization procedure performed achieves the required result. This requires validation and routine monitoring of the procedure. The staff member who completes the procedure bears sole responsibility for any deviation on his part from the instructions provided. Deviations necessitate revalidation of the effectiveness of the procedure as well as of the technical resilience of the motor with regard to the modified sterilization process.

8.3 Tubing set, Ref. 6024



- Single-use tubing sets 6024 may not be reused.
- Tubing sets must be disposed of properly after use!
- Do not use tubing sets when packaging is already open or damaged!
- Do not use tubing sets when expiry date has passed.
- Use only Nouvag tubing sets with Ref. 6024!



Sterility cannot be guaranteed by reusing and re-sterilization of tubing sets. The characteristics of the material change in a manner that can result in failure of the system. This may result in serious infections or even patient death worst-case.

8.4 Handpiece cradle

Soiled handpiece cradles are cleaned using a neutral cleaning agent and then sterilized in accordance with the same instructions as for electronic motor 21.

9 Maintenance

9.1 Replacing the control unit fuse

Users can replace faulty control unit fuses themselves. These are located at the rear of the device in the fuse slot beside the power switch:

- Unplug the power plug.
- Open the fuse slot using a screw driver.
- Replace the faulty fuse T 3.15 AL 250 V AC.
- Slide the fuse holder back in and close the fuse slot.
- Check the mains voltage shown on the fuse slot.
- Plug in the power plug again.



1. Fuse slot locking mechanism
2. Display window for voltage setting
3. Fuse slot
4. Fuse 1
5. Fuse 2

9.2 Safety inspections

The performance of safety inspections on medical devices is required by law in several countries. The safety inspection is a regular safety check that is compulsory for those operating medical devices. The objective of this measure is to ensure that device defects and risks to patients, users or third parties are identified in time.

An inspection interval of **2 years** applies to the OFA-Drill.

NOUVAG AG offers a safety inspection service for its customers. Addresses can be found in the appendix of this operation manual under “Service centers”. For further information please contact our technical service department.

Further international service centers are listed on the Nouvag website:

www.nouvag.com > Service > Service centers

10 Malfunctions and troubleshooting

| Malfunction | Cause | Solution | Refer to operating instructions |
|---|---|---|---|
| Device is not operational | Control unit is not switched on | Set the power switch "I/O" to "I" | 7.1 Switching the device on and off |
| | Power connection not established | Connect the control unit to the mains power supply | 6.2 Connection to the power supply |
| | Incorrect operating voltage | Check the mains voltage | 6.2 Connection to the power supply |
| | Faulty fuse | Replace the fuse | 9.1 Replacing the control unit fuse |
| Motor does not run | Motor not switched on | Switch on the motor using the treadplate | 7.7 Operation using the Vario pedal |
| | Motor not connected | Connect the motor cable to the control unit | 5.0 Device overview 6.2 Connection to the power supply |
| | Handpiece or contra angle not correctly assembled | Press the handpiece firmly onto the electronic motor until it clicks into position and check that it is secure by moving it slightly in the opposite direction. | 6.3 Device preparation |
| No irrigation fluid for instrument | Peristaltic pump not switched on | Switch on the peristaltic pump | 7.7 Operation using the Vario pedal 7.4.5 Setting the pump supply quantity |
| | Tubing set incorrectly inserted | Insert tubing set correctly (note the direction) | 6.3 Device preparation |
| | Tubing set clogged/crusted matter visible | Replace the tubing set | 6.3 Device preparation |
| | Bottle with sodium chloride solution not ventilated | Open the ventilation filter at the drip chamber | 6.3 Device preparation |
| | Tubing set is dripping | Replace the tubing set | 6.3 Device preparation |
| | Roller clamp of tubing set is closed | Open roller clamp all the way | 6.3 Device preparation |
| Pedal is not operational | Pedal not connected | Connect the pedal to the control unit | 6.3 Device preparation |
| | Incorrect operation | Check operating instructions | 7.7 Operation using the Vario pedal |

If a fault cannot be rectified, please contact your supplier or an authorized service centre. The addresses are provided on the last page of the operating instructions.

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| OFA-Drill, error-messages on display | | |
|--------------------------------------|--|--|
| Error-messages/error code | Cause | Solution |
| Basic Initialisation/ W00 | First Initialisation | |
| Set default value/ W01 | Parameter reset to default value | |
| Memory error/ E02 | System Error | Send Control Unit to Service Center. |
| Handling error/ E03 | System Error | Send Control Unit to Service Center. |
| Program SW error/ E04 | System Error | Send Control Unit to Service Center. |
| UserConfig SW error/ E05 | System Error | Send Control Unit to Service Center. |
| Display error/ E06 | System Error | Send Control Unit to Service Center. |
| Pump error/ E07 | System Error | Send Control Unit to Service Center. |
| Storing factory settings/ Program | Message while default values of programs are stored. | |
| Pedal not connected/ E10 | a) Pedal is not plugged in. b) Plug or cable is defective. | a) Plug in Pedal b) Send Control Unit and pedal to Service Center. |
| Pedal test mode/ W11 | Pedal test mode switched on | Switch off device for 5 seconds, than switch on again. |
| Keyboard test mode/ W12 | Keyboard test mode switched on | Switch off device for 5 seconds, than switch on again. |
| No motor connected/ E13 | a) No motor connected b) Motor, motor cable, motor plug or Control Unit are is defective | a) Plug in motor b) Send motor and Control Unit to Service Center. |
| Unknown motor 2/ E16 | a) Motor 2 is selected but wrong motor is plugged in. b) Right motor is connected to motor socket 2, but motor, motor cable, motor plug or Control Unit is defective. | a) Plug in correct motor b) Send motor and Control Unit to Service Center. |
| Pump is open/ E20 | Motor is not working when pump compartment is open to prevent of injuries. | Close pump compartment. |
| Motor or pump test mode/ W21 | Motor or pump test mode is switched on. | Switch off device for 5 seconds, than switch on again. |
| Pedal locked/ W26, pedal let go | If pedal is pressed at switch on procedure, pedal will not work. | Release pedal for one second. |
| Handpiece XX is faulty/ E29 | At calibrating or testing handpiece was overexposed to high torque. | - Clean handpiece and spray it thoroughly with Nou-Clean spray. - If message is still displayed after test procedure, handpiece has to be sent to Service Center. |
| Handpiece XX is Ok! | Tested handpiece is OK. | |
| Testing the handpiece XX | Handpiece is testing. | |
| NOU-Dongle is plugged in | Message is displayed for 1 second after NOU-dongle was plugged in. | |

The red background coloured error messages on this list above are also on display illuminated red. The other messages have informal character and don't require an action from the user.

11 Spare parts list with order numbers

| Accessories | Ref. |
|---|------|
| Clip set large CL, for attachment to the handpiece, package with 3 units----- | 1881 |
| Clip set motor cable, for attachment to the motor cable, package with 10 units----- | 1873 |
| Single-use tubing set, 3 m, sterile, 10-unit pack----- | 6024 |
| Irrigation fluid, 0.9 % sodium chloride, 1 liter----- | 1707 |
| Nou-Clean clean and care spray----- | 1984 |
| Spray nozzle attachment for surgical instrument e-coupling----- | 1958 |
| Spray nozzle attachment for electronic motor 21----- | 1974 |

To order additional parts, please contact our customer service department.

Operation manual OFA-Drill ----- 31595

No instructions for use in paper form are enclosed with this product. Instructions for use in PDF format are enclosed on CD-ROM and require a CD-ROM drive and Adobe Acrobat Reader software to enable the instructions for use to be displayed or printed out. If you prefer the instructions for use in paper form, it must be requested via the address or website stated on the type plate.

12 Information on disposal

When disposing of the device, device parts and accessories, the regulations prescribed by law must be observed.

Do not dispose of devices with household waste!

To ensure environmental protection, old devices can be returned to the dealer or manufacturer.



Motors that have reached the end of their service life may not be disposed of with household waste. Motors must be sterilized before disposal. Please observe currently valid national disposal regulations for infectious waste.



Contaminated single-use tubing sets are subject to specific disposal requirements. Please observe currently valid national disposal regulations for infectious waste.

| | |
|--------|----|
| Anhang | DE |
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| Appendix | EN |
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| Appendice | FR |
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| Appendice | IT |
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| Apéndice | ES |
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| Appendix | NL |
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| Aneks | PL |
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| Apendix | SK |
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| Appendix | CZ |
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| Függelék | HU |
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Electromagnetic compatibility (EMC)

Remark:

The **Product** subsequently referred to herein always denotes the HighSurg OFA-Drill.

Changes or modifications to this product not expressly approved by the manufacturer may result in increased emissions or decreased immunity performance of the product and could cause EMC issues with this or other equipment. This product is designed and tested to comply with applicable regulations regarding EMC and shall be installed and put into service according to the EMC information stated as follows.

WARNING

Use of portable phones or other radio frequency (RF) emitting equipment near the product may cause unexpected or adverse operation.

WARNING

The product shall not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the product shall be tested to verify normal operation in the configuration in which it is being used.

Compliant Cables and Accessories

WARNING

The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity performance of the product.

The table below lists cables, transducers, and other applicable accessories for which the manufacturer claims EMC compliance.

NOTE: Any supplied accessories that do not affect EMC compliance are not listed.


| Description | Length max. |
|----------------------|-------------|
| Electronicmotor 21 | 2.9m |
| Vario Footpedal IPX8 | 2.9m |

| Guidance and manufacturer's declaration – electromagnetic emissions | | |
|---|------------|--|
| The Product is intended for use in the electromagnetic environment specified below. The customer or the user of the Product should assure that it is used in such an environment. | | |
| Emissions test | Compliance | Electromagnetic environment - guidance |
| RF emissions CISPR 11 | Group 1 | The Product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class B | The Product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/flicker emissions IEC 61000-3-3 | Complies | |

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|--|--|---|
| The Product is intended for use in the electromagnetic environment specified below. The customer or the user of the Product should assure that it is used in such an environment. | | | |
| Immunity tests | IEC 60601 Test level | Compliance level | Electromagnetic environment - guidance |
| Electrostatic discharge (ESD) | +/- 6 kV contact | +/- 6 kV contact | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| IEC 61000-4-2 | +/- 8 kV air | +/- 8 kV air | |
| Electrical fast transient/burst | +/- 2 kV for power supply lines | +/- 2 kV for power supply lines | Mains power quality should be that of a typical commercial or hospital environment. |
| IEC 61000-4-4 | +/- 1 kV for input/output lines | +/- 1 kV for input/output lines | |
| Surge | +/- 1 kV differential mode | +/- 1 kV differential mode | Mains power quality should be that of a typical commercial or hospital environment. |
| IEC 61000-4-5 | +/- 2 kV common mode | +/- 2 kV common mode | |
| Voltage dips, short interruptions and voltage variations on power supply input lines | < 5 % U _T (> 95 % dip in U _T) for 0,5 cycle | < 5 % U _T (> 95 % dip in U _T) for 0,5 cycle | Mains power quality should bet hat of a typical commercial or hospital environment. If the user of the Product requires continued operation during power mains interruptions, it is recommended that the Product be powered from an uninterruptible power supply or a battery. |
| IEC 61000-4-11 | 40 % U _T (60 % dip in U _T) for 5 cycles | 40 % U _T (60 % dip in U _T) for 5 cycles | |
| | 70 % U _T (30 % dip in U _T) for 25 cycles | 70 % U _T (30 % dip in U _T) for 25 cycles | |
| | < 5 % U _T (> 95 % dip in U _T) for 5 sec | < 5 % U _T (> 95 % dip in U _T) for 5 sec | |
| Power frequency (50/60Hz) magnetic field | 3 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| IEC 61000-4-8 | | | |
| Note: U _T is the a.c. mains voltage prior to application of the test level. | | | |

Guidance and manufacturer's declaration – electromagnetic immunity for not life support equipment

The Product is intended for use in the electromagnetic environment specified below. The customer or the user of the Product should assure that it is used in such an environment.

| Immunity tests | IEC 60601 Test level | Compliance level | Electromagnetic environment - guidance |
|-------------------------------|---|--|--|
| | | | Portable and mobile RF communications equipment should be used no closer to any part of the Product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: |
| Conducted RF IEC 61000-4-6 | 3 V rms 150 kHz to 80 MHz outside ISM bands | 10 V rms 150 kHz to 80 MHz outside ISM bands | $d = 1,2 \sqrt{P}$ |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 V/m 80 MHz to 2.5 GHz | $d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800 MHz to 2,5 GHz |
| | | | where P is the maximum output power rating in the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment marked with the following symbol:  |

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Fixed strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the Product is used exceeds the applicable RF compliance level above, the Product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Product.

b over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the not life support equipment

The Product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Product as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output power of transmitter W | Separation distance according to frequency of transmitter m | | |
|--|--|--------------------|--------------------|
| | 150 kHz to 80 MHz | 80 MHz to 800 MHz | 800 MHz to 2.5 GHz |
| | $d = 1,2 \sqrt{P}$ | $d = 1,2 \sqrt{P}$ | $d = 2,3 \sqrt{P}$ |
| 0,01 | 0,12 | 0,12 | 0,23 |
| 0,1 | 0,38 | 0,38 | 0,73 |
| 1 | 1,2 | 1,2 | 2,3 |
| 10 | 3,8 | 3,8 | 7,3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the higher frequency range applies.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Service center

Switzerland

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

**CE**0197

Germany

Nouvag GmbH • Schulthaisstrasse 15 • DE-78462 Konstanz
Phone +49 7531 1290-0
info-de@nouvag.com • www.nouvag.com



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

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

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

Nouvag GmbH • Schulthaisstrasse 15 • DE-78462 Konstanz
Tel. +49 7531 1290-0
info-de@nouvag.com • www.nouvag.com

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