

EN Operation manual



MD30

Motor System for Implantology and Oral Surgery

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1 Product description

1.1 Intended use and operation

The MD 30 in combination with a motor and corresponding handpiece or contra angle (separate medical device) is used primarily in dental Implantology. The device can also be used for microsurgical applications as well as in oral and maxillofacial surgical procedures. 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 30 may be operated only 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 MD 30, technical data

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: ----- 3.7 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 ----- 2 m

Pedal:

IP code (pedal)----- IPX8

**Applied part of Type BF is the instrument used with the MD 30.*

1.4 Ambient conditions

















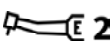










	Transport and storage:	Operation:
Relative humidity:	10 % – 90 %	Max. 80 %
Temperature:	0 – 60°C (32 – 140°F)	10 – 30°C (50 – 86°F)
Atmospheric pressure:	700 – 1060 hPa	800 – 1060 hPa

1.5 Warranty coverage

Purchasing the MD 30 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 134°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 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 1		Motor 2
	Pedal		Protective ground
IPX8	Protection against contact and continual submerging.		Certified by the Canadian Standards Association (CSA)
	Date of manufacturing		Date of expiry
	CE symbol with notified body		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		

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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:

Every use of the MD 30 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 30 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 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 30 and its accessories is prohibited. The manufacturer is not liable for any damages resulting from unauthorized modifications or manipulations. The warranty is no longer valid.
- Use of the MD 30 outside the indications described in Section 1.1 is prohibited. The user or operator is solely responsible for any such use.

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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.



Only use the NouvaClean spray (REF 2127) for the internal cleaning of handpieces and contra-angles. The use of other cleaning products can lead to malfunctions and the warranty becomes void!



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 warranty becomes void!



Repairs may only be performed by authorized NOUVAG service technicians.



The MD 30 may only be operated by qualified and trained personnel.



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.

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 the system is running. This could result in instrument damage.



Handpieces and contra angles may only be attached when the electronic motor is not running.



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



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





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



At operation at a patient, make sure to produce as less as possible friction heat. By excessive thermal influence on the tissue, the tissue easily gets necrotized. The heat generation is directly proportional to the speed delivery of the instrument and the contact pressure delivered by the instrument.

4 Scope of delivery

REF	Description	Quantity
3330	MD 30 control unit-----	1
1510nou	VARIO pedal; IPX8; electronic -----	1
 2097nou	Electronic motor 21 incl. 2 m motor cable, max. speed 50,000 rpm -----	1
 1706	Tube set, sterile, 2 m, single-use-----	1
1873	Clip set (10 pieces) for tube set attachment at motor cable -----	1
1881	Clip set (3 pieces) for 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 -----	1
31686	User Manual MD 30 on CD-ROM -----	1

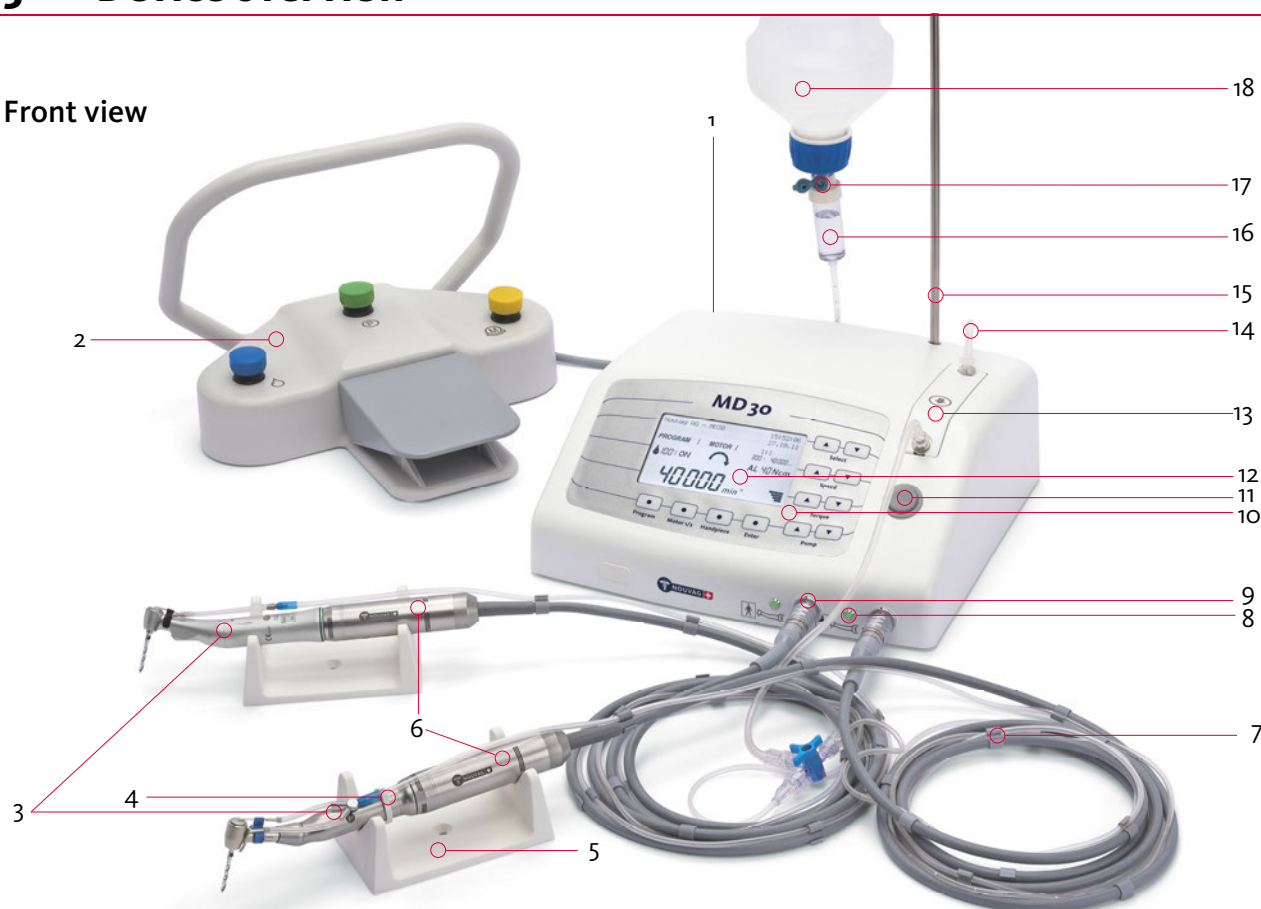


In line with regulations pertaining to hazardous materials, the following items are not delivered with the control unit and must be ordered separately:

2127	NouvaClean cleaning spray for handpieces and contra angles-----	6
2128	NouvaOil-lubricant spray for handpieces, contra angles and electronic motors -----	6

5 Device overview

Front view



- | | |
|---|---|
| 1. Pedal socket (device rear) | 14. Tubing set |
| 2. VARIO pedal | 15. Stand for irrigation fluid bottle |
| 3. Handpiece and contra angle (not included in delivery) | 16. Drip chamber |
| 4. Clip for tubing set attachment at handpieces and contra angles | 17. Bleed valve |
| 5. Handpiece cradle | 18. Bottle with irrigation fluid |
| 6. Electronic motor (delivery includes 1 motor) | 19. 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 | 20. Power entry module with power plug socket |
| 8. Indicator light for each motor | 21. Power entry module with main switch |
| 9. 2 motor sockets | 22. Power entry module with fuse compartment |
| 10. Operation panel | 23. Spray adapter for the lubrication of the electronic motor (REF 19584) |
| 11. Release key for tubing set bracket | |
| 12. Display | |
| 13. Peristaltic pump | |

Rear view



6 Startup

6.1 Device setup

- Installation layout



- Place the MD 30 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 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:







- Switch of the device and unplug the power cable.
- Use a screwdriver or such 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 the grey 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 an 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 one of the motor sockets.  **E 1**
4. Where appropriate, plug the motor plug of a second electronic motor into a motor socket.  **E 2**
5. Plug the pedal plug into the pedal socket at the rear of the control unit. 
6. 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.
7. Assemble the tubing set: Decide whether you will use tubing set REF 1706, for the cooling of a single contra angle or if you need to use tubing set REF 6025 with an integrated 3 way tap for the cooling of both contra angles during a procedure, while both motors are plugged in.



Use only Nouvag tube sets REF 1706 and 6025, 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.



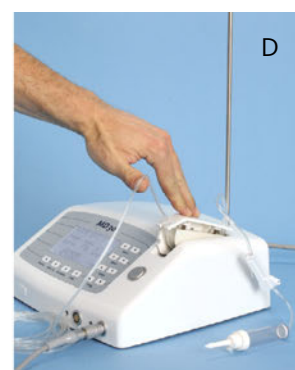
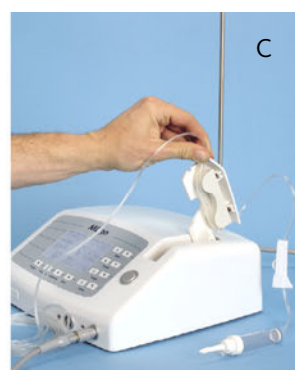
When inserting the tubing set, watch the arrow on the cover of the pump compartment. It indicates the flow direction of the cooling liquid.



Do not regulate the amount of irrigation fluid using the roller clamp on the tubing set; with the MD 30, 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 the tissue and thus to avoid tissue damage. It may only be operated with aqueous solutions, such as sterile 0.9% NaCl rinsing solution or Ringer's solution. The delivery of drugs with the integrated pump is expressly prohibited.



- 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.



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



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

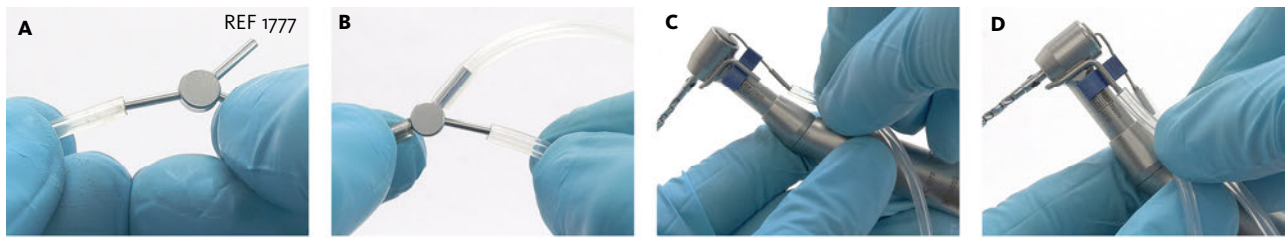
6.4 Assembly of external irrigation system



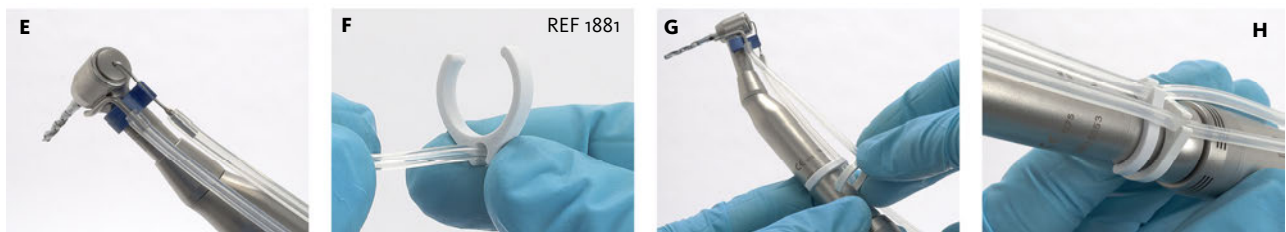
- A) Connect the open end of the irrigation tube (REF 1706 or REF 6025) set with the cooling pipe of the Contra Angle.
- B) Attach white clip (REF 1881) to the tube set.
- C) Attach white clip with tube set to the Contra Angle.
- D) Connect the electronic motor with the Contra Angle.
- E) Attach grey clip (optional, REF 1873) to the tube set.
- F) Attach grey clip with tube set to the cable of the motor
- G) Ready to use drill unit with attached external cooling system.

If required, secure additional clips to the motor cable.

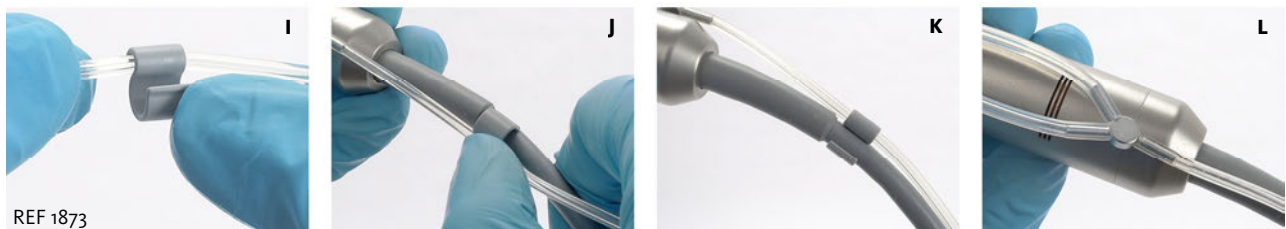
6.5 Assembly of internal and external irrigation system (optional)



- A) Attach open end of the tube 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 a 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 tube set leading to the Y-connector.
- J) Fix tube set with the gray clip to the motor cable.
- K) Motor cable with ready attached tube set to the motor cable. Secure further gray clips to the motor cable if needed.
- L) Tube set routing with Y-connector for internal and external cooling of the instrument.



Essential accessories for internal cooling:

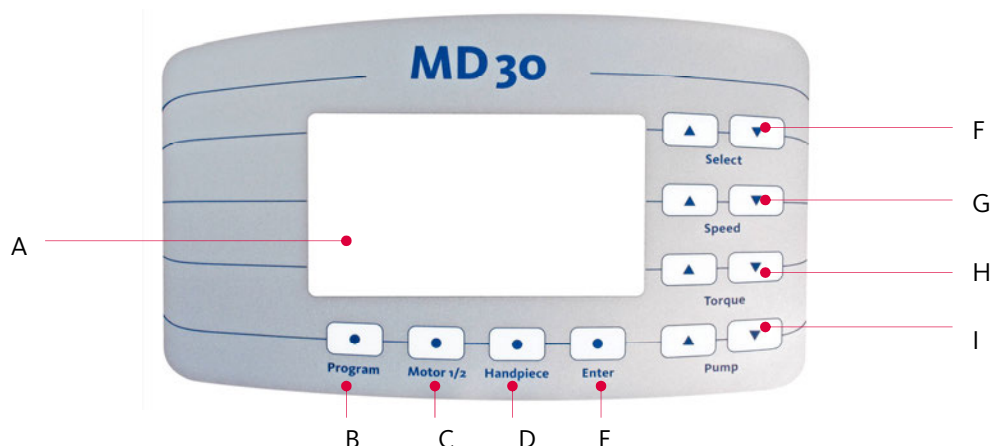


7 Operation

7.1 Switching the device on and off

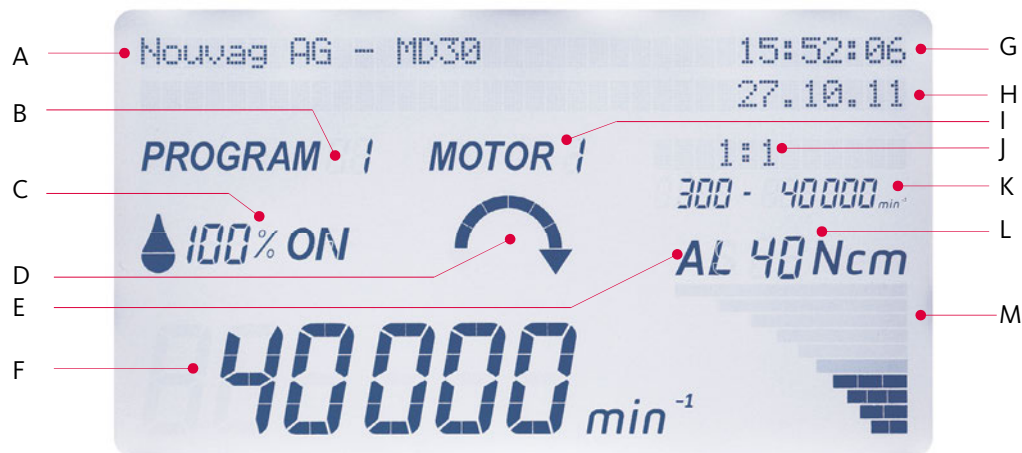
The power switch "I/O" (at the rear) is used to switch the control unit on and off.
The device can be switched off at any time irrespective of any procedure for switching off the device.


7.2 Overview: Control elements on the operating panel



- A) **Display:** Shows the operating values (See chapter "7.3 Overview: Standard display").
- B) **"Program" key:** Selection of program 1 to 10. There are 10 selectable programs for each motor. (To facilitate the selection of programs, the number of selectable programs can be limited to the ones you need. Refer to "7.8 Configuration Menu", Level 1, Programs/Number of programs).
- C) **"Motor 1/2" key:** Switching between the connected motors (the green indicator lights beside the motor sockets indicate the active motor). Pressing the Motor key longer changes direction of rotation.
- D) **"Handpiece" key:** Choice of handpieces or contra angle (can be individually deactivated, refer to "7.8 Configuration Menu").
- E) **"Enter" key:** Enters the configuration menu by pressing long (refer to "7.8 Configuration Menu").
- F) **"Select" keys:**
- By pressing the left "Select" key **"Select ▲"** the software version is shown.
 - By pressing both "Select" keys at the same time **"Select ▲ + ▼"** the programs will be reset to factory default settings.
 - The Select keys serve in the configuration menu to change values and parameters
"▲": value adjustment (upwards) **"▼"**: value adjustment (downwards)
- G) **"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").
- H) **"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 and AS are exchanged, provided the maximum speed of the instrument in AS mode is not exceeded (see chapter "7.5 Torque limit function, AL mode (Automatic Limiter)" and chapter "7.6 Torque limit function, AS mode (Automatic Stopper)").
- I) **"Pump" keys:**
- Changing the pump flow rate that can be supplied using 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.
- B) **Program**
Shows selected number of program for the active motor.
- C) **Pump**
The numerical value shows the pump flow rate in percent and the drop symbol together with the ON/OFF indication shows the 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 “” on the pedal or by long pressing of the “Motor 1/2” key at the operating panel. In reverse mode, the unit emits an acoustic signal during operation.
- E) **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”).
- F) **Current speed**
Shows current revolutions per minute of the motor.
- G) **Clock**
- H) **Date**
- I) **Motor**
Shows selected motor → see also the green indicator light beside the motor sockets.
- J) **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 the contra angle or transmission ratio”)
- K) **Speed range**
Shows speed range of the handpiece used.
- L) **Maximum torque**
Shows maximum torque setting.
- M) **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 is activated by pressing the pedal.

7.4 Adjusting the programs

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

7.4.1 Step 1: Selecting the handpiece or transmission ratio



The handpiece or contra angle, connected to the motor, must match with the selected and displayed gear ratio.



Press the **“Handpiece”** key repeatedly until the name of the required handpiece or contra angle with the corresponding transmission ratio is shown on the display. When the key is pressed constantly the handpieces or contra angles will be shown in fast forward mode.

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 contra angle, 1:5	1 : 5	1500	240,000	1	1	No	–
Drill contra angle, 1:3	1 : 3	900	150,000	1	2	No	–
Drill contra angle, 1:2	1 : 2	600	100,000	1	2	No	–
Drill handpiece, 1:1	1 : 1	300	50,000	1	6	No	–
Drill contra angle, 4:1	4 : 1	75	12,000	1	20	up to 75	75 – 80 *
Drill contra angle, 16:1	16 : 1	20	2,800	5	27	up to 20	20 – 45 *
Drill contra angle, 20:1	20 : 1	15	2,100	10	70	up to 20	15 – 45 *
Drill contra angle, 32:1	32 : 1	10	1,200	10	55	up to 20	10 – 45 *
Drill contra angle, 70:1	70 : 1	5	700	10	55	up to 20	5 – 45 *
Micro saws	Micro Saw	fixed 15,000			fixed 6	No	–
Mucotome	Mucotome	fixed 8,000			fixed 6	No	–
Kirschner handpiece	Kirschner	500	2,800		fixed 6	No	–

* 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, Parameter Level 1, 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 handpieces

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.

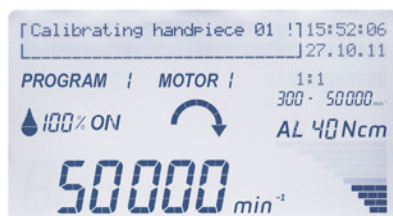
It's a procedure as simple as it is important to guarantee safety and precision of each handpiece or contra angle being used.

After you take care of all prior preparations such as sterilization, maintenance and care of handpieces, device preparation and the selection of the handpiece of use, 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. Hold motor with mounted handpiece or contra angle in your hand at safe distance from your body.
2. Press both «**Speed**» - keys at the same time (**Speed ▲ + ▼**).
3. Motor and handpiece start running and pass several speed cycles up to maximum speed.
4. After a tone is emitted and a message is displayed the calibration is finished.



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 following contra angles (4:1, 16:1, 20:1, 32:1, 70:1) the control unit is additionally adjusted to altered conditions of the contra angle to keep it delivering the appropriate torque.

7.4.3 Step 3: Setting the speed

The possible speed range depends on the attached handpiece or contra angle. 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.





The following handpieces run only with one specific speed, it cannot be changed. The specific rpm values of all handpieces are shown in the table of chapter 7.4.1.

- Micro saws (Micro Compass Saw MSS 5000, Micro Oscillating Saw OMS 5000, Micro Sagittal Saw MOS 5000)
- Mucotome

7.4.4 Step 4: Setting the torque

Once the speed has been selected, the torque can be determined from the corresponding torque range. 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 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 fixed torque only (6 Ncm) and cannot be changed.

- Micro saws
- Mucotome
- Kirschner Handpiece

7.4.5 Step 5: Setting the pump supply quantity

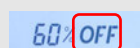
Press the “**Pump**” keys “▲” to increase or “▼” to decrease the pump supply quantity. By pressing the key continuously the values are fast forwarded.



Minimum and maximum of pump supply quantity as well as operating 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 use the foot switch .



7.5 The function of the torque limiter, 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 at the speeds where the AS mode takes effect.

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")

AS	Contra angle	4:1	16:1	20:1	32:1	70:1
	rpm	75	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.

AS	Contra angle	4:1	16:1	20:1	32:1	70:1
	From rpm:	75	20	15	10	5
	To rpm:	80	45	45	45	45
AL	Factory setting rpm.	12000	2800	2100	1200	700

7.7 Storing various programs

With the MD 30, up to 10 different settings can be set per motor as fixed program (program 1 to program 10). Which program is currently active is shown on the display.

At the switch-off of the device, the settings made by the 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 3 to 10 programs.



When the MD 30 is switched on, the display shows the prior used program with the last used Handpiece respectively Contra angle.

7.8 Configuration menu

In the configuration menu the user can customize the device after his needs. The parameters are organized in two levels. The following information can be found in the configuration menu or parameters can be set according to your own needs.

<ul style="list-style-type: none"> • Software version • Mainboard serial number • Date and Time • Display illumination, brightness • Number of programs • Operating hours MD 30 • Operating hours Motor 1 • Operating hours Motor 2 • Operating hours of irrigation pump 	<ul style="list-style-type: none"> • Error-messages (the last 8) • Activation of available handpieces • Speed limitation for each handpiece • Range of action of AS mode • Pump behavior • Motor behavior for 4 different motors • Behavior of torque at reverse mode • Reset to factory default
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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 the configuration menu:

- Press “**Enter**” for about **3 seconds**, until a tone is emitted. On the display the first position of the configuration menu shows up:



The arrows at the beginning of the line indicate the configuration menu.



2. Selection of parameters:

- Choose the desired parameter by pressing “**Select ▲**” or “**Select ▼**”.
- To be able to change the values press “**Enter**”.
- Change the value by pressing “**Select ▲**” or “**Select ▼**”.
- For confirmation of the setting press “**Enter**” for **1 second**, until a tone is emitted.
- To cancel the setting, press the “**Enter**” button **only briefly**. The setting jumps back to the former value.



3. Exit the configuration menu:

- To exit the configuration menu press “**Enter**” for **3 seconds**, until a long tone is emitted.



Parameter Level 1

EN

Group/Parameter	Rights	Factory	Definition
Software/Version	read	VX.XX	Shows current software version
Hardware/Serial number MB	read	XXXXXXXXXX	Shows serial number of the main board
Date-Time/Date format US	read/write	no	Set to US Date format
Date-Time/Date	read/write	–	Change current date
Date-Time/Time	read/write	–	Change current time
Backlight/brightness (0..10)	read/write	9	Display brightness, changeable: 0, ... , 10
Programs/Number of programs	read/write	10	Number of activated Programs: 3, ... , 10
Operating hours/MD 30	read	0	Shows operating hours of MD 30
Operating hours/Motor 1	read	0	Shows operating hours of motor 1
Operating hours/Motor 2	read	0	Shows operating hours of motor 2
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 01	1 : 5	yes/no	no	Deselect handpieces that do not belong to your product range by switching to “no”. This will later shorten the scrolling list for “Handpieces”. Otherwise you will later have to scroll down the complete list of available handpieces, each time you select a handpiece. <i>*Handpiece 1 : 1 cannot be deactivated.</i>
Handpiece existing/HP 02	1 : 3	yes/no	no	
Handpiece existing/HP 03	1 : 2	yes/no	no	
Handpiece existing/HP 04	1 : 1	yes*	yes	
Handpiece existing/HP 05	4 : 1	yes/no	yes	
Handpiece existing/HP 06	16 : 1	yes/no	yes	
Handpiece existing/HP 07	20 : 1	yes/no	yes	
Handpiece existing/HP 08	32 : 1	yes/no	yes	
Handpiece existing/HP 09	70 : 1	yes/no	no	
Handpiece existing/HP 10	Micro Saw	yes/no	yes	
Handpiece existing/HP 11	Mucotome	yes/no	yes	
Handpiece existing/HP 12	Kirschner	yes/no	yes	

Parameter level 2

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

1. Accessing parameter level 2 menu: Press **Enter** briefly.
2. Setting the access code: Press **Speed ▲** to increase, or **Speed ▼** to decrease the value.
3. Confirm access code: Press **Enter for 1 second**, until a tone is emitted.

(for fast forwarding or rewinding keep keys pressed)

Handpiece Max. Speed	Name of handpiece on the display	Speed range rpm	Factory default	Definition
Handpiece max speed/HP 01	1 : 5	1500 – 240,000	240,000	Limit the maximum speed of your handpieces according to your own experience.
Handpiece max speed/HP 02	1 : 3	900 – 150,000	150,000	
Handpiece max speed/HP 03	1 : 2	600 – 100,000	100,000	
Handpiece max speed/HP 04	1 : 1	300 – 50,000	50,000	
Handpiece max speed/HP 05	4 : 1	75 – 12,000	12,000	
Handpiece max speed/HP 06	16 : 1	20 – 2,800	2800	
Handpiece max speed/HP 07	20 : 1	15 – 2,100	2100	
Handpiece max speed/HP 08	32 : 1	10 – 1,200	1200	
Handpiece max speed/HP 09	70 : 1	5 – 700	700	
Handpiece max speed/HP 10	Micro Saw	fix 15,000	15,000	
Handpiece max speed/HP 11	Mucotome	fix 8,000	8000	
Handpiece max speed/HP 12	Kirschner	500 – 2,800	2800	

AS-Zone for handpieces	Handpiece on display	Speed range rpm	Factory default	Definition
Handpiece AS-Mode/HP 05	4 : 1	75 – 80	75	Effective AS-range 75 – 80 rpm
Handpiece AS-Mode/HP 06	16 : 1	20 – 45	20	Effective AS-range 20 – 45 rpm
Handpiece AS-Mode/HP 07	20 : 1	15 – 45	20	Effective AS-range 15 – 45 rpm
Handpiece AS-Mode/HP 08	32 : 1	10 – 45	20	Effective AS-range 10 – 45 rpm
Handpiece AS-Mode/HP 09	70 : 1	5 – 45	20	Effective AS-range 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.

The MD 30 can recognize the type of a plugged-in motor. This enables the adaption of future motors and their safe operation.

Motor type 1	Range	Factory default	Definition
Motor type 1, min. speed	300 – 5,000 rpm	300 rpm	Set the min. speed of motor 2
Motor type 1, max. speed	5000 – 50,000 rpm	50'000 rpm	Set max. speed of motor 2
Motor type 1, Start ramp	1 – 1000 ms/10,000 rpm	100 ms	Set acceleration time to 10,000 rpm
Motor type 1 Stop ramp	1 – 1000 ms/10,000 rpm	50 ms	Set breaking time from 10,000 – 0 rpm

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 – 2,000 ms	500 ms	Time during which torque is raised.

The maximum torque of the motor is boosted at starts and in reverse rotation.

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.



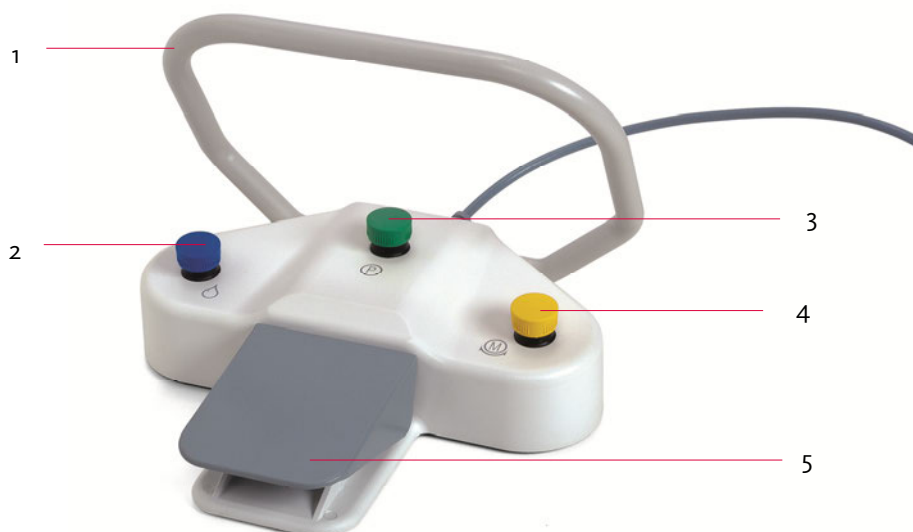
- **Attention:** Upon resetting to factory default all parameters will appear with factory default values (except date and time).
- **Note:** For resetting the “programs” to factory default press both “Select” keys at the same time (“Select ▲ + ▼”). For this procedure you have to be out of the Configuration Menu.




Exit the configuration menu:

- To exit the configuration menu press **“Enter” for 3 seconds**, until a long tone is emitted.



7.9 Operation using the VARIO pedal



1. **Carrying bracket**
The carrying bracket can be operated by foot.
2. **Key **:
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).
3. **Key **:
Pressing the key briefly: switches the program (+1, see information on display).
Pressing the key longer: switches the program (-1, see information on display).
4. **Key **:
Pressing the key briefly: switches the rotational direction (see information on display).
Pressing the key longer: switches the motor (see also the indicator lights beside the motor sockets on the control unit).
5. **Treadplate**
With the treadplate of the 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 (speed as set on the control unit)	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.

The following handpieces run only with one specific speed, it cannot be changed.

- Micro saws
- Mucotome

7.10 Functional check

Prior to MD 30 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 and the green LED for motor 1 lights up.


7.10.1 Electronic 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 up and accelerates to up to 50,000 rpm. When the treadplate is released, the electronic motor slows down again.




- The electronic motor is designed for intermittent duty operation at maximum speed of "1 min ON/3 min OFF" at 4 cycles. 15 minutes brake after.
- 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  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  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.

7.10.4 Program

The required program can be set by repeatedly pressing the key  on the pedal.

8 Cleaning, disinfection and sterilization

The instructions described here are intended for the parts supplied in the set. The cleaning, disinfection and sterilization instructions for extensions and accessories are described in their respective operating instructions.

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.

- It is recommended to include 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 Tubing set, REF 1706 and REF 6025



Single-use tubing sets 1706 and 6025 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 Nougag tubing sets with REF 1706 and REF 6025!



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 a household cleaning agent and then sterilized in accordance with the same instructions as for electronic motor 21.

8.4 Electronic motor 21

For the reprocessing instructions of the Electronic Motor 21, please refer to the operating instructions 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 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 (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 30 shall be executed every 2 years by authorized experts. Results shall be documented.

The service instructions, 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 providers

10 Malfunctions and troubleshooting

Malfunction	Cause	Solution	See 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	Switch main switch "I/O" to position "I", wait 10 sec. and switch back to position "O".	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
	Incorrect motor active	Switching to the other motor, using the VARIO pedal	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 30 Error messages on display"**.

MD 30 Error-messages on Display		
Error-messages/Error Code	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.
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/ User Config & Program	Message while default values of parameters and programs are saved to the MD 30 dongle.	
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.
Motor 2 not connected/ E14	a) Motor 2 is selected but no motor plugged in b) Motor connected to motor socket 2, but motor, motor cable, motor plug or Control Unit is defective.	a) Plug in motor b) Send motor and Control Unit to Service Center.
Motor 1 not connected/ E15	a) Motor 1 is selected but no motor plugged in. b) Motor connected to motor socket 1, but motor, motor cable, motor plug or Control Unit 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.
Unknown motor 1/ E17	a) Motor 1 is selected but wrong motor is plugged in. b) Right motor is connected to motor socket 1, 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.

M2 AS-mode torque reached	If in AS mode, the set maximum torque is reached, motor 2 stops and this message is displayed.	Take your foot off the pedal and step on the pedal again to restart the engine.
M1 AS-mode torque reached	If in AS mode, the set maximum torque is reached, motor 1 stops and this message is displayed.	Take your foot off the pedal and press the pedal again to restart the engine.
Pedal locked/ W26, pedal release	If pedal is pressed at switch on procedure, pedal will not work.	Release pedal for one second.
Battery is almost empty/ W27, continue with „Enter“	Battery is almost empty.	<ul style="list-style-type: none"> - After pressing „Enter“, work can be continued. - Send Control Unit as soon as possible to Service Center.
Watch Error XX/ E28, continue with „Enter“	a) Clock at Control Unit is defective. b) Device was switched on after battery change but clock is not set yet.	a) After pressing „Enter“, work can be continued but Control Unit has to be sent to Service Center as soon as possible. b) Set date and time.
Handpiece XX is faulty/ E29	At calibrating or testing handpiece was over-exposed to high torque.	<ul style="list-style-type: none"> - Clean handpieces / contra-angles with NouvaClean spray and lubricate with NouvaOil 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.	
Calibrating HPXX is Ok!	Calibrated handpiece is OK.	
Testing the handpiece XX	Handpiece is testing.	
Calibrating handpiece XX!	Handpiece is calibrating.	
NouDongle is plugged in	This message is displayed for 1 second after the NouDongle was plugged in.	

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
Single-use tubing set with integrated 3 way cock, 2 m, sterile, 10-unit pack -----	6025
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 interior cleaning spray for handpieces and contra angles -----	2127
NouvaOil, interior lubrication spray for handpieces, contra-angles and electronic motors -----	2128
Spray adapter for the E-coupling of the electronic motor 21 -----	19584

User Manual for MD 30 ----- 31686

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.

Handpieces and contra angles

1:3 handpiece, for instruments with 44 mm length of shaft, Ø 2.35 mm, ISO3964 coupling, 900-150,000 rpm -	1047nou
1:1 contra angle, for instruments with dental shaft, Ø 2.35 mm, ISO3964 coupling, 300-50,000 rpm -----	5051nou
2:1 contra angle, for instruments with dental shaft, Ø 2.35 mm, ISO3964 coupling, 150-25,000 rpm -----	5109nou
16:1 contra angle, for instruments with dental shaft, Ø 2.35 mm, ISO3964 coupling, 20-2,800 rpm -----	5200nou
20:1 contra angle, for instruments with dental shaft, Ø 2.35 mm, ISO3964 coupling, 15-2,100 rpm -----	5053nou
32:1 contra angle, for instruments with dental shaft, Ø 2.35 mm, ISO3964 coupling, 10-1,200 rpm -----	5201nou
70:1 contra angle, for instruments with dental shaft, Ø 2.35 mm, ISO3964 coupling, 5-700 rpm -----	5065nou
20:1 LED-contra angle, for instruments with hexagonal shaft, Ø 2.35 mm, ISO3964 coupling, 15-2,100 rpm -----	5052nou

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

12 Information on disposal



When disposing of the device, device components and accessories, the statutory regulations must be followed.

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 is 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 control units with household waste! To protect the environment, old devices can be returned to the dealer or the 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**

Appendix **EN**

Appendice **FR**

Appendice **IT**

Apéndice **ES**

Appendix **NL**

Aneks **PL**

Apendix **SK**

Appendix **CZ**

Függelék **HU**

KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY / DECLARATION DE CONFORMITE / DICHIARAZIONE DI CONFORMITA / DECLARACIÓN DE CONFORMIDAD

Wir, die Firma
We, of the company
Nous, la firme
Noi, della ditta
Nosotros, la empresa

NOUVAG AG
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CH-9403 Goldach
Switzerland

erklären in alleiniger Verantwortung, dass das Medizinprodukt
declare on our own responsibility that the medical device
déclarons sous notre propre responsabilité que le dispositif médical
dichiariamo sotto propria responsabilità che il dispositivo medico
declaramos bajo nuestra propia responsabilidad que el dispositivo médico

MD 30 SET (REF 2004 / 2005 / 2007 / 2008 / 2009 / 2016)

REF	Bezeichnung / Description	Klassifizierung nach MDD / Classification acc. MDD
3330	Steuergerät MD 30 / Control unit MD 30	Ila
1706	Schlauchset / Tubing set	Ila
5052nou	Winkelstück 20:1 LED / Contra angle 20:1 LED	Ila
5053nou	Winkelstück 20:1 / Contra angle 20:1	Ila
5200nou	Winkelstück 16:1 / Contra angle 16:1	Ila
5201nou	Winkelstück 32:1 / Contra angle 32:1	Ila

allen Anforderungen der Medizinprodukte-Richtlinie 93/42/EWG entspricht.
meets all the provisions of the medical directive 93/42/EEC which apply to him.
remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE qui le concernent.
adempie a tutte le esigenze della direttiva 93/42/CEE che lo riguardano.
cumple con todos los requisitos establecidos en la Directiva Médica 93/42/CEE que le corresponden.

Konformitätsbewertungsverfahren
Conformity assessment procedures
Procédure d'évaluation de la conformité
Procedimento di valutazione della conformità
Procedimiento de evaluación de la conformidad

93/42/EWG, Anhang II
93/42/EEC, Appendix II
93/42/CEE, Appendice II
93/42/CEE, Appendice II
93/42/CEE, Apéndice II

Gültigkeitsdauer Konformitätserklärung
Validity of declaration of conformity
Durée de validité de la déclaration de conformité
Durata della validità della dichiarazione di conformità
Tiempo de validez de la declaración de conformidad

**26. Mai 2024 (Gültigkeit EG-Zertifikat
Reg.-Nr. HD 1709948-1)**

Benannte Stelle / Notified body / Organisme notifié /
Organismo notificato / Organismo notificado

TÜV Rheinland LGA Products GmbH
Tillystrasse 2
DE-90431 Nürnberg



Goldach, 27.01.2021
Ort, Datum / place, date
lieu, date / luogo, data / lugar, fecha


W. Miesch, CEO

Electromagnetic compatibility (EMC)

Remark:

The **Product** subsequently referred to herein always denotes the MD 30.

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 – 50'000 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 1510nou	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) 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.			

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