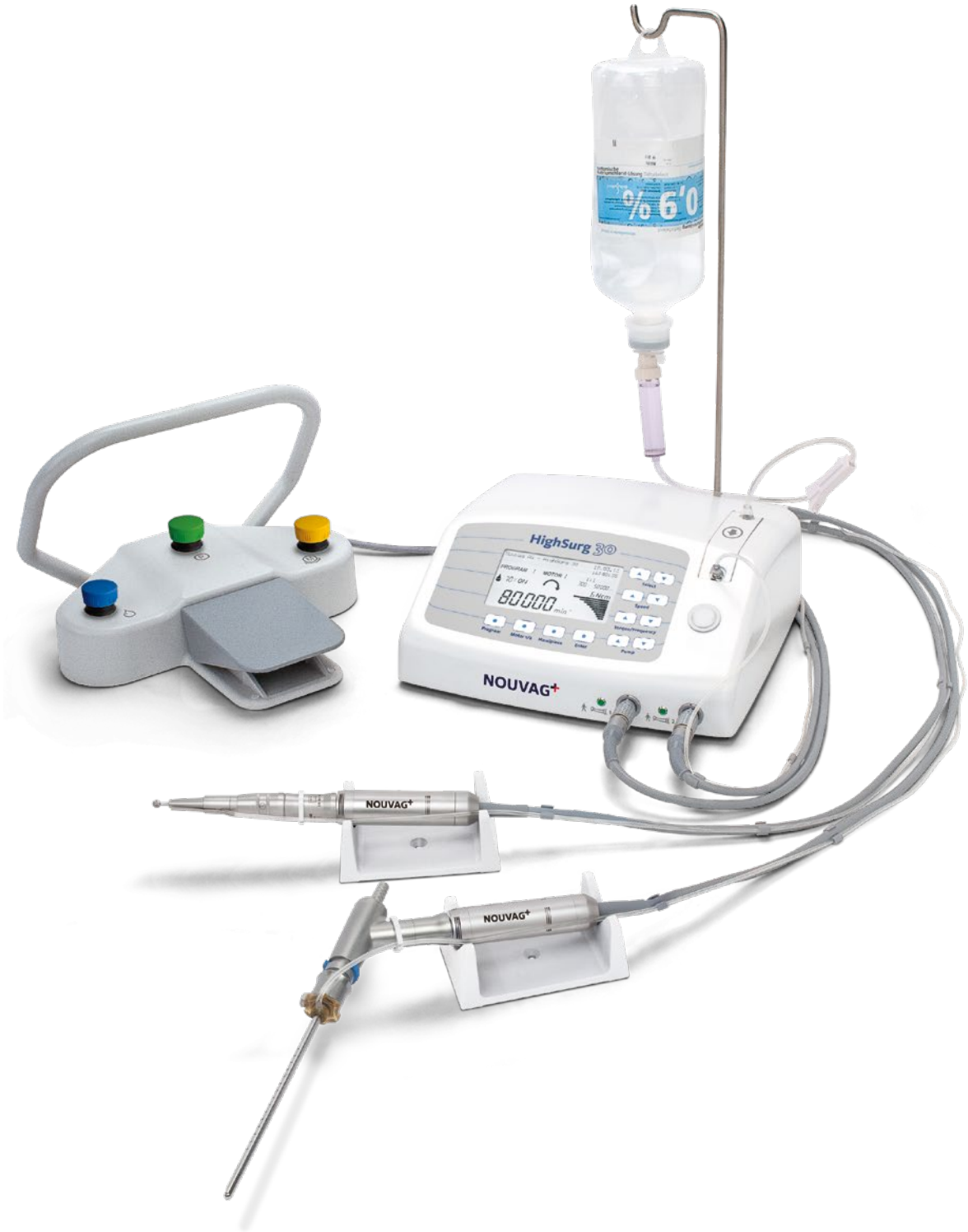
EN

Instructions for use

HighSurg 30

NOUVAG



CONGRATULATIONS ON YOUR PURCHASE OF A PRODUCT FROM NOUVAG.

We are pleased that you have chosen a quality product from NOUVAG and thank you very much for the trust you have placed in us.

These instructions for use will familiarize you with the device and its functions so that you can apply and use them correctly.

SYMBOLS

 General warning sign	 General mandatory action	 Refer to instructions for use
 Manufacturer	 Date of manufacture	 Distributor
 Use-by date	 Separate collection required (WEEE)	 Biological hazard
 Do not use if package is damaged	 Not for reuse	 Contains or Presence of Phthalate
 Batch code	 Catalog number	 Serial number
 Medical device	 Authorized representative in the European Community	 Sterilized using ethylene oxide
 Type BF applied parts are the instruments used	 Autoclavable at 134°C	 For thermal disinfection
 Indication of pump flow direction	 Equipotentiality	 Foot switch
 Protective ground	 Socket for motor 1	 Socket for motor 2
IPX8 Water resistance	CE 0197 European Conformity mark	
 Certified by the TÜV Rheinland North America Group		

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INTENDED PURPOSE

MEDICAL INDICATIONS

The HighSurg 30 is a control unit which is used in combination with an electronic motor, handpieces, sterile single use tubing set (independent medical devices) to perform surgery in the following medical indications:

// **Plastic surgery**
// **Spinal surgery**
// **Head, neck and cranial surgery**
// **ENT surgery**
// **Hand and foot surgery**
// **Microsurgery**

CONTRAINDICATIONS

Relative or absolute contraindications can arise from the general medical diagnose, or in special cases by a significantly increased risk to the patient using powered instruments. General contraindications concern patient health status, such as severe cardiopulmonary disease, local inflammation, sepsis, and coagulation disorders. Relevant cases in the literature must be taken into consideration.

SIDE EFFECTS

Side effects of the control unit are related to the specific application. The following known side effects may occur (non-exhaustive list):

¬ Damages (such as bleeding, cerebrospinal fluid leak, orbital injury, eye injury, etc.)
¬ Nerves injury by mechanical or thermal hazard
¬ Thermal necrosis
¬ Inflammation
¬ Hearing loss
¬ Introduction of foreign particles in the skin (allergic reaction)
¬ Pain
¬ Post-surgical complications (surgical wound infection; anastomotic leak; deep vein thrombosis; surgical mortality)

INTENDED USERS

The device is designed to be used by professional and trained users only, in professional contexts (e.g., hospital, clinic). The device is not to be used by patients or by untrained users.

TARGET POPULATION

Not limited by age and gender. See contraindications for limiting health factors.

AMBIENT CONDITIONS

	TRANSPORT AND STORAGE	DURING USE
Relative humidity	max. 90 %	max. 80 %
Temperature	0 °C – 50 °C	10 °C – 30 °C
Atmospheric pressure	700 – 1’060 hPa	800 – 1’060 hPa

SAFETY INFORMATION

Every use of the HighSurg 30 different to the [Intended purpose >4] 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.

INDICATIONS

The use of the devices outside of the intended purpose is prohibited.
Non intended modifications to the control unit and accessories are not allowed.
Use of third party's devices and accessories not indicated by NOUVAG is not allowed.
Repairs must only be performed by authorized NOUVAG service centres.
Devices and accessories must be perfectly operational before use.
Ensure that the operating voltage settings correspond to the local main voltage.
Before use, read thoroughly all instructions for use of the devices and accessories.

WARNINGS

Do not use the device if the shipping box has holes/cracks on the flat surfaces, and/or if the Styrofoam protective packaging is broken.
The reprocessing instructions must be followed to the letter. Deviations can cause malfunctions of the devices and hazard to patients' health, users, and third party.
Devices must be cleaned and disinfected before and after each use.
All sterilizable parts and accessories must be sterilized before use.
Devices must be operated outside the danger zone of explosives and flammable mixtures, or gases.
Instruments must be removed only when handpiece is completely still.
The devices and accessories ventilation slots must be kept clear to avoid overheating.
Disregarding the indication of intermittent operation of the handpiece may lead to patient's burns on contact.
High speeds and high application pressure may cause thermal necrosis of patient's tissue.
Only 0.9% NaCl physiological solution must be used as instrument's cooling liquid.

SCOPE OF DELIVERY

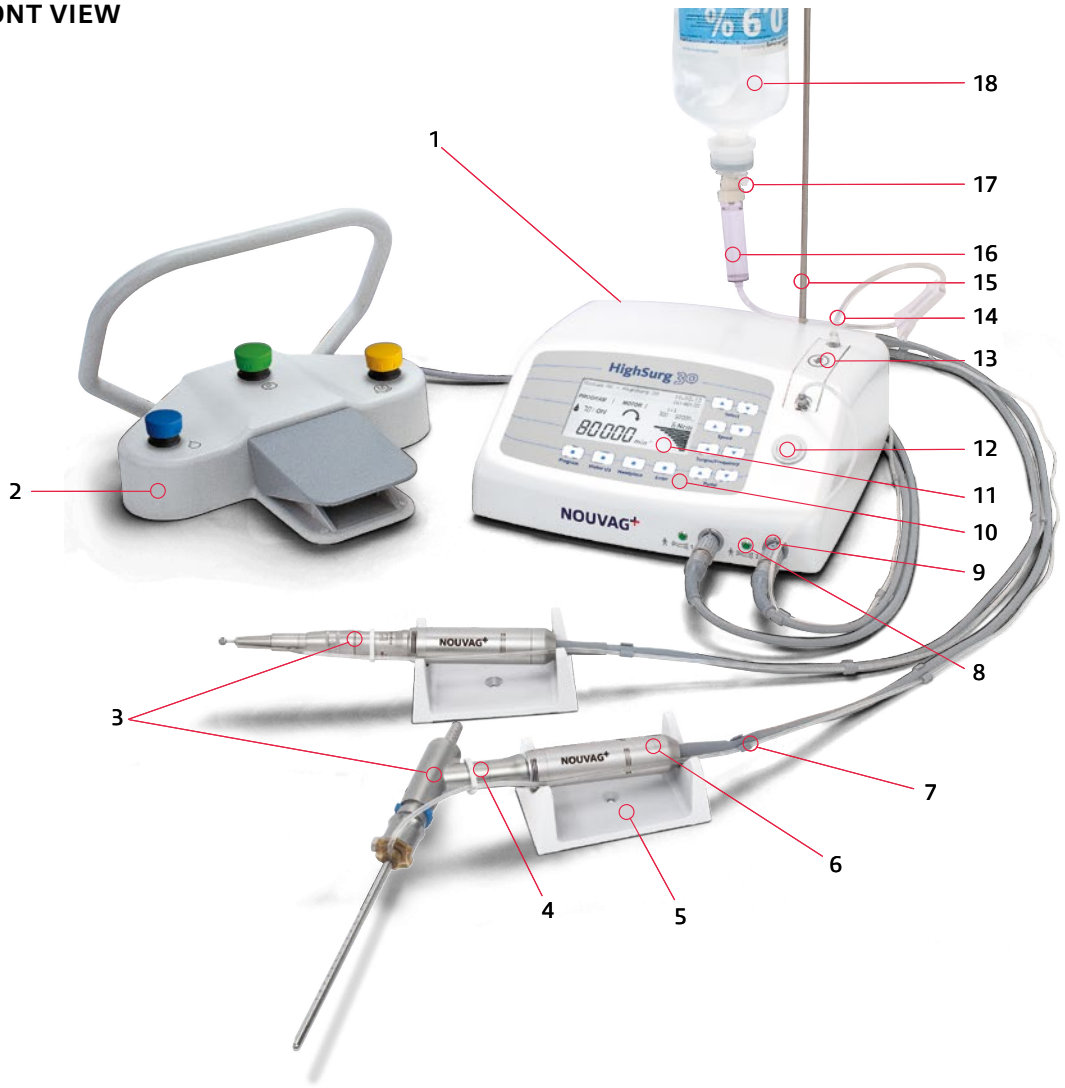
REF	DESCRIPTION	QUANTITY
3360	HighSurg 30 control unit	1
1510nou	VARIO foot switch	1
2099nou	Electronic motor 21, 50'000 rpm	1
6024	Disposable tubing set, sterile, 3 m	1
6025	Disposable tubing set three-way valve, sterile, 3 m	1
1873	Clip set, for tube set attachment to motor cable, PU 10 pcs.	1
1770	Stand for irrigation fluid bottle	1
1170	Handpiece tray	1
19584	Spray adapter with thread, for lubricant spray (REF 2128)	1
31666	HighSurg 30 instructions for use	1

OPTIONAL

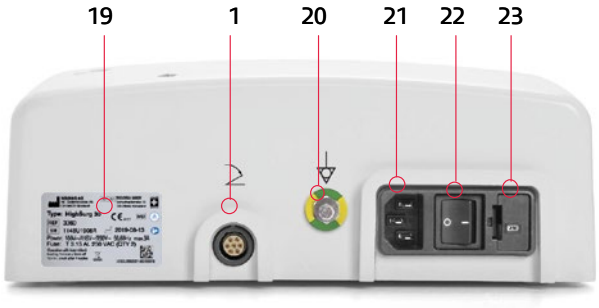
REF	DESCRIPTION	QUANTITY
2098nou	Electronic motor 21, 80'000 rpm	1

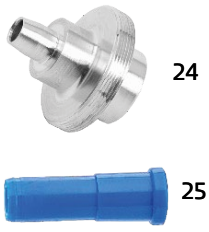
DEVICE OVERVIEW

FRONT VIEW



REAR VIEW





1 Pedal socket (device rear) **2** VARIO pedal **3** Handpiece (not included in delivery) **4** Clip for tubing set attachment to handpieces and contra angles **5** Handpiece cradle **6** Electronic motor (delivery includes 1 motor) **7** Clip for tubing set attachment to motor cable **8** Indicator light for each motor socket **9** Motor sockets (2) **10** Operating panel **11** Display **12** Release key for tubing set bracket **13** Peristaltic pump **14** Tubing set **15** Stand for irrigation fluid bottle **16** Drip chamber **17** Bleed valve **18** Bottle with irrigation fluid **19** Type plate with type designation, reference number, serial number, information on power supply and device fuse **20** Potential equalization connection **21** Power plug socket **22** Main switch **23** Fuse compartment **24** Threaded spray adapter for the lubrication of the electronic motor (REF 19584) **25** Spray nozzle (blue)

SETUP

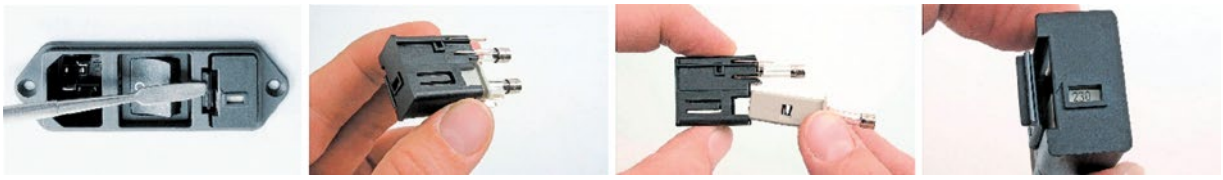
DEVICE AND ACCESSORIES SETUP

- ¬ Place the HighSurg 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 near other devices is prohibited due to EMC.
- ¬ Do not allow the operating range of the device and accessories to be compromised by limiting factors.
- ¬ The system display must be always fully visible.
- ¬ 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 always accessible.
- ¬ The motor ventilation slots must be kept clear to prevent the motor from overheating.

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:



1 **Unplug the power cable.**

2 **Use a screwdriver to open the fuse slot.**

3 **Remove the fuse holder.**

4 **Remove the grey fuse holder and reinsert it so that the local mains voltage setting is shown in the small window.**

5 **Slide fuse holder back in and close the fuse slot.**

6 **Check the mains voltage shown on the fuse slot.**

7 **Plug the power cable back into the device.**

⚠ To prevent of risks of an electric shock, the device may only be connected to a power network with a PE protective ground conductor.

SETUP

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 of the control unit.**

3 **Plug the motor plug of the electronic motor into one of the motor sockets.**

4 **Where appropriate, plug the motor plug of a second electronic motor into a motor socket.**

If you want to use a handpiece with the 80'000 rpm high speed motor and change its parameter, then the motor must be plugged-in in one of the motor sockets. Otherwise only the values of the standard 50'000 rpm motor will be displayed.

Note: Always plug in the motor first, then change the parameters of the selected handpiece.

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. Check the correct seating by a slight counter movement of the handpiece.**

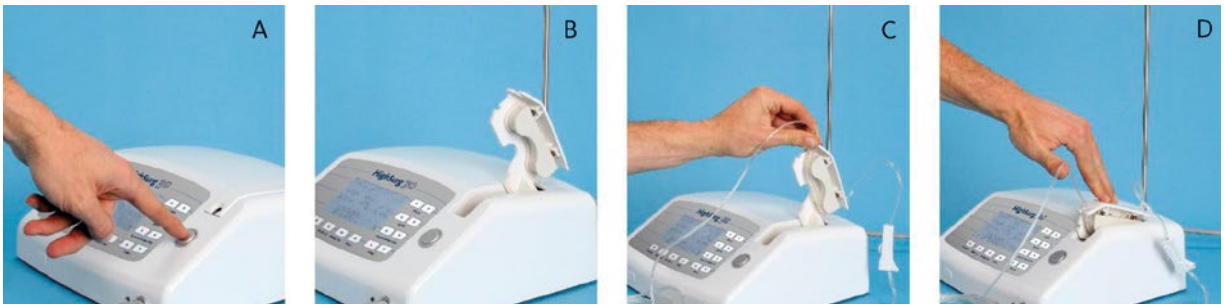
7 **Assembling of the tubing set: Decide whether you will use the tubing set REF 6024, for the cooling of a single handpiece or if you need to use the tubing set REF 6025 with an integrated 3 way tap for cooling two handpieces at the same time with the use of two motors.**

Use only NOUVAG tube sets REF 6024 and REF 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 cause death.

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 HighSurg 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. [Step 5 Setting the pump supply quantity >16]



A **Press the release key for tubing set bracket to open the pump.**

B **The compartment with the integrated tubing bracket opens.**

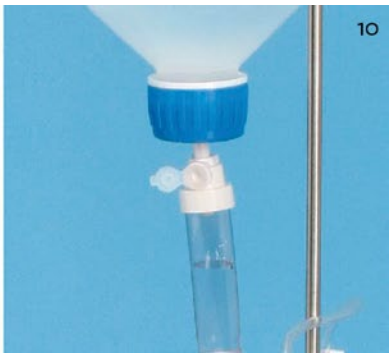
C **Place the tubing set into the tubing bracket provided in such a way that the end of the tubing set with the spike exits the pump to the rear of the control unit. Check that the tubing is secure.**

D **With the tubing set inserted, press the compartment downwards until it clicks into place.**

SETUP

8 **Insert the spike at the end of the tubing set into the irrigation fluid bottle and hang the bottle onto the stand.**

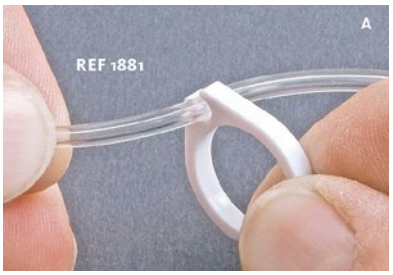
9 **Open the roller clamp on the tubing set as far as it will go.**



10 **Open the bleed valve beneath the drip chamber.**

11 **Connect the control unit to the power socket.**

ASSEMBLY OF EXTERNAL IRRIGATION SYSTEM



A **Secure handpiece clips to the irrigation tube.**

B **Connect the tube set with the external cooling tube of the Instrument (Example: Shaver blade).**

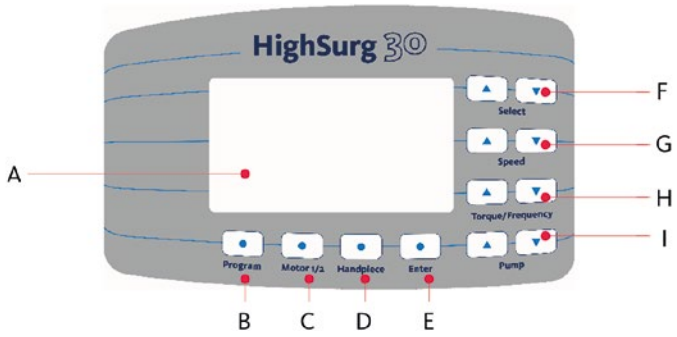
C **Secure clips to the handpiece.**

OPERATION

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.

OVERVIEW: CONTROL ELEMENTS ON THE OPERATION PANEL



A **Display** — *Shows the operating values.*
[Overview: Standard Display >12]

B **«Program» key** — *Selection of program 1 to 10.*
There are multiple programs for each motor selectable.
To keep the overview, the number of selectable programs can be limited in the configuration menu.
[Parameter | Level 1 >18]

C **«Motor 1/2» key** — *Switching between the connected motors.*
The green indicator lights beside the motor sockets indicate the active motor.
Pressing the key longer changes the direction of rotation.

D **«Handpiece» key** — *Choice of handpieces or contra angle.*
Can be individually deactivated
[Configuration Menu >17]

E **«Enter» key** — *Used in the configuration menu.*
[Configuration Menu >17]

F **«Select» keys**
By pressing the «Select ▲» key, the software version is displayed.
By pressing the «Select ▼» key, the type of connected motor is displayed.
By pressing both «Select ▲» and «Select ▼» keys simultaneously, the programs will be reset to factory default settings.
In the configuration menu, these keys are used to change values and parameters:
«▲» value adjustment upwards
«▼» value adjustment downwards

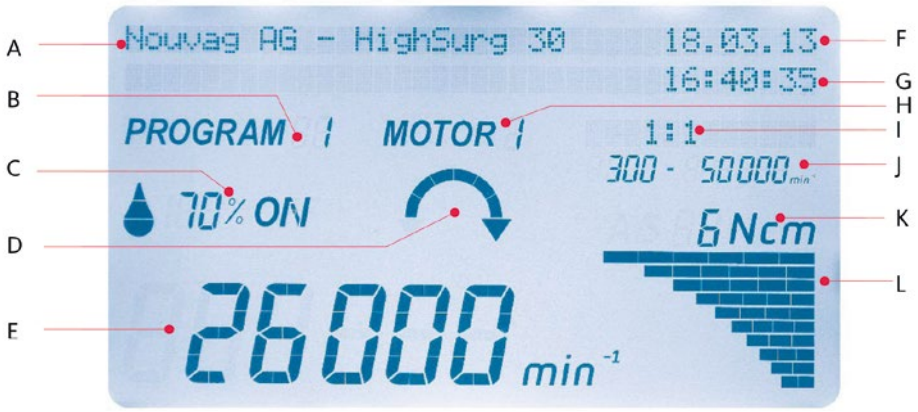
G **«Speed» keys** — *Restrict the maximum speed that can be selected using the pedal.*
«▲» increases the maximum speed
«▼» reduces the maximum speed
By pressing both «Speed ▲» and «Speed ▼» keys simultaneously, the handpiece calibration will be started.
[Step 2 Test of handpiece and contra angle >14]

H **«Torque/Frequency» keys** — *Restricts the maximum torque.*
«▲» increases the maximum torque
«▼» reduces the maximum torque
With the shaver handpiece attached the key pair is used to set the oscillation period, if oscillation mode is selected.

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 ▲» and «Pump ▼» keys simultaneously, the pump will be put on call, pressing again will switch it off.

OPERATION

OVERVIEW: STANDARD DISPLAY



A **Information line** — *Information and error messages are displayed here.*
Display is illuminated red when error messages are displayed.

B **Program** — *Shows selected number of the 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 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 «(M)» on the pedal or by long pressing of the «Motor 1/2» key at the operating panel.
In oscillating Shaver mode both arrows are displayed at the same time, which symbolizes the oscillation mode of the shaver.

E **Current speed** — *At stand still of the motor the set maximum speed is displayed.*
As the motor starts to run when the pedal is pressed, the evolving speed is shown in real-time.

F **Date**

G **Clock**

H **Motor** — *Shows selected motor.*
Also confirmed by the green LEDs next to each of the motor sockets.

I **Name of the handpiece or corresponding transmission ratio** — *Shows name of the handpiece used or the selected transmission ratio.*
[Step 1 Selecting handpiece or transmission ratio >13]

J **Speed range** — *Shows speed range of the handpiece used.*

K **Maximum torque** — *Shows maximum torque setting.*

L **Current torque** — *Bar graph providing a graphical representation of the current torque.*
All bars active means max. torque reached.

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

For handpieces with a selected speed greater than 50'000 rpm, the warning W34 appears for 1 second and the display lights up red. The user is reminded not to exceed the maximum speed of the handpiece.

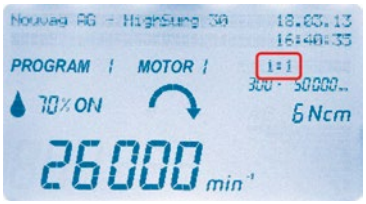
OPERATION

ADJUSTING THE PROGRAMS

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

STEP 1 SELECTING HANDPIECE OR TRANSMISSION RATIO

Depending on the handpiece or contra angle attached to the motor, the corresponding transmission ratio must be adapted accordingly by using the key «Handpiece».



1 **Press the «Handpiece» key repeatedly until the name of the required handpiece with the corresponding transmission ratio is shown on the display.**
When the key is pressed constantly the handpieces will be shown in fast forward mode.

POSSIBLE HANDPIECES 50'000 rpm MOTOR

HANDPIECE NAME WITH TRANSMISSION RATIO	HANDPIECE NAME ON DISPLAY	SPEED MIN. rpm	SPEED MAX. rpm	TORQUE MIN. Ncm	TORQUE MAX. Ncm
Handpiece, 1:5	1 : 5	1'500	240'000	fix 1	fix 1
Handpiece, 1:3	1 : 3	900	150'000	1	2
Handpiece, 1:2	1 : 2	600	100'000	1	2
Handpiece, 1:1	1 : 1	300	50'000	fix 6	fix 6
Micro saws (Com., Osc., Sag.)	Micro Saw	fix 15'000	fix 15'000	fix 6	fix 6
Dermatome	Dermatome	fix 14'000	fix 14'000	fix 6	fix 6
Kirschner Handpiece	Kirschner	500	2'800	fix 48	fix 48
Jacobs Chuck	Jacobs Chuck	200	2'600	fix 60	fix 60
Perforator	Perforator	80	900	fix 120	fix 120
Craniotome	Craniotome	1'000	50'000	fix 6	fix 6
Handpiece 4:1	4 : 1	200	12'000	1	18

The Shaver parameters are listed in a separate table.

POSSIBLE HANDPIECES 80'000 rpm MOTOR

HANDPIECE NAME WITH TRANSMISSION RATIO	HANDPIECE NAME ON DISPLAY	SPEED MIN. rpm	SPEED MAX. rpm	TORQUE MIN. Ncm	TORQUE MAX. Ncm
Handpiece, 1:5	1 : 5	1'500	240'000	fix 1	fix 1
Handpiece, 1:3	1 : 3	900	150'000	fix 1	fix 1
Handpiece, 1:2	1 : 2	600	100'000	fix 2	fix 2
Handpiece, 1:1	1 : 1	300	80'000	fix 3	fix 3
Jacobs Chuck	Jacobs Chuck	200	2600	fix 35	fix 35
Perforator	Perforator	80	1200	fix 80	fix 80
Craniotome	Craniotome	1'000	60'000	fix 3	fix 3

OPERATION

SHAVER FUNCTIONS 50'000 rpm AND 80'000 rpm MOTORS

HANDPIECE NAME WITH TRANSMISSION RATIO	HANDPIECE NAME ON DISPLAY	SPEED MIN. rpm	SPEED MAX. rpm	OSCILLATION PERIOD FROM ... seconds	OSCILLATION PERIOD TO ... seconds
Continuous Shaver	Cont. Shaver	300	6000	–	–
Oscillating Shaver	Osc. Shaver	300	5000	0.20	3.00

The oscillation period for oscillating shavers is determined by the speed. If the oscillation period is set too low for the set speed, it switches automatically to the next possible level. This ensures that the shaver knife makes a full rotation for the speed setting.

Handpieces that don't belong to one's own assortment can be deactivated in the Configuration Menu [PARAMETER | LEVEL 1 >18], «Handpiece existing». That makes finding the right handpiece in the handpiece list easier, because the list of available handpieces becomes shorter.

STEP 2 TEST OF HANDPIECE AND CONTRA ANGLE

To make sure the handpieces work in perfect condition, the HighSurg 30 can check them in a test run for their torque behavior. This is a simple procedure, which helps to detect disorders and defects in the handpieces at an early stage, to ensure safety during application to the patient.
After you take care of all prior preparations such as sterilization, maintenance and care of handpieces, device preparation and the selection of the handpiece in use, the test procedure can be performed.

1 **Select the correct handpiece, corresponding to the one mounted on the motor and double check on the display for correct selection.**

2 **Hold motor with mounted handpiece in your hand at safe distance to your body.**

3 **Press both «Speed ▲» and «Speed ▼» keys simultaneously.**
«Testing the handpiece XX» is displayed.

Motor and handpiece start running and pass several speed cycles up to maximum speed.
After a tone is emitted, the test is finished. The display shows the message «Handpiece is OK».

If a handpiece does not work within the parameters of the test procedure, even after cleaning and lubrication, the device displays a red-illuminated error message: «Handpiece XX is faulty». This indicates insufficient lubrication, soiling, wear, or a technical defect. Such handpieces must be repaired or replaced.

OPERATION

STEP 3 SETTING THE SPEED

The possible speed range depends on the attached handpiece. The maximum speed within this speed range can be restricted to the required value. Using the pedal, the speed can be varied from the minimum speed up to the maximum speed as set.

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

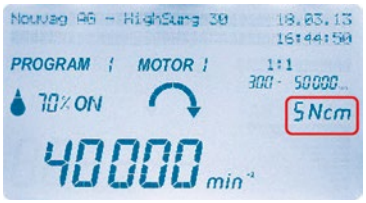
The following handpieces run **only with one specific speed**, which cannot be changed:
// Micro Saws (Oscillating Saw, Sagittal Saw, Compass Saw)
// Dermatoms

The specific rpm values of all handpieces are shown in the tables [POSSIBLE HANDPIECES 50'000 RPM MOTOR >13] and [POSSIBLE HANDPIECES 80'000 RPM MOTOR >13].

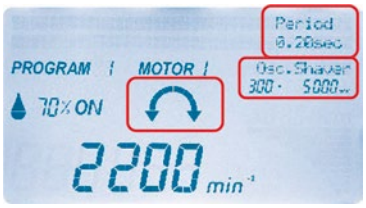
STEP 4 SETTING THE TORQUE

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

1 **Press «Torque/Frequency ▲» to increase or «Torque/Frequency ▼» to decrease the maximum torque range.**
By pressing the key continuously, the torques are shown in fast forward mode.



When using the Shaver handpiece in oscillation mode, this pair of keys is used to set the time required for one revolution of the shaver blade (time for a complete rotation of the shaver blade). In this function, the arrow indicates both directions.



The following handpieces run on a fixed torque:
// Handpiece 1:5 (1 Ncm) // Handpiece 1:1 (6/3 Ncm)* // Micro Saws (6 Ncm) // Dermatome (6 Ncm)
// Kirschner Handpiece (48 Ncm) // Continuous Shaver (12/12 Ncm)* // Oscillating Shaver (12/12 Ncm)*
// Perforator (120/80 Ncm)* // Jacobs Chuck (60/35 Ncm)* // Craniotome (6/3 Ncm)*

* The value before the slash refers to the use with the 50'000 rpm motor, the value after the slash to the 80'000 rpm motor. With the 80'000 rpm motor all the torques are fixed.

OPERATION

STEP 5 SETTING THE PUMP SUPPLY QUANTITY

1 **Press «Pump ▲» to increase or «Pump ▼» 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 [Parameter | Level 2 >19], «Pump».

To activate or deactivate the pump, press both «Pump ▲» and «Pump ▼» keys simultaneously or use the foot switch.

TORQUE LIMITER

The device has an automatic torque limiter, which functions like a torque wrench. If the attached instrument meets resistance, the torque increases as far as the maximum level and the speed then reduces, if necessary to standstill. The torque on the instrument is maintained. If the load on the instrument reduces, the speed increases again up to the set maximum level.
This process can easily be seen on the display by means of the bar chart. The segments of the bar chart fill up as the resistance on the instrument increases. When the torque has reached the set maximum, that is, when all segments are visible, the speed reduces. As soon as the pressure on the instrument is reduced, the torque falls again. The bar chart on the display regresses and the instrument speed increases again.

PROGRAM MEMORY

When switching the HighSurg 30 off, all the settings, made by the user are automatically stored in each program place. At switch off from the HighSurg 30 all the settings made by the user are automatically stored in each program place. The display shows every setting of the selected program place. The following parameters are automatically stored:

// Handpiece/Transmission ratio // Maximal speed // Maximal torque // Pump On/Off // Pump performance
// Shaver oscillation period

To change a program, go to the specific parameter and change it. When the device is switched off all parameters are automatically stored under the same program number.

In the configuration menu the number of storable programs can be limited for each motor separately.
In the configuration menu it can be chosen what the display shows at start-up of the device. Choose between Program 1 with Motor 1 or the last used setting before the device was switched off.

NUMBER OF AVAILABLE STORING PLACES FOR EACH MOTOR AND BOTH MOTOR CONNECTION

MOTOR TYPE	MOTOR CONNECTION 1		MOTOR CONNECTION 2	
	Available storing places	Factory default	Available storing places	Factory default
Motor 21, 50'000 rpm	3 – 10	10	3 – 10	10
Motor 21, 80'000 rpm	1 – 7	6	1 – 7	6

OPERATION

CONFIGURATION MENU

In the Configuration Menu the user can customize the device after his favor. The parameters are organized in two levels. «Parameter Level 1» comprises all basic information and possible settings that affect the device itself. «Parameter Level 2» includes all information and settings that involve the surgeon's work. In the configuration menu the following information can be obtained, or parameters can be set according to one's own needs:

- Software version
- Mainboard serial number
- Date formats US.
- Date
- Time
- Battery voltage
- Language, DE/EN
- Display brightness
- Number of programs for 50'000 rpm motor
- Number of programs for 80'000 rpm motor
- Number of programs for Motor 16 OTO-Drill
- Behavior after switching on
- Operating hours HighSurg 30
- Operating hours Motor 1
- Operating hours Motor 2
- Operating hours of irrigation pump
- Error-messages (the last 8)
- Activation of available handpieces (14 pos.)
- Enter Password
- Speed limitation for each handpiece
- Pump behavior (10 pos.)
- Motor behavior for 50'000 rpm motor
- Motor behavior for 80'000 rpm motor
- 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 must be verified and tested.

ACCESS TO CONFIGURATION MENU

1 **Press «Enter» key for 3 seconds until a long tone is emitted.**
The right arrow «>» in the information line on the display indicates that you're in the Configuration Menu.

CHANGING CERTAIN PARAMETERS

1 **Choose the desired parameter by pressing «Select ▲» or «Select ▼».**

2 **Press «Enter» to activate setting mode.**
The value of the parameter is now displayed in parentheses [XX].

3 **To change the value press «Select ▲» or «Select ▼».**

4 **To confirm the changes made, press «Enter» for 1 second, until a short tone is emitted.**

5 **To abort the settings made, press «Enter» briefly.**
The setting returns to its previous value, without emitting a tone.

EXIT FROM CONFIGURATION MENU

1 **To leave the Configuration Menu press «Enter» for 3 seconds, until a long tone is emitted.**

OPERATION

PARAMETER | LEVEL 1

GROUP/PARAMETER	RIGHTS	FACTORY DEFAULT	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
Battery/Voltage	read	e.g. 3120 mV	State of charge of battery (Capacity about 3100 mV, Low 1800 mV)
Language/0 = German, 1 = English	read/write	1	Change display language between German and English
Backlight/brightness (0. .10)	read/write	9	Display brightness, variable: 0, … , 10
Program/No. of Prog. M21-50'000	read/write	10	Number of activated Programs: 3, … , 10, for the 50'000 rpm motor
Program/No. of Prog. M21-80'000	read/write	6	Number of activated Programs: 1, … , 7 for the 80'000 rpm motor
Program/No. of Prog. M16	read/write	1	Number of activated Programs: 1, … , 3
Program/Power on at last program	read/write	Yes	No: Display of Motor 1 with Program 1 Yes: Display of the last used program/motor
Operating hours/Control unit	read	XX:XX:XX	Shows operating hours of HighSurg 30
Operating hours/Motor 1	read	XX:XX:XX	Shows operating hours of motor 1
Operating hours/Motor 2	read	XX:XX:XX	Shows operating hours of motor 2
Operating hours/Pump	read	XX:XX:XX	Shows operating hours of pump
Error memory/ 1 – 8	read	X	8 Error messages in chronological order. [Error-messages on Display >26]

HANDPIECE ACTIVATION	HANDPIECE NAME 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.
Handpiece existing/HP 02	1 : 3	yes / no	yes	
Handpiece existing/HP 03	1 : 2	yes / no	no	
Handpiece existing/HP 05	Micro Saw	yes / no	yes	
Handpiece existing/HP 06	Dermatome	yes / no	yes	
Handpiece existing/HP 07	Kirschner Hp	yes / no	yes	
Handpiece existing/HP 08	Tattoo Hp	yes / no	no	
Handpiece existing/HP 09	Cont.Shaver	yes / no	yes	
Handpiece existing/HP 10	Osc.Shaver	yes / no	yes	
Handpiece existing/HP 11	Jacobs Chuck	yes / no	yes	
Handpiece existing/HP 12	Perforator	yes / no	yes	
Handpiece existing/HP 13	Craniotome	yes / no	yes	
Handpiece existing/HP 14	4 : 1	yes / no	no	
Handpiece existing/HP 16	Articulated	yes / no	yes	

Because HP 04, 1:1 is permanently active, it's not listed in this table.
HP 15, OTO drill motor handpiece is also always activated and therefore does not appear on this list.

OPERATION

PARAMETER | LEVEL 2

Values in Parameter Level 2 can only be adjusted after the password «9403» was entered. The password cannot be changed.

Entering Password

1 **Press «Enter».**

2 **Press «Select ▲» or «Select ▼». For fast forward or backward keep key pressed.**

3 **To confirm press «Enter» for 1 second, until a tone is emitted.**

HANDPIECE MAX. SPEED	HANDPIECE NAME ON DISPLAY	SPEED RANGE rpm	FACTORY DEFAULT	DEFINITION
Handpiece max speed/HP 01	1 : 5	1'500 – 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 – 80'000	80'000	
Handpiece max speed/HP 07	Kirschner Hp	500 – 2'800	2'800	
Handpiece max speed/HP 08	Tattoo Hp	9'000 – 12'000*	12'000	
Handpiece max speed/HP 09	Cont.Shaver	300 – 6'000	6'000	
Handpiece max speed/HP 10	Osc.Shaver	300 – 5'000	5'000	
Handpiece max speed/HP 11	Jacobs Chuck	200 – 2'600	2'600	
Handpiece max speed/HP 12	Perforator	80 – 1'200	1'200	
Handpiece max speed/HP 13	Craniotome	1'000 – 60'000	60'000	
Handpiece max speed/HP 14	4 : 1	200 – 12'000	12'000	
Handpiece max speed/HP 15	OTO-Drill Hp	1'000 – 16'000	16'000	
Handpiece existing/HP 16	Articulated	yes / no	yes	

* Speed selection in 4 steps: 9'000, 10'000, 11'000 and 12'000 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%	1%	Adjustment steps in section 1
Pump/Range 1 end	5 – 50%	20%	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
Pump switch mode on/off	No / Yes	No	No: Pump starts simultaneously with the handpiece drive. Yes: Pump starts separately by pressing the foot switch.

OPERATION

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

MOTOR 21 50'000 rpm	SPEED RANGE rpm	FACTORY DEFAULT	DEFINITION
Motor 21, 50'000 rpm / Min. speed	300 – 5000	300 rpm	Set min. speed
Motor 21, 50'000 rpm / Max. speed	5'000 – 50'000	50'000 rpm	Set max. speed
Motor 21, 50'000 rpm / Ramp start	1 – 1'000 ms / 10'000	250 ms	Set acceleration time to 10'000 rpm
Motor 21, 50'000 rpm / Ramp stop	1 – 1'000 ms / 10'000	50 ms	Set breaking time from 10'000 – 0 rpm

MOTOR 21 80'000 rpm	SPEED RANGE rpm	FACTORY DEFAULT	DEFINITION
Motor 21, 80'000 rpm / Min. speed	300 – 5000	300 rpm	Set min. speed
Motor 21, 80'000 rpm / Max. speed	5'000 – 80'000	80'000 rpm	Set max. speed
Motor 21, 80'000 rpm / Ramp start	1 – 1'000 ms / 10'000	250 ms	Set acceleration time to 10'000 rpm
Motor 21, 80'000 rpm / Ramp stop	1 – 1'000 ms / 10'000	50 ms	Set breaking time from 10'000 – 0 rpm
Max. speed warning delay	0 – 1'000 ms	1'000 ms	0: Warning is switched off 1 – 1000: Delay time of warning when exceeding 50'000 rpm

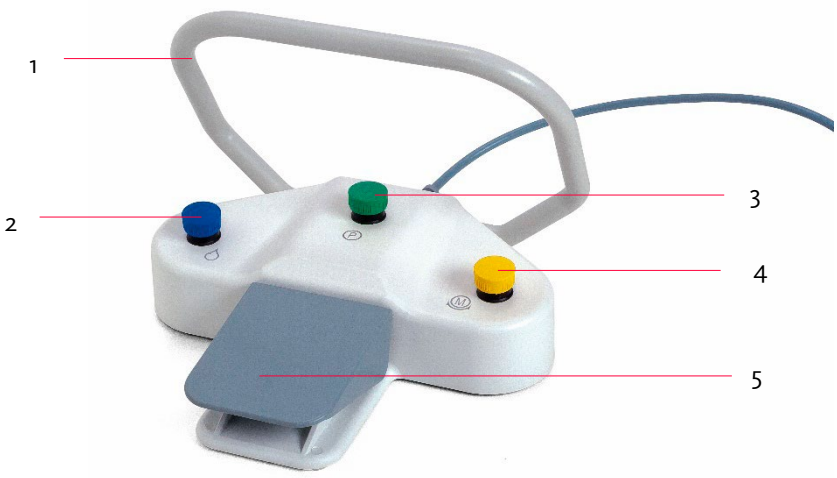
RESETTING TO FACTORY DEFAULT	SPEED RANGE rpm	FACTORY DEFAULT	DEFINITION
Motor 21, 80'000 rpm / Min. speed	300 – 5000	300 rpm	Set min. speed
Motor 21, 80'000 rpm / Max. speed	5'000 – 80'000	80'000 rpm	Set max. speed
Motor 21, 80'000 rpm / Ramp start	1 – 1'000 ms / 10'000	250 ms	Set acceleration time to 10'000 rpm
Motor 21, 80'000 rpm / Ramp stop	1 – 1'000 ms / 10'000	50 ms	Set breaking time from 10'000 – 0 rpm
Max. speed warning delay	0 – 1'000 ms	1'000 ms	0: Warning is switched off 1 – 1000: Delay time of warning when exceeding 50'000 rpm

Attention
Upon resetting to factory default, all parameters will appear with factory default values (except date, time and the operating hours counter).

To reset the programs to factory default, press both «Select ▲» and «Select ▼» keys simultaneously. For this procedure you must be out of the Configuration Menu.

OPERATION

OPERATION USING THE VARIO PEDAL



1 **Carrying bracket**
The carrying bracket can be operated by foot (collapsible).

2 **Button** (water drop)
Pressing the button briefly: switches the pump on or off (check display).
Pressing the button longer: increases the pump speed (check display).

3 **Button** (P)
Pressing the button briefly: switches the program (+1) (check display).
Pressing the button longer: switches the program (-1) (check display).

4 **Button** (M)
Pressing the button briefly: switches the rotational direction (check display).
Pressing the button longer: changes the motor (check display and indicator lights beside the motor sockets on the control unit).

5 **Step plate**
With the step plate pedal the motor speed is variably adjusted and the pump is activated.

STEP PLATE...	MOTOR	PUMP	PUMP PERMANENTLY ON*
not pressed	Motor off	Pump off	Pump on if «Pump ON» displayed (speed as set on the control unit)
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)	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)	Pump on if «Pump ON» displayed (speed as set on the control unit)

* If in the configuration menu, [PARAMETER | LEVEL 2 >19] «Pump switch mode on/off» is activated and the pump is started by pressing the foot switch.

For safety reasons, the unit can only be operated by pedal.
The speed of the following handpieces is fixed and cannot be changed:
// Micro Saws (Oscillating Saw, Sagittal Saw, Compass Saw) // Dermatoms

OPERATION

FUNCTIONAL CHECK

Prior to HighSurg 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, depending on configuration, the most recent settings entered appear on the display and the green LED for motor 1 lights up.

ELECTRONIC MOTOR

The performance of the electronic motor is checked without a handpiece or contra angle. Nevertheless, the 1:1 handpiece must be activated via the «Handpiece» key to check the maximum speed.

1 **Use the «Select ▲» and «Select ▼» keys to set the speed of the electronic motor to 50'000 rpm.**

2 **Press the pedal step plate**
The electronic motor starts and accelerates to up to 50'000 rpm.

3 **When the step plate is released, the electronic motor slows down again.**
For motor types with a permitted speed of 80'000 rpm, the maximum speed must be set accordingly to 80'000 rpm and for the Motor 16 with integrated Handpiece to 16'000 rpm.

The motor ventilation slots must be kept clear to prevent the motor from overheating.

PUMP

1 **Press the button (◌) on the pedal briefly**
The peristaltic pump is switched on, which is shown on the display by the symbol of a drop.

2 **Press the pedal step plate**
The peristaltic pump and the electronic motor start up.
Water sprays from the irrigation needle onto the contra angle.

In the Configuration Menu [Parameter | Level 2 >19] (Pump switch mode on/off) the pump can be set to work permanently without pressing the step plate. Therefore, only a press on the footswitch is needed and the pump runs with the present value. Pressing the footswitch again stops the pump. In this case the pressing of the pedal has no effect.

ROTATIONAL DIRECTION OF THE ELECTRONIC MOTOR

1 **Press the button (M) on the pedal briefly**
The rotational direction of the electronic motor changes.

2 **Press the pedal step plate**
The electronic motor rotates to the left and a continuous tone is emitted.

3 **Release the step plate**
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.

PROGRAM

1 **The required program can be set by repeatedly pressing the button (P) on the pedal.**

CLEANING AND DISINFECTION

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 are important regarding the caring for the material:

Perform cleaning, disinfection and sterilization after every treatment.
Always autoclave the material in sterilization packaging.
Make sure that the sterilization packaging is not more than 80% filled.
Autoclave material for at least 5 minutes at 134°C.
If sterilized material is not used immediately, the sterilization packaging must be labeled with the sterilization date.
NOUVAG recommends including a sterility indicator.

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.

TUBING SET, REF 6024 AND REF 6025

Single-use tubing sets REF 6024 and REF 6025 may not be reused!
Used tubing sets must be disposed of properly.
Do not use tube set when packaging is already opened or damaged!
Do not use tubing set if expired.
Use only NOUVAG tubing sets with REF 6024 and REF 6025.
Sterility cannot be guaranteed by reusing and re-sterilization of tubing sets. The characteristics of the material may change resulting in serious infections or, in worst case, the death of the patient.

HANDPIECE CRADLE

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

ELECTRONIC MOTOR 21

For the reprocessing instructions of the electronic motor 21, please refer to the instructions for use supplied with the electronic motor.

MAINTENANCE

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:

1 **Switch off device.**

2 **Unplug the power plug.**

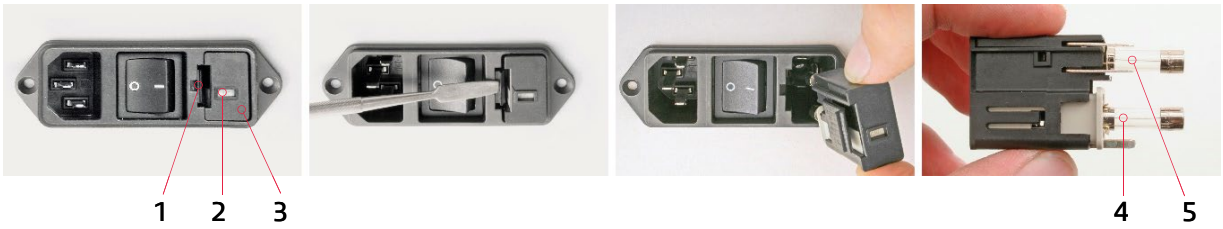
3 **Open the fuse slot using a screwdriver.**

4 **Replace the faulty fuse T 3,15 A, 250 V AC.**

5 **Slide the fuse holder back in and close the fuse slot.**

6 **Check the mains voltage shown on the fuse slot.**

7 **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

SAFETY INSPECTIONS

The essential requirements have been defined and assessed within the risk analysis. The results of the analysis are stored in the risk management file of 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 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 HighSurg 30 shall be executed every 2 years by authorized experts. Results shall be documented. The service manual, wiring diagrams, and descriptions are available upon request from the manufacturer.

NOUVAG offers a safety inspection service for its customers. Addresses can be found in the appendix of this instructions for use under [Service points >30]. For further information please contact our technical service department.

MALFUNCTIONS AND TROUBLESHOOTING

MALFUNCTION	CAUSE	SOLUTION	REFER TO INSTRUCTIONS FOR USE
Device is not functional	Control unit not switched on	Set the power switch «I/O» to «I»	[Switching the device on and off >11]
	Power connection not established	Connect the control unit to the mains power supply	[Connection to the power supply >8]
	Incorrect operating voltage	Check the mains voltage	[Connection to the power supply >8]
	Faulty fuse	Replace fuse	[Replacing the control unit fuse >24]
	Processor error	Set the power switch «I/O» to «O», wait 10 seconds and switch back to position «I»	[Switching the device on and off >11]
Motor doesn't work	Motor not switched on	Switch on the motor using the step plate	[Operation using the VARIO pedal >21]
	Incorrect motor active	Switching to the other motor, using the VARIO pedal	[Operation using the VARIO pedal >21]
	Motor not connected	Connect the motor cable to the control unit	[Device overview >7] [Device preparation >9]
	Handpiece or contra angle not correctly assembled	Press the handpiece firmly onto the electronic motor until it clicks in position and check, that it's secure by moving it slightly in the opposite direction.	[Device preparation >9]
No irrigation fluid for instrument	Peristaltic pump not switched on	Switch on the peristaltic pump	[Operation using the VARIO pedal >21]
	Tubing set incorrectly inserted	Insert tubing set correctly (note the direction)	[Device preparation >9]
	Tubing set clogged/crusted matter visible	Replace the tubing set	[Device preparation >9]
	Bottle with sodium chloride solution not ventilated	Open the ventilation filter at the drip chamber	[Device preparation >9]
	Tubing set is dripping	Replace the tubing set	[Device preparation >9]
	Roller clamp of tubing set is closed	Open roller-clamp all the way	[Device preparation >9]
	Non-conform tube set (not from NOUVAG or wrong type)	Use the tube set recommended by NOUVAG	[Device preparation >9]
Pedal is not functional	Pedal not connected	Connect the pedal to the control unit	[Device preparation >9]
	Incorrect operation	Check operating instructions	[Operation using the VARIO pedal >21]
Display is illuminated red	Motor is not connected	Connect motor	[Device preparation >9]
	Motor is defective or cable is defective	Check motor and cable	[Device preparation >9]

If the problem cannot be solved please contact your supplier or an authorized service center. Addresses can be found in the appendix of this instructions for use under [Service points >30].

If the display is illuminated red by an error warning, the error code can be found under [Error-messages on Display >26].

MALFUNCTIONS AND TROUBLESHOOTING

ERROR-MESSAGES ON DISPLAY

ERROR-MESSAGE/ 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.
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 are saved to NOU-dongle.	
Storing factory settings/ Program	Message while default values of programs are stored.	
Pedal not connected/ E10	Pedal not plugged in.	Plug in Pedal.
	Plug or cable defective.	Send control unit and pedal to Service Center.
Pedal test mode/ W11	Pedal test mode switched on.	Switch off device for 5 seconds, then switch back on again.
Keyboard test mode/ W12	Keyboard test mode switched on.	Switch off device for 5 seconds, then switch back on again.
No motor connected/ E13	No motor connected.	Plug in motor.
	Motor, motor cable, motor plug or control unit defective.	Send motor and control unit to Service Center.
Motor 2 not connected/ E14	Motor 2 is selected but no motor plugged in.	Plug in motor.
	Motor connected to motor socket 2, but motor, motor cable, motor plug or control unit defective.	Send motor and control unit to Service Center.
Motor 1 not connected/ E15	Motor 1 is selected but no motor plugged in.	Plug in motor.
	Motor connected to motor socket 1, but motor, motor cable, motor plug or control unit defective.	Send motor and control unit to Service Center.
Unknown motor 2/ E16	Motor 2 is selected but wrong motor plugged in.	Plug in correct motor.
	Right motor is connected to motor socket 2, but motor, motor cable, motor plug or control unit defective.	Send motor and control unit to Service Center.

MALFUNCTIONS AND TROUBLESHOOTING

ERROR-MESSAGES ON DISPLAY (CONTINUED)

ERROR-MESSAGE/ ERROR CODE	CAUSE	SOLUTION
Unknown motor 1/ E17	Motor 2 is selected but wrong motor is plugged in.	Plug in correct motor.
	Right motor is connected to motor socket 1, but motor, motor cable, motor plug or control unit defective.	Send motor and control unit to Service Center.
Hp not allowed for motor 2/ E18	Handpiece may not be operated with motor plugged in at motor socket 2.	Choose appropriate handpiece or change to correct motor type.
Hp not allowed for motor 1/ E19	Handpiece may not be operated with motor plugged in at motor socket 1.	Choose appropriate handpiece or change to correct motor type.
Pump is open/ E20	To prevent injuries, motor does not work when pump compartment is open.	Close pump compartment.
Motor or pump test mode/ W21	Motor or pump test mode switched on.	Switch off device for 5 seconds, then switch back on again.
Pedal locked/ W26, pedal let go	If pedal is pressed at switch on procedure, pedal will not work.	Release pedal for one second.
Battery is almost empty/ W27, continue with «Enter»	Battery almost empty.	After pressing «Enter», work can be continued but control unit has to be sent to Service Center as soon as possible.
Clock Error XX/ E28, continue with «Enter»	Clock at control unit defective.	After pressing «Enter», work can be continued but control unit has to be sent to Service Center as soon as possible.
	Device was switched on after battery change, but clock is not set yet.	Set date and time.
Handpiece XX is faulty/ E29	Handpiece was overexposed to high torque during calibrating or testing.	Clean handpiece and spray it thoroughly with Lubrifluid spray. If message is still displayed after test procedure, handpiece must be sent to Service Center.
Handpiece XX is Ok!	Tested handpiece is OK	
Testing the handpiece XX	Handpiece is testing	
Check max. speed handpiece/ W30, wait 1 second	Message is displayed when motor with 80'000 rpm is selected and max. speed is set to 50'000 rpm. Check Handpiece for max. speed clearance before proceeding.	Check handpiece and wait for message to disappear. Motor starts if the pedal still is pressed.
NOU-Dongle is plugged in	Message is displayed for 1 second after NOU-dongle 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.

ACCESSORIES AND SPARE PARTS

ACCESSORIES

DESCRIPTION	REF
Clip set, for tube set attachment to motor cable, PU 10 pcs.	1873
Disposable tubing set, sterile, 3 m	6024
Disposable tubing set three-way valve, sterile, 3 m	6025
Lubricant spray LUBRIFLUID	2128
Spray adapter with thread, for lubricant spray (REF 2128)	19584
HighSurg 30 instructions for use	31666

POWER CORDS

DESCRIPTION	REF
Power cord CH, with device socket, 3 m	22261
Power cord DE, with device socket, 3 m	22262
Power cord GB, with device socket, 3 m	22264
Power cord US, with device socket, 3 m	22266

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

INFORMATION ON DISPOSAL

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. Prevailing national and local disposal regulations apply.

When disposing of the device, device components and accessories, the requirements specified in legislation must be followed. To ensure environmental protection, old devices can be returned to the dealer or manufacturer.

TECHNICAL DATA

HIGHSURG 30

Voltage, switchable	100 V~ / 115 V~ / 230 V~, 50 / 60 Hz
Fuse power supply	2 fuses, T 3,15 A, 250 V AC
Power consumption	max. 120 VA
Type of applied part	Type BF*
Protection class	Class I
Pedal	IPX8
Dimensions (W x D x H)	260 x 250 x 110 mm
Net weight of control unit	3,7 kg

* Applied parts are the instruments used with the HighSurg 30.

ELECTRONIC MOTOR 21 50'000 rpm (REF 2099nou)

Motor coupling	INTRA coupling, ISO 3964
Speed	300 – 50'000 rpm
Torque	max. 7,5 Ncm
Weight	340 g
Cable length	2,9 m

ELECTRONIC MOTOR 21 80'000 rpm (REF 2098nou)

Motor coupling	INTRA coupling, ISO 3964
Speed	300 – 80'000 rpm
Torque	max. 4 Ncm
Weight	340 g
Cable length	2,9 m

WARRANTY COVERAGE

NOUVAG warrants this product to be free from defects in workmanship and materials for a period of twelve (12) months from the original date of purchase. If the warranty card is returned for registration or the warranty extension is requested on our website within 4 weeks from the date of purchase, the warranty coverage is extended for a period of 6 months, wear parts are excluded from the warranty. During this warranty period, NOUVAG agrees to either repair or replace the product at its option if the product fails to function properly under normal use and service and such failure is due solely to a defect in workmanship or materials.
This warranty is void if repair or service of the product is performed or attempted by anyone not authorized by NOUVAG to do so, or if a replacement part not authorized by NOUVAG is used in any repair or service.

POST MARKET SURVEILLANCE

In the event of incidents related to the use of the medical device, please contact immediately the manufacturer by email complaint@nouvag.com or by phone.

To provide adequate information, please compile the incident questionnaire at the web address Nouvag.com > Contact us > Incident questionnaire.

SERVICE POINTS

Switzerland
NOUVAG AG
St. Gallerstrasse 25
9403 Goldach

Phone +41 71 846 66 00
info@nouvag.com
www.nouvag.com

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NOUVAG GmbH
Schulthaissstrasse 15
78462 Konstanz

Phone +49 7531 1290-0
info-de@nouvag.com
www.nouvag.com

CE 0197

A complete list of NOUVAG certified service points are found on the NOUVAG website: Nouvag.com > Service

APPENDIX

Electromagnetic compatibility (EMC)

Remark:
The **Product** subsequently referred to herein always denotes the HighSurg 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 ± 5% at a range between 300 – 80'000 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 2098nou / 2099nou	2.9m
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.

APPENDIX

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 bet hat 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 b 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.

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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 electromagnet 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 fort 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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NOUVAG

EN

Instructions for use

Electronic Motor 21

REF 2090nou | REF 2097nou | REF 2116nou

NOUVAG

SYMBOLS

General warning sign	Warning! Hot surface	Observe instructions for use	Note
Manufacturer	Date of manufacture	Importer	Suitable for thermal disinfection
LOT Batch code	REF Catalog number	134 °C Autoclavable at 134 °C	Type BF applied part
SN Serial number	EC REP Authorized representative in the European Community	Separate collection required (WEEE)	

INTENDED PURPOSE

The electronic motors 21 are equipped with handpiece carriers according to ISO 3964, which enable the attachment of handpieces and contra angles and ensure secure hold.

MEDICAL INDICATIONS

The electronic motor 21 in conjunction with a control unit and corresponding handpiece is used in the following medical indications:
// **Laparoscopic hysterectomy** (REF 2090nou)
// **Dental implantology** (REF 2097nou | REF 2116nou)

CONTRA INDICATIONS

Relative or absolute contra indications can arise from the general medical diagnose, or in special cases by a significantly increased risk to the patient through the use of motor-driven devices. Relevant cases in the literature must be taken into consideration.

INTENDED USERS

Intended users are trained and qualified personnel, in professional settings (e.g. hospital, ambulatory).

AMBIENT CONDITIONS	TRANSPORT AND STORAGE	DURING USE
Relative humidity	max. 90%	max. 80%
Temperature	0 °C – 50 °C	10 °C – 30 °C
Atmospheric pressure	700 hPa – 1'060 hPa	800 hPa – 1'060 hPa

SAFETY INFORMATION

⚠ We deliver an unsterile electronic motor. Clean, disinfect, and sterilize the electronic motor before the first application and immediately after each use!

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

Improper use or repair of the device, or failure to observe these instructions, relieves NOUVAG from any obligation arising from warranty provisions or other claims.

⚠ The use of the product other than that for which it was designed is not permitted. The responsibility is solely carried by the operator.

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

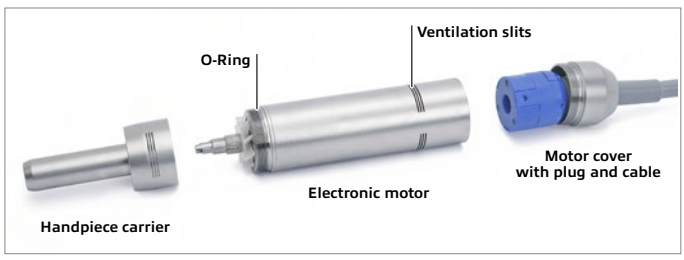
Manipulate the handpiece only when the motor is at a standstill.

The device shall only be operated by qualified and trained personnel.

To avoid cable breakage, do not bend the motor cable!

The electronic motor may only be connected with connection sockets marked with the symbol «Type BF».

OVERVIEW

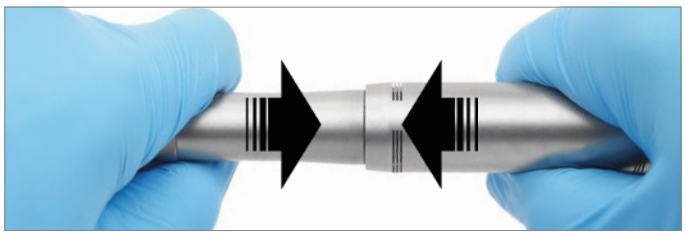


POSSIBLE COMBINATIONS

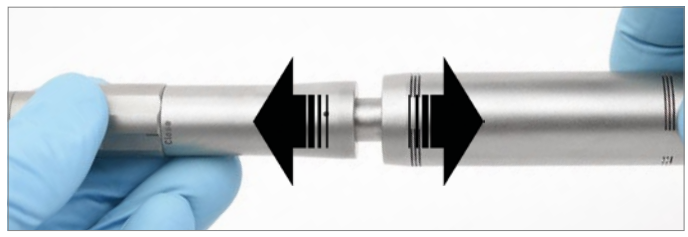
REF	CONTROL UNIT	INTENDED USE
2090nou	TCM 3000 BL Morcellator	Laparoscopic hysterectomy
2097nou	MD 11 | MD 30	Dental implantology
2116nou	MD 11 | MD 30	Dental implantology

OPERATION

COUPLING HANDPIECES WITH THE ELECTRONIC MOTOR 21



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



Disconnect coupling with a short, strong pull and slide off the handpiece from the handpiece carrier of the electronic motor.

REPROCESSING INSTRUCTIONS

⚠ In relation to patients with Creutzfeldt Jakob disease or its variant (vCJK) no responsibility can be assumed for re-use of the electronic motor. The Robert-Koch Institute recommends removing used products from circulation after use in order to avoid infecting other patients, users and third parties.

⚠ Never clean the electronic motor in an ultrasonic bath! This impairs the functionality of the electronic motor.

Reprocessing restrictions	Frequent reprocessing has only a limited impact on the electronic motor. The end of the products service life is normally determined by wear and damage through use. The electronic motor is designed for 250 sterilization cycles.
General handling	**1.** The electronic motor must be thoroughly cleaned, disinfected and sterilised before initial operation (products straight from the factory) and also immediately following each use. Only a cleaned and disinfected electronic motor enables correct sterilisation! **2.** The electronic motor should always be treated with utmost care when being transported, cleaned, serviced, sterilised and stored. **3.** We recommend the use of mildly alkaline and enzymatic cleaners with as low a silicate content as possible to avoid staining (silicatization) on the electronic motor. **4.** Only commercial grade DGHM-/VAH-listed agents may be used for cleaning and disinfection. See these agent manufacturers' specifications for the method of use, action time and suitability of disinfection and cleaning substances. **5.** Operating instructions for the equipment and chemicals etc. used during reprocessing must be strictly followed. **6.** Dosage of chemicals, exposure times and exposure temperatures for cleaning and disinfection must be strictly followed. **7.** The end of product life may be reached before the 250 sterilization cycles in case of excessive wear and damage from use. **8.** Do not overload the washer. Avoid rinsing blind spots. Ensure secure storage in the machine. **9.** Observe the regulations valid in your country for the reprocessing of medical devices. **10.** NOUVAG recommends the use of a screen basket with rinsing bar from 3mach (NOUVAG REF 51401), a reusable container for convenient preparation and storage (including transport) of the products. The screen basket can be used for safe storage of the products during the rinsing process as well as during and after sterilization until the products are used. The screen basket is suitable for use with sterilization paper or a rigid sterilization container. It does not have a barrier effect on its own to protect sterility.
Preparation at the point of use	After surgery immediately remove blood, secretion, tissue and bone residue with a disposable cloth/paper towel, do not allow to dry! Dried residues cause corrosion.
Safe-keeping and transport	Contaminated products must be stored and transported to the preparation site in a closed container to avoid damaging the products and the contamination of the environment.
Cleaning and disinfection, pre-cleaning	**1.** Wipe the electronic motor with a damp disposable cloth/paper towel, removing all visible dirt. **2.** Unscrew motor cap and remove cable including motor cap. **3.** Unscrew handpiece carrier and remove O-ring.  **4.** Clean the plastic parts of the electronic motor and its accompanying parts under running tap water using a soft brush (e.g. Insitumend GmbH, REF MED100.33). **5.** Rinse the outer surface of the electronic motor for 10 seconds with a water pressure gun at a pressure of at least 2.0 bar (manufacturer for example HEGA Medical, REF 6010 or REF 7060). Local tap water is sufficient for this purpose, since the last step is always a machine cleaning with deionized water, so possibly hard water with lime traces from the pre-cleaning cannot remain on the electronic motor.

Cleaning	**Mechanical cleaning** 1. After pre-cleaning place the electronic motor and its accessories in the strainer basket. 2. Mechanical cleaning is only successful if the pre-cleaning, described above, is adhered to! 3. Cleaning is done using the Vario TD programme in the cleaning and disinfection unit (CDU). For the cleaning process it is advisable to use DI water (fully desalinated water). 4. After completing the cleaning program (incl. thermal disinfection) check the electronic motor, motor cap with cable, handpiece carrier and O-ring for visible contamination in the grooves and gaps. Repeat cleaning if necessary.	**Automatic cleaning process (Vario TD programme)** 1. Pre-clean with cold water for 4 minutes. 2. Empty 3. Clean for 5 minutes at 55°C with 0.5% alkaline or at 40°C with 0.5% enzymatic cleaner. 4. Empty 5. Neutralise with cold water for 3 minutes. 6. Empty 7. Inter-rinse for 2 minutes with cold water. 8. Empty
Disinfection	**Mechanical disinfection** The cleaning/disinfection unit has a thermal disinfection programme which follows after the cleaning. When performing mechanical thermal disinfection, give due consideration to the national requirements relating to the A0 value (see DIN EN ISO 15883-1). We recommend an A0 value of 3.000 for the electronic motor and the attachments. Disinfection must be carried out with DI water.	**Warning** When inadequately rinsed or exposed to the disinfectant or detergent for too long, the electronic motor can corrode. Please see the corresponding detergent and disinfectant's package insert for dwell times.
Drying	**Mechanical drying** Drying of the electronic motor by the drying cycle of the cleaning/disinfection unit's (CDU). If required, manual drying can also be achieved by using a lint-free cloth. Pay particular attention to the grooves and spaces between the electronic motor. Then spray the electronic motor again with lubricant. Every CDU must provide a corresponding drying procedure through the manufacturer (see ISO 15883-1). Please follow the corresponding CDU-manufacturer's directions and operating instructions.	**Manual drying** Set up the electronic motor vertically. Allow the electronic motor and the small parts to dry for at least 30 minutes. Then spray the electronic motor again with lubricant.
Inspection and care	1. Perform a visual inspection for damage, corrosion and wear. 2. Spray the electronic motor with a lubricant for maintenance. Screw the spray adapter (REF 19584) onto the electric motor instead of the cable plug. Attach the blue spray adapter to the spray can and spray the electronic motor from the coupling side for about 3 seconds until only clear liquid flows out of the electronic motor.  3. Then wipe off with a moistened cloth (observe the product's instructions for use). 4. After spraying the electronic motor, screw the O-ring, handpiece holder and motor cap with cable back onto the electronic motor.	
Sterilisation	Sterilisation of the electronic motor is performed with a fractionated pre-vacuum steam sterilisation process (in accordance with DIN EN 13060 / DIN EN 285) giving due consideration to the respective national requirements. **Minimum requirements:** 1. Pre-vacuum phases: 3 2. Sterilisation temperature: minimum 132 °C – maximum 137 °C (within the sterile band) 3. Holding time: At least 5 minutes (full cycle) 4. Drying time: At least 10 minutes When sterilising several products during one sterilisation cycle, do not exceed the maximum steriliser load (see manufacturer's details). A drying cycle must be added in the case of autoclaves without a vacuum function. After sterilisation an immaculate sterilisation result must be detected by examining the appropriate indications. According to the Robert-Koch Institute preparation ends with the documented release for use of the medical device. If the sterilised electronic motor is not used immediately after sterilisation, it must be labelled with the sterilisation date on the packaging.	
Storage	**Storing the sterile packaging** The sterilised product must be stored away from dust, humidity and contamination. During storage, direct sunlight should be safely avoided. After the expiry date has passed, do not use the product any longer.	**Handling the sterile packaging** Before taking out the product, check for the packaging to be intact. When taking out the product, follow the respective aseptic procedures.
Information for validating the preparation	The above preparation process has been verified by a validated procedure. The following materials and machines were used: 1. Alkaline cleaner: Neodisher® Mediclean; Chemische Fabrik Dr. Weigert GmbH & Co. KG 2. Enzymatic cleaner: Neodisher® MediZyme; Chemische Fabrik Dr. Weigert GmbH & Co. KG 3. Cleaning and disinfection unit: Miele G 7836 CD 4. Rack trolley: Miele E429 5. Strainer basket/flush socket bar: 3mach (NOUVAG REF 51401) 6. Autoclave: Selectomat 666-HP (MMM) 7. Sterile packaging: Sterisheet 100; Broemeda Amcor Flexibles GmbH Chemicals and machines other than those mentioned can also be used. In such a case consult the manufacturers or suppliers to find out whether their products confer the same performance as the products that the procedure was validated with. If you should opt for a different procedure for reprocessing to the one given above, you are required to correspondingly establish the suitability	

There is no experience available from conducting other sterilisation procedures such as plasma sterilisation, low temperature sterilisation procedure, etc. Users bear full responsibility if they use a procedure which differs from the validated sterilisation procedure described!

Please also comply with the applicable legislation in your country and the medical practice or hospital's hygiene rules. This especially applies to the varying requirements for an effective inactivation of prions.

MALFUNCTIONS AND TROUBLESHOOTING

PROBLEM	CAUSE	SOLUTION
Motor is not running.	Plug is not inserted properly.	Insert plug and check fitting.
Motor stops when cable is moved.	Defective cable.	Replace cable.
Motor is running but tool is not turning.	Handpiece is not properly connected to the motor.	Press handpiece firmly to the motor until it clicks in place.

TECHNICAL DATA

REF	2090nou	2097nou	2116nou
Weight, without cable	325 g	310 g	300 g
Torque max.	7.5 Ncm	7.5 Ncm	7.5 Ncm
Speed max.	40'000 rpm	50'000 rpm	50'000 rpm
Rated voltage	35 V	35 V	35 V
Current max.	8 A	8 A	8 A
Output max.	120 VA	120 VA	120 VA
Coupling	ISO 3964	ISO 3964	ISO 3964
Cable length	3.0 m	2.0 m	2.0 m
Pin assignment of the connector	8	10	10

POST MARKET SURVEILLANCE

If you have any complaints in relation to the use of the medical device, please contact the manufacturer immediately by e-mail complaint@nouvag.com or by phone.

In order to provide adequate information, please complete the complaint form:
Nouvag.com > Contact > Complaint Form.

ACCESSORIES AND SPARE PARTS

REF	DESCRIPTION	QUANTITY
19584	Spray adapter with thread, to lubricant spray	1
24119	O-ring	1
76052	Motor cable, pre-assembled, for motor 2090nou, 2112nou	1
76066	Motor cable, pre-assembled, for motor 2097nou, 2116nou	1

INFORMATION ON DISPOSAL

When disposing of the device, device components and accessories, the regulations issued by the legislator must be followed.
Used electrical and electronic equipment is hazardous waste and must not be disposed of with household waste.

MANUFACTURER AND SERVICE POINTS

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