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1 Product description

1.1 Intended use and operation

The MD 11 in combination with a motor and corresponding handpiece or contra angle (separate medical device) is used primarily in dental Implantology. The device is designed for drilling, milling and sawing bone as well as for screw insertion into bone. An integrated peristaltic pump is provided in order to cool the rotating instruments so that damage to tissue can be prevented.

The MD 11 may only be operated by qualified and trained personnel.

It is used specifically in Implantology for:

- Milling and drilling the implant bed
- Cutting the thread for the implant
- Screwing in the implant
- Removing the fixture mount
- Placing the cover screw

1.2 Contraindications

Relative or absolute contraindications 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 systems.

Relevant cases in the literature must be taken into consideration.

1.3 Technical data MD 11

Voltage: ----- variable: 100 V~/ 115 V~/ 230 V~, 50/60 Hz

Fuse, power supply: ----- 2 fuses T 3.15 AL 250 VAC

Power consumption: ----- 120 VA

Applied part: ----- Type BF*

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 - 40,000 rpm

Max. Motor torque: ----- 6 Ncm

Motor weight: ----- 0.280 kg

Motor cable length ----- 2 m

Pedal:

IP code (pedal) ----- IPX8

Peristaltic pump:

Max. volumetric displacement of pump ----- 100 ml/min.

**Applied part of Type BF is the instrument used with the MD 11.*



























1.4 Ambient conditions

| | Transport and storage: | Operation: |
|------------------------------|------------------------|-----------------------|
| Relative humidity: | 10 % – 90 % | Max. 80 % |
| Temperature: | 0 – 50°C (32 – 122°F) | 10 – 30°C (50 – 86°F) |
| Atmospheric pressure: | 700 – 1060 hPa | 800 – 1060 hPa |

1.5 Warranty coverage

Purchasing the MD 11 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 |  | Suitable for thermal disinfection |
|  | Do not use if the packaging is damaged |  | Autoclavable at 134°C |
|  | 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" 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 BF 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 |  | Date of expiry |
|  | Pedal |  | Protective ground |
| IPX8 | Protection against contact and continual submerging. |  | Certified by the TÜV Rheinland North America Group |
|  | Date of manufacturing |  | Indication of the pump flow direction |
|  | Dangerous goods Aerosol spray: Environmentally hazardous NouvaClean/NouvaOil |  | Dangerous goods Aerosol spray: Extremely flammable NouvaClean/NouvaOil |
|  | Dangerous goods Aerosol spray: Warning NouvaClean/NouvaOil |  | European authorized representative |

EN

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:

Every use of the MD 11 different to the product description defined in chapter “Intended use and operation”, causes risks for patients and trained personnel. If physical examinations and therapies are carried out without use of the devices then the devices must be removed from the place of treatment. Avoid any connection or close adjacency to other devices.

3.1 EMC Manufacturer's Declaration of Conformity

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 MD 11 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 reorientation of the product.

Use only accessories and cables as specified in the product description. Further observe the EMC manufacturer declaration of conformity.

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 or “Ringer” solution. Supplying medication using the integrated pump is expressly prohibited.

3.3 Modification and misuse



- Modification or manipulation of the MD 11 and its accessories is prohibited. The manufacturer is not liable for any damages resulting from unauthorized modifications or manipulations. The warranty will be canceled.
- Use of the MD 11 outside the indications described in Section 1.1 is prohibited. The user or operator is solely responsible for any such use.

3.4 Essential requirements



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



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 NouvaClean spray (REF 2127) for the cleaning of handpieces and contra angles. Using other cleaning products can result in malfunctions, the warranty to be revoked.



Only use the NouvaOil spray (REF 2128) to lubricate electronic motors, handpieces and contra-angles. The use of other care products can lead to malfunctions. The guarantee expires!



Repairs may only be performed by authorized NOUVAG service technicians.



The MD 11 may only be operated by qualified and trained personnel.



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

3.5 During use



The device is not sterile on delivery. All sterilizable parts must be sterilized before use (see Chapter 8.0 Cleaning, disinfection and sterilization).



Never operate the clamping mechanism of the handpieces or contra angles while they are running or coasting! Instruments can be damaged.



Handpieces and contra angles may only be attached to the electronic motor when it is in a stand still.



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



When selecting the instrument, the user must ensure that it is biocompatible in accordance with EN ISO 10993.






Do not use the device, pedal and motor in the vicinity of flammable mixtures!



When used on patients, utmost care must be taken that as little frictional heat as possible occurs. Excessive thermal influence causes necrosis of the tissue. The heat development is directly related to the speed and the contact pressure of the instrument.

4 Scope of delivery

| REF | Description | Quantity |
|---|---|----------|
| 3335 | MD 11 control unit ----- | 1 |
| 1866nou | VARIO pedal; IPX8; electronic ----- | 1 |
|  2097nou | Electronic motor 21 incl. 2 m motor cable, max. speed 40'000 rpm ----- | 1 |
|  1706 | Tubing set, sterile, 2 m, single-use ----- | 1 |
| 1873 | Clip set (10 pieces) for the tube set attachment to the motor cable----- | 1 |
| 1881 | Clip set (3 pieces) for the tube set attachment at handpieces and contra angles ----- | 1 |
| 1770 | Stand for irrigation fluid----- | 1 |
| 1170 | Handpiece cradle ----- | 1 |
| 19584 | Spray adapter for NouvaOil-Spray for the care of electronic motors, handpieces and contra-angles ----- | 1 |
| 31665 | Information for use, MD 11 on CD-ROM----- | 1 |
|  | In line with regulations pertaining to hazardous materials, the following items are not delivered with the control unit and must be ordered separately: | |
| 2127 | NouvaClean spray for the cleaning of handpieces and contra angles----- | 6 |
| 2128 | NouvaOil spray for the lubrication of handpieces, contra angles and electronic motors ----- | 6 |

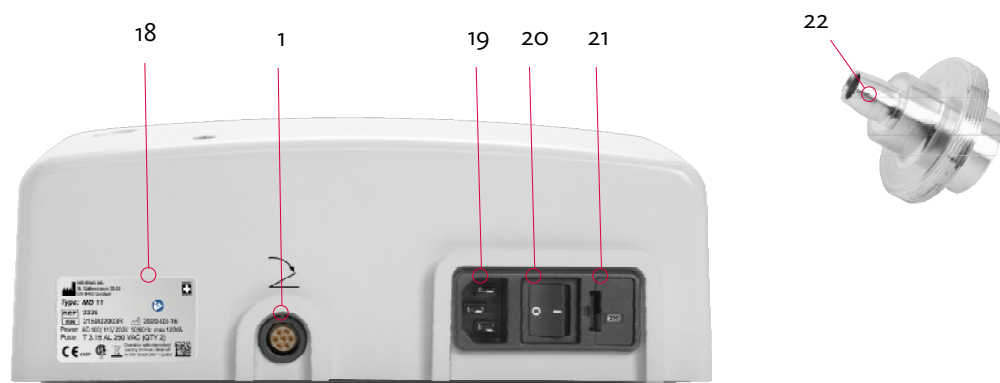
5 Device overview

Front view



- | | |
|---|---|
| 1. Pedal socket, device rear | 13. Tubing set |
| 2. VARIO pedal | 14. Stand for irrigation fluid bottle |
| 3. Contra angle (optional) | 15. Drip chamber |
| 4. Clip for tubing set attachment at handpieces and contra angles | 16. Bleed valve |
| 5. Handpiece cradle | 17. Bottle with irrigation fluid |
| 6. Electronic motor | 18. Type plate with type designation, reference number, serial number, information on power supply and device fuse. |
| 7. Clip for tubing set attachment at motor cable | 19. Power plug socket |
| 8. Motor socket | 20. Main switch |
| 9. Operating panel | 21. Fuse compartment |
| 10. Release key for tubing set bracket | 22. Spray adapter for the lubrication of the electronic motor |
| 11. Display | |
| 12. Peristaltic pump | |

Rear view



6 Startup

6.1 Device setup

- Installation layout



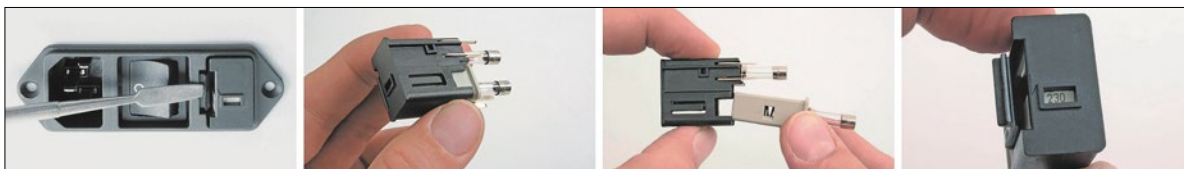
- Place the MD 11 and all required accessories and instruments on an even, non-slip surface and make sure you have good access to all controls.
- The installation of the device in close proximity to other devices is prohibited due to EMC – please see section 3.1 and the manufacturer's EMC declaration in the appendix of this manual.
- 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 onto 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:



- Switch the device off and unplug the power cable.
- Use a screwdriver to unlock the fuse holder.
- Pull out 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 the fuse holder back in and lock it with a click.
- Double check the mains voltage shown on the fuse slot window.
- Plug the power cable back into the device.






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



Only a certified power cord may be used to connect the device to the power supply.

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 socket. 
4. Plug the pedal plug into the pedal socket at the rear of the control unit. 
5. Attach the sterilized handpiece or contra angle to the electronic motor. Press the handpiece or contra angle firmly onto the electronic motor until it clicks into position. Check seating with a slight countermovement.
6. Assemble the tubing set: Attach tubing set REF 1706, for the cooling of the contra angle, like described in the following article.



Use only Nouvag tube set REF 1706, otherwise the proper functioning 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.



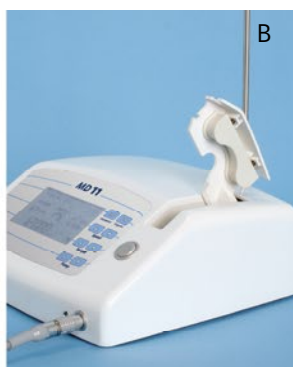
Do not regulate the amount of irrigation fluid using the roller clamp on the tubing set; with the MD 11, this is regulated instead using the integrated pump. For this reason, make sure to open the roller clamp as far as it will go (please refer to 7.4.5 Setting the pump supply quantity).



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 or "Ringer" solution. Supplying medication using the integrated pump is expressly prohibited.



A



B



C



D

- 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. Pierce the spike of the tubing set into the rubber membrane of the cap of the coolant bottle and hang the bottle on 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.

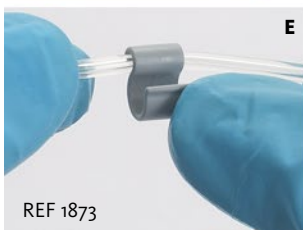


Ensure that the operating voltage setting corresponds to the local mains voltage.



"When selecting the instrument / tubing set, the user must ensure that it is biocompatible in accordance with EN ISO 10993."

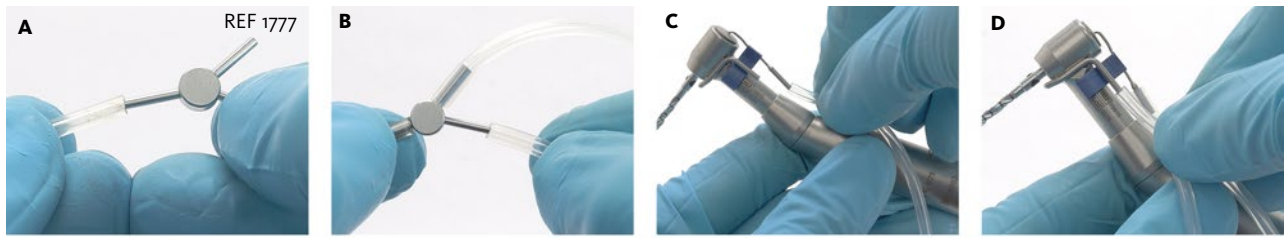
6.4 Assembly of the external cooling system



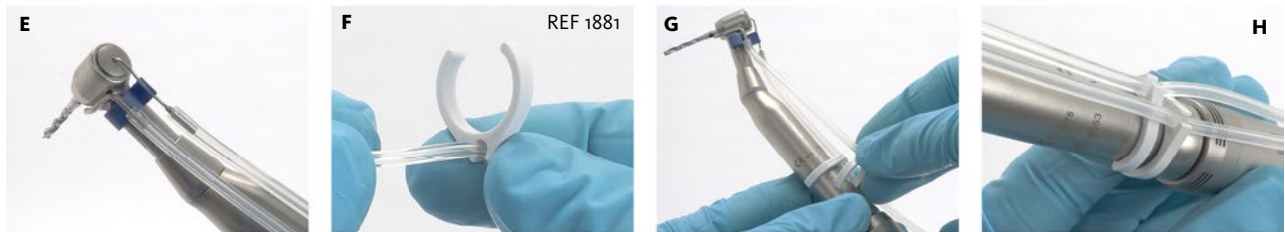
- A) Connect the open end of the irrigation tubing set (REF 1706) with the cooling pipe of the contra angle.
- B) Attach white clip (REF 1881) to the tubing set.
- C) Attach the white clip, connected with the tubing set, to the contra angle.
- D) Connect the electronic motor with the Contra Angle.
- E) Attach the grey clip (optional, REF 1873) to the tubing set.
- F) Attach grey clip, connected with the tubing set, to the cable of the electronic motor.
- G) Ready to use drill unit with attached external cooling system.

If required, secure additional clips to the motor cable.

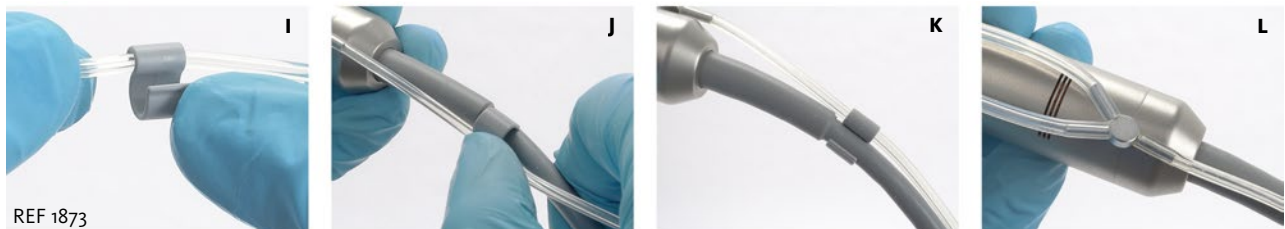
6.5 Assembly of internal and external cooling system (optional)



- A) Attach open end of the tubing set (REF 1706) to the single out branch of the Y-connector (optional, REF 1777).
- B) Connect a 16 cm piece of tube (optional, REF 1773) to each of the branching tubes of the Y-connector.
- C) Connect one of the 16 cm pieces of tube, that branch out of the Y-connector, with the internal cooling tube of the contra angle (delivered together with the contra angle, REF 39116).
- D) Connect the second piece of tube that branches out of the Y-connector with the external cooling pipe of the contra angle (welded on laterally to the contra angles head).



- E) Both 16 cm pieces of tube are now connected to the cooling system of the contra angle.
- F) Secure white tube clips (included with the contra angle, REF 1881) to each of the short tube pieces.
- G) Secure tube clips to the contra angle.
- H) Contra angle with attached tube clips.



- I) Fix a gray clip (optional, REF 1873) to the tubing set, leading to the Y-connector.
- J) Fix tubing set with the gray clip to the motor cable.
- K) Motor cable with ready attached tubing set to the motor cable. Secure further gray clips to the motor cable if needed.
- L) Tubing set routing with Y-connector for internal and external cooling of the instrument.



Essential accessories for internal cooling:

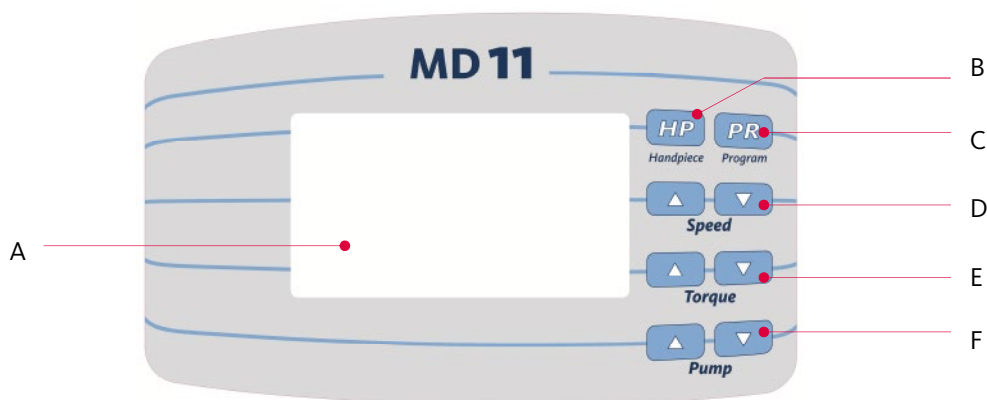


7 Operation

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.

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/contra angle
- The factory default settings contain the handpiece/contra angles 1:1, 16:1, 20:1 and 32:1. If you want to use your 70:1 contra angle it has to be activated in the configuration menu (refer to "7.8 Configuration menu/handpiece existing").
- C) **"Program" key:** Selection of program 1 to 6. The factory setting is adjusted to 4 usable programs.
- The number of usable programs can be altered from 2 to 6 available programs (refer to „7.8 Configuration menu/handpiece existing“).
 - By pressing both „HP + PR“ keys at the same time the programs can be reset to the factory default setting.
- 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 calibration will be started (refer to "7.4.2 Calibrating handpieces").
- E) **"Torque" keys:**
- Restricts the maximum torque.
"▲": increases the maximum torque "▼": reduces the maximum torque
 - By pressing both "Torque" keys at the same time "Torque ▲ + ▼" the torque modes AL or AS are selected (see chapter "7.5 Torque limit function, AL mode (Automatic Limiter)" and chapter "7.6 Torque limit function, AS mode (Automatic Stopper)").
 - If a speed of 20 rpm is set, irrespective of the selected handpiece/contra angle, the pressing of both torque keys, "Torque ▲ + ▼" causes the activation of the **thread cutting function**.
- 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



EN

- A) **Information line**
Information and error messages are displayed here. Display is illuminated red at error messages. At standby the display shows "Nouvag AG – MD 11 V2.0" with the note of the device history.
- B) **Program**
Shows the selected program number 1 to 6. The factory setting is adjusted to 4 usable programs. In the configuration menu the number of available programs can be set from 2 to 6 (refer to "7.8 configuration menu/number of programs").
- 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. Change the rotation direction by pressing the button "FOR/REV" on the pedal.
- E) **Current speed**
At stand still of the device the set maximum speed is displayed. If the pedal is activated and the motor begins to run, the current speed is displayed in real time.
- F) **Transmission ratio of contra angle**
Shows transmission ratio of used contra angle, e.g. 1:1, 16:1, 20:1, 32:1 or 70:1.
- G) **Speed range**
Shows speed range of the handpiece used.
- H) **Maximum torque**
Shows maximum torque setting.
- I) **Bar graph (current torque)**
The bar graph is providing a graphical representation of the current torque. All bars active means max. torque reached.
- J) **AS/AL**
Indication of the Auto Stopper (AS) mode or the Automatic Limiter (AL) mode, (see chapter "7.5 Torque limit function, AL mode" and chapter "7.6 Torque limit function, AS mode").



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

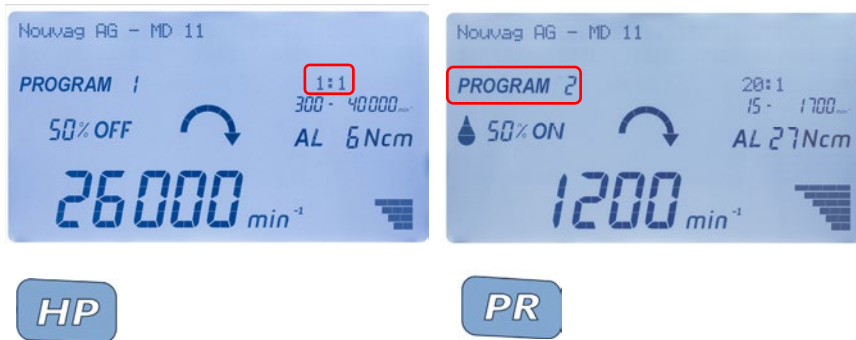
7.4 Adjusting the programs

The values for operation settings depend on the connected handpiece/contra angle as well as the task to be performed.

7.4.1 Step 1: Selecting the handpiece/contra angle to be used



The selected handpiece/contra angle must comply with the factual used handpiece/contra angle.



Press the “**HP**” key to select the handpiece/contra angle

Press the “**PR**” key to choose between programs 1 to 6. The factory setting is adjusted to 4 usable programs.



In the configuration menu the number of available programs can be set from 2 to 6 (refer to “7.8 configuration menu/number of programs”).

Table of possible handpieces/contra angles

| Name of the handpieces/contra angles with transmission ratio | Display | Speed min. rpm | Speed max. rpm | Torque min. Ncm | Torque max. Ncm | AS-range (Factory def.) rpm | Limit AS-range rpm (*) |
|--|---------|----------------|----------------|-----------------|-----------------|-----------------------------|------------------------|
| Drill handpiece, 1:1 | 1 : 1 | 300 | 40,000 | 1 | 6 | - | - |
| Drill contra angle, 16:1 | 16 : 1 | 20 | 2400 | 5 | 27 | up to 20 | 20 – 45 * |
| Drill contra angle, 20:1 | 20 : 1 | 15 | 1700 | 10 | 70 | up to 20 | 15 – 45 * |
| Drill contra angle, 32:1 | 32 : 1 | 10 | 1000 | 10 | 55 | up to 20 | 10 – 45 * |
| Drill contra angle, 70:1 | 70 : 1 | 5 | 600 | 10 | 55 | up to 20 | 5 – 45 * |

* The limitation of the AS-range (Automatic Stopper) can be adjusted in the configuration menu.

Handpieces or contra angles that don't belong to one's own assortment can be deactivated in the Configuration Menu (refer to “7.8 configuration menu/handpiece existing”). As a result by pressing the button «Handpiece» not all handpieces will be recalled, but only those that belong to the assortment.

7.4.2 Step 2: Calibrating handpiece or contra angles

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

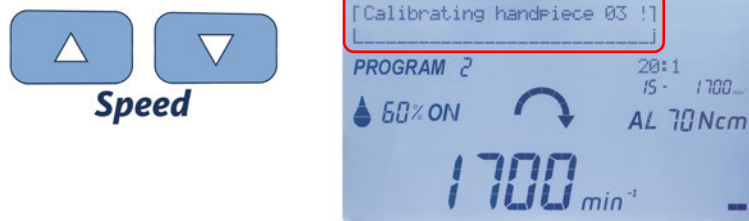
It's a procedure as simple as it is important to guarantee safety and precision of each handpiece or contra angle being used.

After you take care of all prior preparations such as sterilization, care of handpieces and motor, device preparation and the selection of the handpiece according to the chapter 7.4.1, the calibration procedure can be performed.



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

1. Select the handpiece, attached to the motor, by pressing the “**handpiece**” key. Make sure that this handpiece attached to the motor is also on the display.
2. Hold motor with mounted handpiece or contra angle in your hand at safe distance from your body.
3. Press both “**Speed**” keys at the same time (**Speed ▲ + Speed ▼**). Display indicates “**Calibrating handpiece XX**”.



4. Motor and handpiece start running and pass several speed cycles up to maximum speed.
5. After a tone is emitted and a message is displayed the calibration is finished. The display returns to normal mode.



If a handpiece is not working within the range of the calibration algorithms, even when it was cleaned and lubricated before, the display shows an error with a red backlit display, “**Handpiece XX is faulty**”. This indicates soiling, wear or a technical defect of the handpiece. These handpieces have to undergo a maintenance and care cycle or have to be repaired or replaced.



At the calibration procedure, the handpieces are tested on their torque delivery behavior. With the 1:1 handpiece the control unit is additionally adjusted to altered conditions of the handpiece to keep it delivering the appropriate torque.

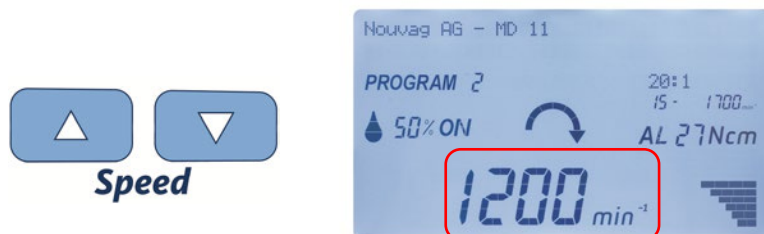
7.4.3 Step 3: Setting the speed

The possible speed range depends on the contra angle to be used. 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.

Setting the speed:

Press the “Speed” keys “▲” to increase or “▼” to decrease the maximum speed. When key is pressed constantly 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 limited from the torque range of the corresponding handpiece or contra angle.

Depending on the speed, the torque mode AL or AS is applied.



For information on AL and AS mode, see Chapter “7.5 Speed reduction AL (Automatic Limiter)” and Chapter “7.6 Torque limit function: AS (Automatic Stopper)”

Press the “Torque” keys “▲” to increase or “▼” to decrease the maximum torque. By pressing the key continuously the torques are changed 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.

7.4.5 Step 5: Setting the pump supply quantity

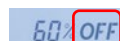
Press the “Pump” keys “▲” to increase or “▼” to decrease the pump supply quantity. By pressing the key continuously the values are fast forwarded.



Minimum and maximum of pump supply quantity as well as incremental steps can be adjusted in the Configuration Menu (refer to «7.8 Configuration Menu, Parameter level 2, Pump»).



To activate or deactivate the pump, press both “Pump” keys at the same time, “Pump ▲ + ▼”, or push the foot switch “PUMP” shortly.



7.5 Torque limit function, AL mode (Automatic Limiter)

The **AL** function limits the torque applied to the instrument, for example to prevent crack initiation and bone fracture.

The speed at the instrument remains constant until the preset torque is reached. If the applied force gets over this limit the speed will be reduced, if necessary down to a stop, but the torque remains constant. If the applied force is reduced the speed picks up again.

On the display this procedure is shown as a bar graph. The bars in the graph fill up to their full range as the torque increases to its preset value. When the bar graph shows full capacity the speed will be reduced. As soon as the force on the instrument is reduced the torque decreases and the speed starts to pick up again as shown on the display.

The AL mode is active at all speeds, except where the AS mode is active.

7.6 Torque limit function, AS mode (Automatic Stopper)

The **AS** function limits the torque applied to the instrument. As soon as the preconfigured torque is reached, the electronic motor stops immediately. The electronic motor no longer generates any force. In order to restart the electronic motor, the treadplate must be released and pressed again.

On the display, the bar graph completes up to its full range, until the maximum torque is reached, then drops to zero.



The function “**AS**” is just active for certain contra angles and only in a certain speed range.

From the minimal speed up to the speeds shown at the right the AS-mode is activated automatically. (refer to “7.8 Configuration Menu, Parameter level 2, AS-Zone”)

| Handpiece | 16:1 | 20:1 | 32:1 | 70:1 |
|------------|------|------|------|------|
| Speed rpm: | 20 | 20 | 20 | 20 |

The upper limit of the AS range can be adjusted in the configuration menu.



In the following speed ranges the AS-/AL-mode can also be switched manually by pressing both torque keys “Torque ▲ + ▼” at the same time.

| Handpiece | 16:1 | 20:1 | 32:1 | 70:1 |
|-----------|------|------|------|------|
| From rpm: | 20 | 15 | 10 | 5 |
| To rpm: | 45 | 45 | 45 | 45 |

7.7 Storing various programs

With the MD 11, up to 6 different settings can be set as fixed program (program 1 to program 6). Which program is currently active is shown on the display.

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

- Handpiece/Transmission ratio
- Maximal speed
- Maximal torque
- Pump On/Off
- Pump performance
- AS/AL mode

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.



The number of storable programs can be limited in the configuration menu from 2 to 6 programs.



When the MD 11 is switched on, the display shows the prior used program and motor.

7.8 Configuration Menu

In the Configuration Menu the user can customize the device after his favor. The parameters are organized in two levels. The following information and parameters are stored in there.

- Software version
- Mainboard serial number
- Language selection, DE/EN
- Display illumination
- Number of programs
- Power on, at last program
- Operating hours MD 11
- Operating hours Motor
- Operating hours of irrigation pump
- Error log
- Activation of available handpiece
- Speed limitation for each handpiece
- Range of action of AS mode
- Pump behavior
- Motor behavior
- Behavior of torque at reverse mode
- Pedal behavior
- Reset to factory default



Be cautious when changing parameters. Unusual behavior of instruments while operating may provoke false reactions and jeopardize the patient. Every setting and the new behavior of the instrument has to be verified and tested.

1. Access to Configuration Menu:

- Press “HP” and “Speed ▼” key for about 3 sec. until you hear a tone. On the display the first position of the configuration menu shows up.



The arrows at the beginning of the lines indicate the operation in the Configuration Menu.



2. Selection of parameters:

- Press “HP” or “PR” to choose the desired parameter.
- Press “Speed ▼” to select the parameter.
- Change the value by pressing “HP” for up or “PR” for down.
- To confirm the changes made, press “Speed ▼” for about one sec., until you hear a short tone.
- To abort the settings made, press “Speed ▼” briefly. The setting returns to its previous value.



3. Exit from Configuration Menu:

- To leave the Configuration Menu press “HP” and “PR” for 3 sec. until you hear a tone.

Parameter Level 1

| Group/Parameter | Rights | Factory | Definition |
|------------------------------|------------|------------|--|
| Software/Version | read | VX.XXXX | Shows current software version |
| Hardware/Serial number MB | read | XXXXXXXXXX | Shows serial number of the main board |
| Language, 0 = DE, 1 = EN | read/write | 1 | Select language between German and English |
| Backlight/brightness (0..10) | read/write | 9 | Display brightness, changeable: 0, ... , 10 |
| Number of programs | read/write | 4 | Select between 2 and 6 available programs |
| Power on at last program | read/write | Yes | Display of the last program after switching device on. |
| Operating hours/Control Unit | read | 0 | Shows operating hours of Control Unit |
| Operating hours/Motor | read | 0 | Shows operating hours of motor 1 |
| Operating hours/Pump | read | 0 | Shows operating hours of pump |
| Error memory/ 1 – 8 | read | 0 | 8 Error messages in chronological order. |

| Handpiece activation | Name of handpiece on display | Choice | Factory default | Definition |
|--------------------------|------------------------------|--------|-----------------|---|
| Handpiece existing/HP 02 | 16 : 1 | yes/no | no | Only one handpiece or contra angle can be selected. |
| Handpiece existing/HP 03 | 20 : 1 | yes/no | yes | |
| Handpiece existing/HP 04 | 32 : 1 | yes/no | no | |
| Handpiece existing/HP 05 | 70 : 1 | yes/no | no | |

Parameter Level 2

To change the values in level 2 the password „9403“ must be entered. *The password can not be changed.*

1. Entering the access code: Press **Speed ▼**.
2. Selecting the access code by pressing **HP** to increase, or **PR** to decrease the value.
3. To confirm the access code press **Speed ▼ for one second**, until a sound is emitted.

(for fast forwarding or backwarding keep keys pressed)

| Handpiece Max. Speed | Name of handpiece on the display | Speed range rpm | Factory default | Definition |
|---------------------------|----------------------------------|-----------------|-----------------|--|
| Handpiece max speed/HP 01 | 1 : 1 | 300 – 40,000 | 40,000 | Limit the maximum speed of your handpieces according to your own experience. |
| Handpiece max speed/HP 02 | 16 : 1 | 20 – 2400 | 2400 | |
| Handpiece max speed/HP 03 | 20 : 1 | 15 – 1700 | 1700 | |
| Handpiece max speed/HP 04 | 32 : 1 | 10 – 1000 | 1000 | |
| Handpiece max speed/HP 05 | 70 : 1 | 5 – 600 | 600 | |

| AS-Zone for handpieces | Handpiece on display | Selection ... to ... rpm | Factory default | Definition |
|-------------------------|----------------------|--------------------------|-----------------|-------------------------------------|
| Handpiece AS-Mode/HP 02 | 16 : 1 | 20 – 45 | 20 | Selection range AS mode 20 – 45 rpm |
| Handpiece AS-Mode/HP 03 | 20 : 1 | 15 – 45 | 20 | Selection range AS mode 15 – 45 rpm |
| Handpiece AS-Mode/HP 04 | 32 : 1 | 10 – 45 | 20 | Selection range AS mode 10 – 45 rpm |
| Handpiece AS-Mode/HP 05 | 70 : 1 | 5 – 45 | 20 | Selection range AS mode 5 – 45 rpm |

| Pump parameters | Range | Factory default | Definition |
|-----------------------------------|------------|-----------------|--|
| Pump/Backwards turn mode variable | No/Yes | Yes | The pressures in the tube set vary according to the pump speed. In “variable mode” this is considered, to prevent of spilling when pump is switched off in backwards mode. |
| Pump/Way backwards | 1 – 100 % | 25 % | Specify how far the pump turns backwards |
| Pump/Speed backwards | 10 – 50 % | 33 % | Specify how fast the pump has to turn backwards to prevent of spilling after the switch off of the motor. |
| Pump/Range 1 increment | 1 – 10 % | 5 % | Adjustment steps in section 1. |
| Pump/Range 1 end | 5 – 50 % | 10 % | Set the range where section 1 is active |
| Pump/Range 2 increment | 1 – 10 % | 5 % | Adjustment steps in section 2 |
| Pump/Range 2 end | 10 – 90 % | 50 % | Set the range where section 2 is active. |
| Pump/Range 3 increment | 1 – 10 % | 10 % | Adjustment steps in section 3 |
| Pump/Range 3 end | 20 – 100 % | 100 % | Set the range where section 3 is active. |
| | | | |

| Motor type 21, 40,000 rpm | Range | Factory default | Definition |
|---------------------------------------|------------------------|-----------------|---------------------------------------|
| Motor type 21, 40,000 rpm/Min. speed | 300 – 5000 rpm | 300 rpm | Set the min. speed of the motor. |
| Motor type 21, 40,000 rpm/Max. speed | 5000 – 40,000 rpm | 40,000 rpm | Set max. speed of the motor. |
| Motor type 21, 40,000 rpm /Start ramp | 1 – 1000 ms/10,000 rpm | 100 ms | Set acceleration time to 10,000 rpm |
| Motor type 21, 40,000 rpm /Stop ramp | 1 – 1000 ms/10,000 rpm | 50 ms | Set breaking time from 10,000 – 0 rpm |



The maximum torque of the motor is boosted while starting the reverse rotation to disengage stuck implants or screws.

| Reverse torque | Range | Factory default | Definition |
|------------------------------|---------------|-----------------|--|
| Reverse torque/Increase | 5 – 30 % | 25 % | Increase of the selected torque in reverse rotation. |
| Reverse torque/Increase time | 100 – 2000 ms | 500 ms | Time during which torque is raised. |

| Pedal button motor | Range | Factory default | Definition |
|--|--------|-----------------|--|
| Pedal button motor/Long pressed next program | Yes/No | No | Resetting all parameters of the Configuration Menu to factory default. |



- **Attention:** Upon resetting to factory default all parameters will appear with factory default values (except date and time).

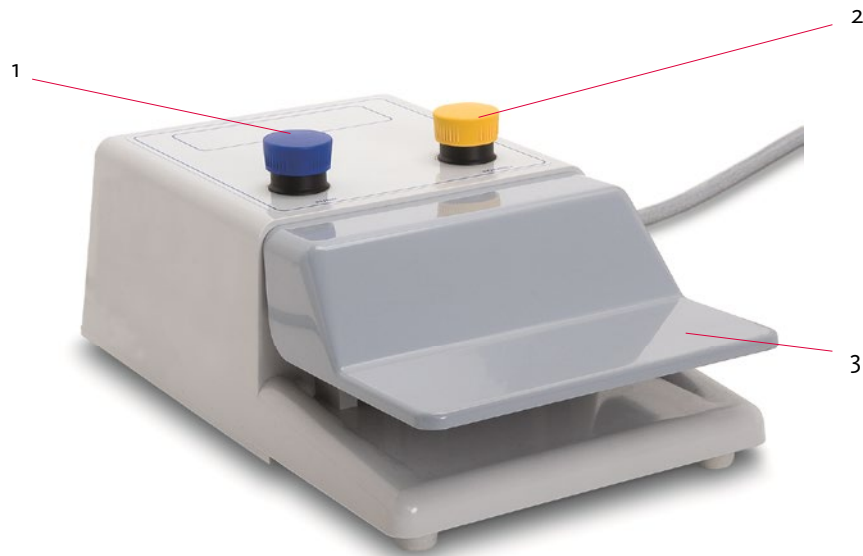
| Resetting to factory default | Choice | Factory default | Definition |
|---------------------------------|--------|-----------------|--|
| Default value/Set default value | Yes/No | No | Resetting all parameters of the Configuration Menu to factory default. |

Exit from Configuration Menu

- To leave the Configuration Menu press **“HP”** and **“PR”** for 3 sec., until you hear a long tone.



7.9 Operation using the VARIO pedal



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1. **Key "PUMP":**
Pressing the key briefly: switches the pump on or off (see information on display).
Pressing the key longer: increases the pump speed (see information on display).
2. **Key "FOR/REV":**
Pressing the key briefly: switches the direction of revolution. (see information on 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.

7.10 Functional check

Prior to MD 11 startup or 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.

7.10.1 Electronic motor

Use the **“Speed ▲”** key to set the speed of the electronic motor to its maximum. With the 1 : 1 Contra Angle attached, it is 40,000 rpm. With all the other Contra Angles the maximum Speed is lower, according to the transmission ratio of the Contra Angel. Press the pedal treadplate; the electronic motor starts running and accelerates to 40,000 rpm. When the treadplate is released, the electronic motor slows down again.



- The electronic motor is designed for an intermittent duty operation at maximum speed of **“1 min ON/3 min OFF” at 4 cycles. Brake after 15 min.** Otherwise the electronic motor can be damaged by excessive heat generation, and by touching the motors hull it could cause serious burnings.
- The motor ventilation slots must be kept clear in order to prevent the motor temperature from becoming excessive.

7.10.2 Pump

Press the key **“PUMP”** 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 contra angle.

7.10.3 Rotational direction of the electronic motor

Press the key **“FOR/REV”** 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 heard. By pressing the motor 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 following points in particular are important with regard to caring for the material:



- 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 % full.
- Always autoclave the material at 134°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.

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8.1 Control unit and pedal

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 Tubing set, REF 1706



Single-use tubing set 1706 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 1706!



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.

8.3 Handpiece cradle

Soiled handpiece cradles are cleaned using neutral or alkaline cleaning agents in the recommended concentration. It can be sterilized in accordance with the same instructions as for electronic motor 21.

8.4 Electronic motor 21

The reprocessing instructions for the electronic motor 21 can be found in the instructions for use, supplied with the electronic motor.

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 holder, beside the power switch:

- Switch off the main switch of the device.
- Unplug the power plug.
- Open the fuse compartment 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 compartment with a click.
- Double check the mains voltage shown on the fuse slot window.
- Plug in the power plug again.



1. Fuse compartment clamp
2. Display window for local voltage setting
3. Fuse compartment
4. Fuse 1
5. Fuse 2

9.2 Safety inspections (STI)

The essential requirements have been defined and within the risk analysis assessed. The approved results have been filed in the risk management deposited with the manufacturer.

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.

The STI (Safety technical inspection) for the MD 11 shall be executed every 2 years by authorized experts. Results shall be documented.

The service instructions, circuit diagrams and descriptions are available on request from the manufacturer.

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

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| 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 |
| | Processor error | Main switch "I/O" to "O" position; after 10 sec. to "I" again. | 7.1 Switching the device on and off |
| Motor does not run | Motor not switched on | Switch on the motor using the treadplate | 7.9 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 | 7.9 Operation using the VARIO pedal |
| | 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 |
| | Non conform tube set (Not from Nouvag or from Nouvag but wrong type) | Use the tube set recommended by Nouvag | 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 | 7.9 Operation using the VARIO pedal |
| Red display illumination | Motor is missing | Connect the motor | 6.3 Device preparation |
| | Motor fault or motor cable is broken | Check motor and its cable | 6.3 Device preparation |
| | AS limit reached with an instrument | Release pedal and press again | 7.9 Operation using the VARIO pedal |

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



If the display is illuminated red by an error warning, the error code can be found on the next page in this user manual under "MD 11 Error messages on display".

| MD11, Error-messages on Display | | |
|--|--|---|
| Error-messages/codes | Cause | Solution |
| Basic Initialization/ W00 | First Initialization | |
| 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. |
| User Config 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/ User Config & Program | Message while default values of parameters and programs saved to the NOU-dongle. | |
| Storing factory settings/ Program | Message while default values of programs are stored. | |
| Pedal not connected/ E10 | a) Pedal 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/ E16 | a) Wrong motor plugged in. b) Right motor connected, 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. |
| Torque reached/ 22, pedal let go | Can occur during tapping when the maximum torque has been reached. | Take your foot off the pedal and press it again after a few seconds. |
| AS-mode torque reached | When the max. torque set is reached in AS-mode, this message is displayed. | Release pedal and restart motor by pressing pedal again. |
| Pedal locked/ W26, pedal release | If pedal is pressed at switch on procedure, pedal will not work. | Release pedal for one second. |
| Handpiece XX is faulty/ E29 | The handpiece was exposed to excessive torque, while calibrating or testing. | <ul style="list-style-type: none"> - Clean handpiece/contra angles with NouvaClean-spray and lubrication with NouvaOil spray. - If message still displayed after testing, send handpiece to Service Center. |
| Handpiece XX is Ok! | Tested handpiece is OK. | |
| Calibrating HPXX is Ok! | Calibrated handpiece is OK. | |
| Testing the handpiece XX | Handpiece is testing. | |

| | | |
|--|--|--|
| Calibrating handpiece XX! | Handpiece is calibrating. | |
| Nou-dongle is plugged in | Message is displayed for 1 second after NOU-dongle was plugged in. | |
| Disturbed, Pedal locked E36, Pedal let go | Disturbance while pressing the pedal. | Take your foot off the pedal and press it again after a few seconds. |
| System Message XX Send unit to service point | System error | Send Control Unit to Service Center. |

The red highlighted error messages are also illuminated red on the control device display. The other messages are for information and do not require any action by the user.

11 Spare parts list with order numbers

| Accessories | REF |
|---|---------|
| Clip set large CL, for attachment to the handpiece, package with 3 pieces | 1881 |
| Clip set motor cable, for attachment to the motor cable, package with 10 pieces | 1873 |
| Single-use tubing set, 2 m, sterile, 10-unit pack | 1706 |
| Y-connector, for branching tube set for internal and external cooling | 1777 |
| Internal cooling nozzle for drilling handpieces with latch system | 1712 |
| Internal cooling nozzle clip for drilling handpieces with push button system | 39116 |
| NouvaClean spray for the cleaning of handpieces and contra angles | 2127 |
| NouvaOil spray for the lubrication of handpieces, contra angles and electronic motors | 2128 |
| Spray adapter for the lubrication of electronic motors 21 with NouvaOil spray | 19584 |
| Drilling Contra Angle 1:1, with INTRA EN3964 coupling, max. torque 6 Ncm | 5050nou |
| Drilling Contra Angle 16:1, with INTRA EN3964 coupling, max. torque 27 Ncm | 5200nou |
| Drilling Contra Angle 20:1, with INTRA EN3964 coupling, max. torque 70 Ncm | 5053nou |
| Drilling Contra Angle 20:1 LED, with INTRA EN3964 coupling, max. torque 70 Ncm | 5052nou |
| Drilling Contra Angle 32:1, with INTRA EN3964 coupling, max. torque 55 Ncm | 5201nou |
| Drilling Contra Angle 70:1, with INTRA EN3964 coupling, max. torque 55 Ncm | 5065nou |

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

Operation manual MD 11 31665

The operating instructions are supplied by Nouvag AG as a PDF file on CD-ROM, in each case together with the device. If you prefer a printed copy, we will send it to you by post free of charge. If the operating instructions can no longer be found, we will be happy to send you a new copy as a PDF file by email.

12 Information on disposal



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

Aerosol sprays such as NouvaClean and NouvaOil are hazardous goods that must be declared accordingly when shipping. Nouvag AG / Nouvag GmbH is not liable if this regulation are not observed. Defective or even damaged aerosol containers must not be returned to Nouvag AG / Nouvag GmbH, but must be disposed of locally and properly.



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

Appendix

Appendice

Appendice

Apéndice

Electromagnetic compatibility (EMC)

Remark:

The **Product** subsequently referred to herein always denotes the MD 11.

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, including accessories (antennas e.g.) in distances below 30 cm (12 inches) to the product, may cause unexpected or adverse operation.

WARNING

The product is suitable for use in hospitals other than in the vicinity of active devices of the HF surgical devices or except in HF screening rooms used for magnetic resonance imaging.

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.

Essential Performance

The essential performance is that the drilling, milling and grinding of the bone and tissue, taking into account the speed and max. torque is maintained. The maximum speed deviation is $\pm 5\%$ at a range between 300 – 40'000 RPM and the maximum torque deviation is -10%, +20% at a maximum motor torque of 6 Ncm.

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. |
|---|-------------|
| Power supply cord REF 22261 / 22262 / 22264 / 22266 | 3.0m |
| Electronic motor REF 2097nou | 2.0m |
| Foot pedal IPX8 REF 1866nou | 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 | |
| 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) IEC 61000-4-2 | +/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air | +/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Electrical fast transient/burst IEC 61000-4-4 | +/- 2 kV with 100kHz for power supply lines +/- 1 kV with 100kHz for input/output lines | +/- 2 kV with 100kHz for power supply lines +/- 1 kV with 100kHz for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | +/- 0.5 kV, +/- 1 kV differential mode +/- 0.5 kV, +/- 1 kV, +/- 2 kV common mode | +/- 0.5 kV, +/- 1 kV differential mode +/- 0.5 kV, +/- 1 kV, +/- 2 kV common mode | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines | 0 % U_T ; for 0,5 cycle with 0, 45, 90, 135, 180, 225, 270, 315 degree 0 % U_T ; for 1 cycle | 0 % U_T ; for 0,5 cycle with 0, 45, 90, 135, 180, 225, 270, 315 degree 0 % U_T ; for 1 cycle | Mains power quality should be that of a typical commercial or hospital environment. If the user of the Product requires continued operation during power mains interruptions, it |

| | | | |
|---|--|--|---|
| IEC 61000-4-11 | 70 % U _T ; for 25/30 cycles 0 % U _T ; for 5 sec | 70 % U _T ; for 25/30 cycles 0 % U _T ; for 5 sec | is recommended that the Product be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60Hz) magnetic field IEC 61000-4-8 | 30 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. |

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 0.15 MHz to 80 MHz 6 V rms inside ISM bands between 150 kHz to 80 MHz 80% AM bei 1 kHz | 3 V rms 0.15 MHz to 80 MHz 6 V rms inside ISM bands between 150 kHz to 80 MHz 80% AM bei 1 kHz | $d = 0,35 \sqrt{P}$ |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.7 GHz 80% AM bei 1 kHz | 3 V/m 80 MHz to 2.7 GHz 80% AM bei 1 kHz | $d = 0,35 \sqrt{P}$ 80 MHz to 800 MHz $d = 0,7 \sqrt{P}$ 800 MHz to 2,7 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.

| Electromagnetic immunity against high-frequency wireless communication devices | | | | | | |
|--|-----------------------|--|----------------------------------|--------------------------|---------------|-------------------|
| Test frequency MHz | Frequency band MHz | Communication service | Modulation | Maximum Performance W | distance m | Test level V/m |
| 385 | 380 to 390 | TETRA 400 | Pulse modulation 18 Hz | 1.8 | 0.3 | 27 |
| 450 | 430 to 470 | GMRS 460, FRS 460 | FM ± 5 kHz Hub 1 kHz Sinus | 2 | 0.3 | 28 |
| 710 | 704 to 787 | LTE Band 13, 17 | Pulse modulation 217 Hz | 0.2 | 0.3 | 9 |
| 745 | | | | | | |
| 780 | | | | | | |
| 810 | 800 to 960 | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 | Pulse modulation 18 Hz | 2 | 0.3 | 28 |
| 870 | | | | | | |
| 930 | | | | | | |
| 1720 | 1700 to 1990 | GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25; UMTS | Pulse modulation 217 Hz | 2 | 0.3 | 28 |
| 1845 | | | | | | |
| 1970 | | | | | | |
| 2450 | 2400 to 2570 | Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7 | Pulse modulation 217 Hz | 2 | 0.3 | 28 |
| 5240 | 5100 to 5800 | WLAN 802.11 a/n | Pulse modulation 217 Hz | 0.2 | 0.3 | 9 |
| 5500 | | | | | | |
| 8785 | | | | | | |

| 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 $d = 0,35 \sqrt{P}$ | 80 MHz to 800 MHz $d = 0,35 \sqrt{P}$ | 800 MHz to 2.5 GHz $d = 0,7 \sqrt{P}$ |
| 0,01 | 0,04 | 0,04 | 0,07 |
| 0,1 | 0,11 | 0,11 | 0,22 |
| 1 | 0,35 | 0,35 | 0,7 |
| 10 | 1,1 | 1,1 | 2,2 |
| 100 | 3,5 | 3,5 | 7 |
| 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

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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



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