



Dentalone

Operating instructions



Edition V3-6-5.2

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1. Important notes

In order to get to know the advantages of the treatment unit and to guarantee patient safety it is absolutely necessary to thoroughly read the instructions for use before putting the device into operation.



1.1 General safety guidelines

- 1 The unit is built under consideration of the requirements of the German Act of Medical Devices or the guideline 93/42/EWG for medical devices and meets the essential requirements of annex I. The product is a device of class IIa according to annex IX of regulation 9 of guideline 93/42/EEC for medical devices.
- 2 The safety technical standard is based on the VDE-regulation for electromedical devices DIN IEC 60601 part 1 / DIN VDE 0750 part 1.
- 3 **Caution:** To avoid the risk of electric shock, the device is to be connected with supply networks which are installed according to the regulations for medically used rooms (IEC 60364-7-710:2002-11 or DIN VDE 0100-710).
- 4 The device has to be located in such a way, that a separation from the mains by pulling the mains plug is easily possible in the event of a fault.
- 5 The product is a medical device and must be used in accordance with the rules of the medical devices Act (MPG) by authorized personnel only. The user must guarantee proper handling due to his education or skills and be familiar with the operation of the device.
- 6 Before operating the unit, the user must ensure the reliability and orderly condition of the device.
- 7 For safety reasons, the equipment must remain switched off when it is unattended. In that case the power switch is always to be turned off.
- 8 The unit is not suitable for operation in potentially explosive areas
- 9 The product is subject to regular safety checks. The medical devices Act (MPG) and the corresponding regulations are to be observed by the operator fully.
Scope and deadlines of the technical safety checks are prescribed as follows:
At least every 12 months must be carried out following listed safety controls in compliance with DIN VDE 0750 and DIN VDE 0751 like perform:
Visual inspection of device and accessories, protection ground conductor checking according to DIN VDE 0751, equivalent leakage current measurement according to DIN VDE 0751, functional testing of the unit in accordance with the accompanying documents.
We recommend keeping a medical book in which the test results of the safety checks are documented.
- 10 As manufacturer of the device, we can assume responsibility for the safety properties of the unit only if maintenance and repair is performed by us or an authorised agent, if the prescribed service intervals are observed and the device is used in accordance with the operating instructions.
A further condition is that components, affecting the safety of the device, are replaced only with original parts.
Technical service documents are available for companies authorized by us for the service and repair.
- 11 **Warning:** Any change of the device is NOT permitted.
- 12 In case of maintenance, inspection or repair you should request a certificate of type and scope of work of the company. The certificate must contain the date of implementation, as well as name of the company with signature (see also MDD, DIN VDE 0750 / DIN VDE 0751).
- 13 The user has to comply with all valid laws and directives for medical devices as well as national regulations, in particular, the work safety regulations and accident prevention measures
- 14 Portable communication devices which emit radio waves (E.g. mobile phones) can affect the medical equipment. Don't use such devices near the Dentalone (refer page 8, table 4.3)
- 15 The instruments Motor, Scaler and Syringe are equipped with LED light. Eye damage may result if the LED is directed straight into the eyes. Do not look into or turn it to the eyes of the patient.

1.2. Used symbols



Caution – check for specific warnings or precautions!



Read the instructions for use!



Caution line voltage!



A disposal through household waste/residual waste is not allowed. Note recycling information!



Application components type B: device with earth connection



Manufacturer

IP30 Device is protected against penetration of solid bodies > 2,5 mm;



IPX 1

Device is protected against dripping water. Vertically falling dripping water may not have any adverse effect.



Don't tread on! Do not overload!



Do not use outside closed rooms!



Autoclavable on max. 135°C



Direction up



Protect from moisture



Recycleable



Caution fragile!



Handle with care!



0535

Conformity according to all European Directives



Temperature limits for storage and transport



Limits of humidity for storage and transport



Limits of atmospheric air pressure for storage and transport

1.3 Intended use



The device Dentalone is a portable dental treatment unit and is used for outpatient and stationery general treatment of teeth.

The product is designed only for dental use by qualified personnel.

The NLX nano motor is for cutting / polishing as required during general dental treatment.

The Scaler Varios 170 generates ultrasonic waves intended for use in dental applications such as scaling, root canal treatment, periodontal and cavity preparation.

For the choice of the treatment locations the information in the operating instructions are decisive.

Contra-Indication:

Dentalone: The device should NOT be used for surgical, oral surgical treatments and implant surgery.

Scaler: Do NOT use the scaler on patients with cardiac pacemakers.
Do not use for patients anesthetized under laughter gas (Nitrous Oxide).
Keep away from explosive substances and flammable materials.

1.4 Short description

Dentalone is a self-contained dental unit with an integrated water and compressed air supply as well as a low volume suction. The essential features include:

- Mobile unit
- Ergonomic design due to height-adjustable console
- Compact construction, minimal space requirement.
- Equipped with Ultrasonic Scaler, Electric Micro-motor, Multifunction syringe and Saliva ejector.
- LED Light on Motor, Scaler and Multifunction syringe for better illumination of the treatment area
- Motor control with stable tractive power in each speed range.
- Ergonomic operation of handpieces/ contra-angles in combination with NLXnano electric micro-motor.
- No suck-back spray supply on micro-motor, ultrasonic scaler and multifunction syringe.
- Clearly arranged work console with integrated swivelling instrument holder, centrally arranged multi-function control panel and storage space for accessories.
- Automatic instrument recognition of active instrument
- Clearly visible graphic display of the device status and the set parameter
- Quick release connection of all instrument hoses for easy exchange
- Easy-care housing
- Base with wheels combined with the cover and integrated telescopic handle makes transport comfortable as a trolley

1.5 Combination with other products

The dental micro-motor NLXnano can be used with instruments from NSK, but also with instruments from other manufacturers with E-type fitting.

Furthermore there is no intended combination with other products.



The ultrasonic scaler Varios 170 should be used exclusively with the correct tips from NSK.

The multi-function syringe should only be used with tips of the manufacturer.

The saliva ejector can be used with any 6 mm or ¼" tips which are approved as dental consumables (CE sign).

For all accessories and consumables the hygiene regulations of the manufacturer shall apply.

1.6. Hygiene standards



- 1 All objects which get into the oral cavity of a patient have to be pre-treated to avoid any infection with any disease.
- 2 All objects which directly or indirectly get in touch with the mouth of the patient are regarded as contaminated. Contaminated objects **MUST NOT** get in contact with other patients without any disinfection/sterilization.
- 3 Direct unprotected contact with saliva or blood has to be avoided.
For your own safety you **MUST**, wear suitable protective equipment during the treatment in accordance with country-specific occupational safety and health regulations, E.g. gloves, goggles and face mask.
- 4 It is extremely important that any patient treatments planned in advance, thus all necessary objects are available at the beginning of the treatment to save time and reduce the risk of cross contamination.
- 5 To avoid cross contamination clean and dirty instruments must be kept separately.
- 6 All objects, which are directly or indirectly in contact with the patient, must be either professionally disposed of following treatment or they need to be processed for cross infection control
- 7 The water tank should be filled with of drinking water quality or treated (purified) water. As an additive the product ALPRON is recommended.

1.7 Standards and guidelines

Standard	Contents
2006/42/EC	Machinery Directive
93/42/EC	Medical Device Directive
DIN EN 1041	Information supplied by the manufacturer of medical devices
DIN EN 60529	Degrees of protection provided by enclosures (IP-Code)
IEC 60601-1	Medical electrical equipment; - Part 1: General requirements for safety
IEC 60601-1-2	Medical electrical equipment; Part 1: Electromagnetic compatibility
DIN EN 62304	Medical device software - Software life-cycle processes
IEC 60601-1-6	Medical electrical equipment - Collateral standard: Usability
DIN EN 980	Graphical symbols for use in the labelling of medical devices
DIN EN ISO 10993-1	Biological evaluation of medical devices
DIN EN 14971	Medical devices - Application of risk management to medical devices
EN ISO 7494-1	Dentistry - Dental units - Part 1 General requirements and test methods
EN ISO 7494-2	Dentistry - Dental units - Part 2 Water and air supply
DIN EN ISO 14457	Dentistry – Handpieces and motors
DIN EN ISO 22374	Dentistry - Dental handpieces - Electrical-powered scalers and scaler tips
EN ISO 10079-3	Medical suction equipment - Part 3: Suction equipment powered from a vacuum or pressure source

1.8 Terms

Term	Description
EMC	Electromagnetic Compatibility
Instrument	Applied part

2. Scope of delivery

2.1 Basic unit

The scope of delivery of the basic unit additionally includes the following components:

1 piece	Cover with telescopic handle
1 piece	Water tank incl. screw cap
1 piece	Waste container incl. screw cap with integrated filling level sensor
1 piece	Power Cord with non-heating apparatuses plug
1 piece	Instruction for use
1 piece	Foot pedal
Accessories (not in the sense of the directive)	
Motor:	1 piece Autoclave plug
	1 piece Motor Cap for autoclave
	1 set O-Rings (3 x black o-rings)
	1 piece O-Ring blue
Scaler:	1 piece Sterilization cassette
	3 piece Tip Wrench
	1 piece Scaler Tip type G4
	1 piece Scaler Tip type G6
	1 piece Scaler Tip type G8
	2 pieces O-Ring

2.2 Equipment

(Instrument holder equipped from the left to the right side)

Scaler with light "VARIOS 170 LUX" (separately packed)

Micromotor NLX nano with light (without handpiece/contra-angle *)

Multi-function Syringe

Saliva ejector (without cannula)

2.3 Accessories, consumables, spare parts, service partner

Consult your NSK-dealer for more information about specifications, accessories, consumables, spare parts and service partners.

3. Warranty

The manufacturer's warranty is 1 year from date of purchase for provided the unit has been properly commissioned and used in appropriate conditions. The manufacturer reserves the right to determine the cause of any problems and to analyze.

Consumables parts and wearing parts are not covered by the warranty.

The warranty will lapse,

- if non-approved materials and liquids as described in the instruction for use are being used,
- if any modification on the unit is made by the customer or other unauthorized persons,
- if the device is used for any other purpose as its intended use,
- if damage is caused by gross negligence or due to improper use.

4. EMC Notice



The DENTALONE is subject to special precautions regarding EMC and must therefore be installed and used according to the EMC notes in this operation manual.

The Dentalone may cause radio interference or it can interfere with the operation of devices in the vicinity. If the location in which the DENTALONE is used exceeds the applicable RF compliance level mentioned above, the DENTALONE should be checked to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the DENTALONE.

Portable and mobile RF communications equipment can affect the DENTALONE.


The following cables / components are part of the DENTALONE and can be used exclusively on the DENTALONE (except power cord):

Component	Ident number	Cable type	length
Power cord	31338.1	H05VV-F 3x0.75mm ² unshielded	2,0 m
Scaler cord VALux-SC	37075	2x0.25mm ² unshielded + 2x0.16mm ² unshielded	1,2 m
Motor cord NLX CD	37074	3x0.25mm ² unshielded + 2x0.16mm ² unshielded	1,2 m
Multifunction syringe	57066	2x0.25mm ² unshielded	1,2 m
Foot switch	37100	4x0.16mm ² unshielded	2,0 m
Scaler VA2-LUX-HP	E351050		
Motor NLX nano	E1044051		

Use of other cables may result in increased emissions or decreased immunity.

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

4.2 Guidance and manufacturer's declaration – electric immunity			
The DENTALONE is intended for use in the electromagnetic environment specified below. The customer or the user of the DENTALONE should assure that it is used in such an environment.			
Immunity Test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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	± 1 kV for input / output lines ± 2 kV for power supply lines	± 1 kV for input / output lines ± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV Common mode	± 1 kV differential mode ± 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 IEC 61000-4-11	<5% U_T for 0.5 cycle (>95% dip in U_T) 40% U_T for 5 cycles (60% dip in U_T) 70% U_T for 25 cycles (30% dip in U_T) <5% U_T for 5 seconds (>95% dip in U_T)	<5% U_T for 0.5 cycle (>95% dip in U_T) 40% U_T for 5 cycles (60% dip in U_T) 70% U_T for 25 cycles (30% dip in U_T) <5% U_T for 5 seconds (>95% dip in U_T)	Mains power quality should be that of a typical commercial or hospital environment. Compliance is dependent on the operator following recommended charging and maintenance of the installed battery backup
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at level 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			
The DENTALONE is intended for use in the electromagnetic environment specified below. The customer or the user of the DENTALONE should assure that it is used in such an environment.			
Immunity Test	IEC 60601-1-2 Test level	Compliance	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V rms 150 kHz to 80 MHz outside ISM bands ^{a)} 3 V rms 150 kHz to 80 MHz In ISM bands ^{a)}	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Avea Ventilator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1,17 \sqrt{P}$ $d = 1,17 \sqrt{P}$ on 80 MHz until 800 MHz $d = 2,33 \sqrt{P}$ on 800 MHz until 2,5 GHz Where is P the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and is the recommended separation distance in meters (m). ^{a)} Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, c 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)} Field 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 assess the electromagnetic environment due to fixed FR transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the DENTALONE is used exceeds the applicable RF compliance level above, the DENTALONE should be checked to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the DENTALONE. ^{b)} Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

4.3 Electromagnetic Environmental Recommendations - Separation distances between portable and mobile RF communications equipment and DENTALONE

DENTALONE is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the DENTALONE can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DENTALONE 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 $d=1,17 \sqrt{P}$	80 MHz to 800 MHz $d=1,17 \sqrt{P}$	800 MHz to 2,5 GHz $d=2,33 \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,7	3,7	7,3
100	11,7	11,7	23,3

For transmitters rated at a maximum output power not listed above, the recommended separation distance in metres (m) can be determined 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 transmitter manufacturer.

Note1. At 80 MHz and 800 MHz, the separation distance of the higher frequency range applies.

Note2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

4.4 Essential performance

In accordance with EN 60601-1-2, section 6.2.1.10 are essential features, which under the terms of the immunity guarantee fault-free device functions of the DENTALONE as listed below:

Function of

- Supply of compressed air
- Control of micro-motor
- Control of ultrasonic scaler
- Operation function multi pad
- Suction of saliva ejector
- Automatic detection of removal of the instruments in operation

5. Environmental conditions

Operation		
Temperature area	+15to +40	°C
Relative air humidity, non-condensing, no tropical protection	30to75	%
Air pressure	860to 1060	mbar
Transport		
Temperature area	-10 to+60	°C
Relative air humidity, non-condensing, no tropical protection	10to85	%
Air pressure	500to 1060	mbar
Storage		
Temperature area	-10 to+60	°C
Relative air humidity, non-condensing, no tropical protection	10to 85	%
Air pressure	500 to 1060	mbar

Technical changes reserved

6. Storage and transport

For correct storage of the product please note the storage conditions (see section 5)

The device either has to be stored or transported in outer packaging (original cardboard box) or in transport packaging (with cover).

For a stackability of several devices additional precautions have to be made.

Before t the DENTALONE, also when relocating from one room into another, the fresh water tank (4) and the waste water collection tank (7) have to be emptied! Spilled water can damage the electronic components of the DENTALONE.

The footswitch can be stowed in the space next to the waste water tank.

Before a bigger transport (from location to location) it is recommended to additionally carry out the following measures:

- Cleaning, disinfection and sterilization as required (see section 9)
- Pull out the plug of the footswitch from the connector socket
- Bring console in transport position and lock
- Place foam insert on the console to protect the instruments and fold down instrument holder
- Stow instrument hoses and accessories in the device and fasten with webbing
- Make sure instruction for use manual is always kept with the DENTALONE



Attention! Before transport **at minus temperatures** the device has to be completely emptied from water, which means in addition to the water tank also all internal water ways, until no spray mist escapes at the hand pieces anymore, as otherwise frost damage may occur.

The same also applies to waste container and suction hose.

All internal waterways **MUST** be drained completely before any period of disuse, to prevent the formation and development of germs.

In a final step the cover has to be pushed over the device and locked at 3 points (see fig. 1).

7. Installation instructions / removal of cover

Ensure suitability of the premises with regard to the level and stability of flooring; cleanliness of the room and the climatic conditions and power supply (compare section 1; 4 and 5.)

The DENTALONE should only be unpacked once suitability of the environment has been established, At the first operation please control the outer packaging of the device case for potential external damages.



When determining transport damages please contact your NSK-dealer and clarify further procedures.

First, the outer packaging (box) must be removed by lifting the device from the box using the handle attached to the middle of the cover. We recommend that you keep the packaging.

Afterward the telescopic handle can be pulled out and the device can be rolled to the location where it will be used.

(fig. 1).

There the cover can be removed after opening the three clips (see fig. 2)



fig.1 Unlocking the trolley handle



fig.2 Opening the cover



- Check that the device has been set up on a flat and stable surface! If this is not the case, change the location.
- The ventilation slits in the housing **MUST NOT** be adjusted or covered. Sufficient ventilation of the device is required to avoid that overheating of internal components occurs.



Attention! Wait before switching-on and using the DENTALONE, until it has adapted to the ambient temperature (E.g. after a cold night in the car). Note the admissible operation conditions (see section 5).



- Attention: in order to avoid the risk of an electric shock this device may only be connected to a supply network with protective earth.
- The device has to be installed in such a way that in case of failure a separation from the supply network is easily possible by pulling the power plug.
- Use only the supplied power cord.

8. Use

8.1 Description of components

The DENTALONE consists of a base (10) and height-adjustable console (4), which can be pulled out upwards at two columns (5) and locked.

On the left side of the DENTALONE are the power inlet with the power switch, the fuse holder (1) (fig.3), and the connector socket for the foot switch (2).



fig.3



fig.4

At the rear of the housing a removable water tank (8) with a capacity of 500 ml is located. (see fig.5).

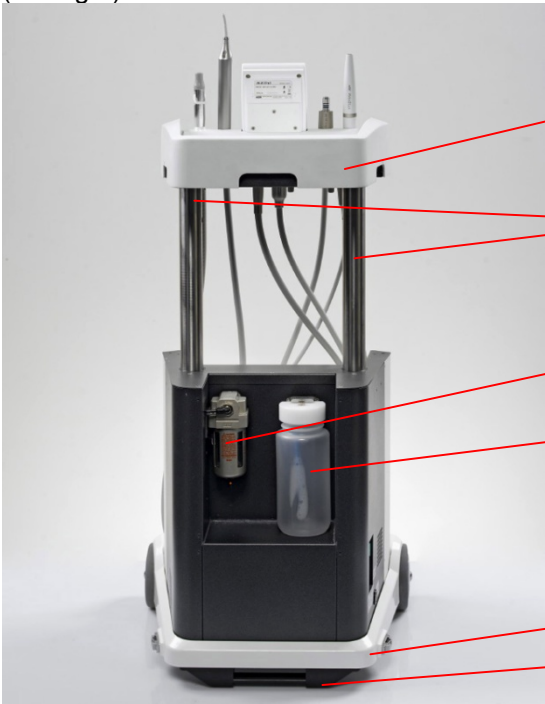


fig.5



fig.6

At the front is placed a removable waste water container (12) for suction waste (fig.6).

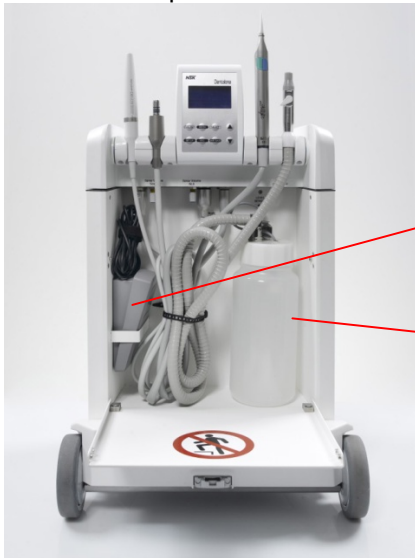


fig.7



fig.8

1. Power switch / power inlet / safety switch
2. Foot pedal connection
3. Foot pedal
4. Console
5. Pillar guide
6. Housing
7. Compressed air filter
8. Water tank
9. Power cord
10. Base
11. Foot stand with handle
12. Waste water container
13. Spray-adjuster for Scaler
14. Spray-adjuster for Motor
15. Spray ON/OFF Switch
16. Moulded foam insert
17. 2 x electrical unlocking switches for console
18. Instrument holder
19. Ultrasonic Scaler
20. Micro-motor
21. Multifunction control panel
22. Multifunction syringe
23. Saliva ejector

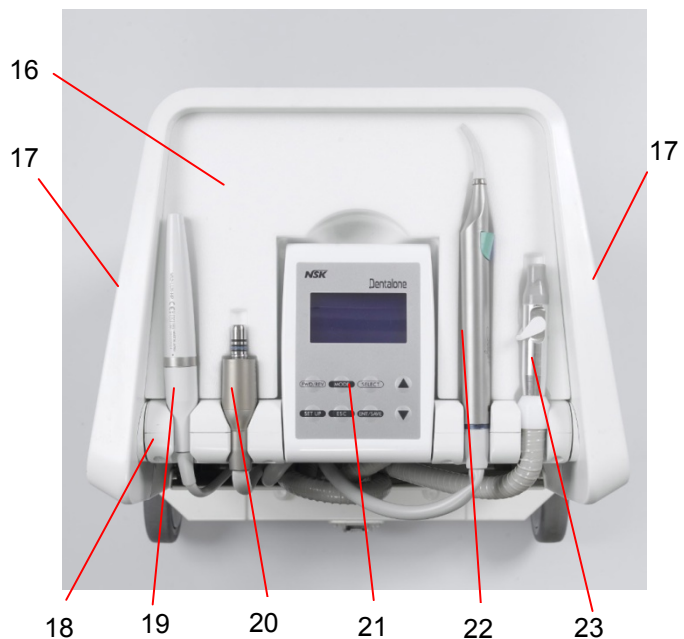


Abb. 9

8.2 Preparation / initial operation

First of all the DENTALONE has to be connected to a suitable power supply using the power cord provided (9) at the power inlet (1).

Please correspondingly consider the regulations for medically used rooms in accordance with DIN VDE 0107.

The instrument tubings and suction hoses have to be taken from the lower storage space and to be structured in such a way that the loops are not entwined with each other.

Now the power switch (1) at the left side of the device can be switched on. The indicator lamp shows a green light.

If the DENTALONE is used for the first time or after a long period out of operation, the internal compressor is working initially until the operating pressure is reached. This process can take up to 20 seconds.

At this stage the console has to be brought into the working position. The procedure is as follows:

In the recessed grips at the left and right side of the console there are unlocking switches (17) and through the activation of the rocker switches (Fig.10) the console (4) can be electrically unlocked. (works only when the DENTALONE is turned on and the device has power)

By activating the rocker switches (see illustration (fig.10) and pulling at the recessed grips on both sides the operating console (4) can manually be moved upwards until it is audibly locked in the working position, as soon.

After pressing both locking switches (17) and unlocking the console (4) (audible click), the console has to be lifted within 1.5 seconds to raise it from the lower position into the upper position. Otherwise, the lock function is activated automatically again. In this case both locking switch (17) must be released again and process must be repeated. The same applies to lowering the console.

You should remove the moulded foam part (16), which is placed on the console (4) for protecting and safeguarding the instruments and store it for future transports.

Please check after transport whether the instruments are still placed properly and in the correct order in the instrument holder (18) (from left to right: Scaler (19); Micro-motor (20); Multifunction syringe (22); Saliva ejector (23)). Refer to fig.9.

Then swivel the instrument holder (18) by gently pulling on the control panel (21) in a comfortable working position until it is audibly locked. (fig.10).

There are 2 additional stop positions which facilitate an individual positioning, so that the instruments can comfortably be taken out and the display i of the control panel (21) can be easily seen (fig.11).



fig.10



fig.11



Please check whether all instruments are completely assembled. Check your device for completeness in accordance with the delivery notes.

The footswitch (3) is located in a holder mounted side on in the lower part of the device. (fig.7). Remove the foot switch from its holder and connect it to foot switch socket (2) at the left side of the device (fig.3 and fig.4).

Before every operation check the device for proper condition.

This concerns the stability of the unit, the two-sided lock in the extended position of the console as well as the measures described in the following sections of these instructions. All cables, tubings and the suction hose should be checked for any damage.

Furthermore, the instrument detection and function of the instruments and also the default settings on the control panel should be checked. (see section 8.5 and annex A (control panel))

Before the initial operation always check whether there is enough clean water in the water tank and the suction container (12) is empty.

8.3 Filling the water tank



Before removing of the water tank (8) the DENTALONE has to be switched off at the main switch (1) or the spray switch (15) has to switch off. Following that any remaining pressure in the system has to be drained by pressing the venting valve (see fig.12). After that the fresh water tank can be pulled off the coupling pins by releasing the coupling. (See fig.13).

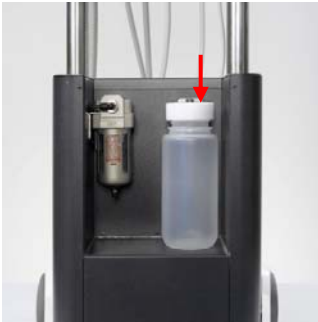


fig.12



fig.13

After unscrewing the screw cap from the bottle any remaining water should be disposed and the container has to be thoroughly cleaned according in accordance with applicable guidelines.

The water tank (8) should be disinfected before refilling in accordance with applicable guidelines. (Refer to section 9.5)

Only use drinking water quality water suitable for dental equipment must be used.

The maximum capacity of the tank is 500 ml

Before closing the bottle also the screw cover has to be cleaned, disinfected and checked for correct seating of the lid gasket. Please screw the cap hand-tight. Do not overtighten!

Now the water tank can be attached again to the quick release fitting and the Spray switch (15) can be switched back on.



The compressor will start again to establish the operating pressure

8.4 Completion and arrangement of instruments

During transport of the device all sterile parts of instruments, i.e. Scaler and Scaler Tips, motor handpiece; the tips of the syringe and the saliva ejector have to be packed separately and must be fitted again by the user.

See the detailed instructions in section 8.6.and annex B (Scaler) and annex C (Motor).

The instrument holders, as already described in section 8.2, have been located with functionality and ergonomic operation in mind



The instruments may not swapped between holders, because this would cause malfunctions!



Each day before the first treatment each instrument should be activated 30 seconds in order to rinse stagnant water in instrument hoses.

Initial operation and practice interruption of more than 24 hours

- Before the initial operation and before and after each treatment pause (> 10 hours), disinfection, cleaning, sterilization has to be carried out! (See section 9.)
- Then fill the water tank (8) with fresh drinking water.
- Start rinsing process: by switching on the spray function two times in succession for approximately 20 seconds all lines are rinsed with water.
The spray regulators (13) and (14) have to be adjusted to maximum flow setting.
By doing so any disinfection agents in the instrument hoses are thoroughly removed from the hoses.



For safety reasons the device is to be switched off at the power switch (1) before leaving the surgery.

8.5 Operating elements / displays

Control panel:

The operation of the device, which means the setting of defined parameters and operating conditions for the Varios scaler and NLX micro-motor is carried out by the multi-control panel (21), located in the centre of the console (4) and the footswitch (3) connected to the device..

Please thoroughly read the instructions for use in annex A before putting the device into operation.

Spray function:

The spray function is switched on and off by means of the rocker switch (15) located at the lower side of the console.

The spray intensity can separately be adjusted for the NLX micro-motor and the Varios scaler at the adjusters (13) and (14) at the lower side of the console.

Multifunction syringe:

Regardless of the NLX micro-motor or the Varios scaler the 3 in 1 syringe (22) can be used by activating their separate buttons on the syringe body..

Water, air or spray is controlled manually. The syringe will operate as long as the corresponding buttons are depressed.

Optionally air or water can be discharged. By simultaneously pressing both buttons spray is released.

The discharged water or air flow can be regulated by more or less intense pressure of the buttons.

Footswitch:

The footswitch (3) has to be connected to the corresponding socket at the rear of the left side panel (2) (fig.3).

By activating the footswitch the respectively active instrument which has been taken from the instrument holder is switched on, at the end of activation again switched off (Dead-man's control) and the rotation speed of the handpiece is controlled. At the same time by activating the footswitch also the instrument lighting of the active handpiece is switched on or off.

Only the scaler function ON / OFF and the motor with functions ON/ OFF + speed are controlled by the foot pedal. For multi-function syringe (22) and saliva ejector (23), the foot switch has no function. These two instruments are simply ready for operation as soon as you take them out of the holder.

8.6 Instruments

All instruments have been developed and constructed for their specific applications. Improper use will lead to injury, premature wear and tear, destruction of instruments and hazard for the user, patient or third party.

Please thoroughly read the corresponding instructions for use of the instruments before putting the device into operation. (Annex A-C)



General information

- YOU MUST ONLY USE technically perfect and hygienically cleaned and sterilized handpieces and contra-angles , scaler and scaler tips (not included in the scope of delivery)
- Do not touch rotating instruments. Risk of injury!
- Change of drill:

During the treatment pause:

The footswitch may not be activated during the change of drill, because otherwise there is the risk of injury. For safety reasons the device has to be brought into stand-by position.

During the treatment:

- Exchange of the bur or instrument only if the motor has stopped.
- Insert drill and abrasive tool as deeply as possible in the chuck system of the instrument (Please observe the manufacturer's information)
- Ensure chuck system is holding bur safely (refer to separate instruction for use of the handpiece)
- Bring instruments to full rotation speed before beginning to operate
- Avoid tilting or levering; increased danger of breakage
- Use of safety glasses is recommended depending on the use
- Improper application leads to poor performance and an increased risk
- Note the separate operating instructions of the respective instruments in annex A-C

- Observing the rotation speed recommendations leads to optimum performance. When exceeding the maximum permissible rotation speed some instruments are prone to can lead to damage or destruction of instruments
- In case of work component diameters which are bigger than the shaft strength strong centrifugal forces can occur which can lead to deflections of the shaft and/or breakage of the instrument. Do not exceed the maximum permissible rotation speed.
- Please refer to manufacturers instructions to ascertain the maximum permissible rotation speed of respective instrument.
- Avoid excessive pressing forces, because this causes damage of the cutting instruments and generates excessive heat.
- Overheating is caused by excessive pressure on the instrument which leads damage of the pulp. Excessive pressure can also lead to rough surfaces and breakages of instruments
- To avoid unwanted heat generation a sufficient cooling with an air/water spray (at least 50 ml/min) has to be guaranteed.
- Insufficient water cooling causes irreversible damage of the tooth and tissue. In case of failure of the compressed air generation, the treatment must be stopped immediately.
- Blunt burs generate excessive heat and cause damage of the pulp.
- Bent instruments not running smoothly have to be disposed of immediately.
- **Disinfection and sterilisation has to be performed in accordance with Manufacturers recommendations and applicable guidelines.**
- Before the first use and immediately after each use rotating instruments have to be cleaned and where appropriate sterilized/autoclaved. Until the first use the instruments should be stored in the original packaging or transport container at room temperature in a dust- und humidity-protected manner.
- Rotating instruments should be stored hygienically on suitable stands or containers. The same applies to sterilized instruments and instruments in sterilized packaging. Instruments **MUST** be stored in a dust-, humidity-free environment with no risk of recontamination.
- In case of non-corrosion resistant instruments disinfection and cleaning agents with corrosion protection (non-corrosive) have to be used.
- The contact with H₂O₂ (hydrogen peroxide) has to be avoided. Hard metal working components are attacked and damaged. Reduction of lifetime.
- Avoid temperature over 180°C. Exceeding 180°C leads to a reduced lifetime.
- Rotating instruments made from metal and non rust-proof instruments are attacked by the thermo-disinfector. This leads to discoloration and a shortened lifetime.
- Advices for use, duration of exposure and suitability of disinfection and cleaning substances for certain types of instruments can be obtained from the manufacturer of the solution.
- Store instruments in a dry place.
- Protect instruments against sun and heat

8.6.1 Handpieces and contra-angles *)

Please obtain the description, handling as well as maintenance and sterilization advices for the used instrument from the accompanying documents of the respective instrument.

Only handpieces and contra-angles with **ISO E-type** fitting can be used.

*) not included in the scope of delivery

8.6.2 Brushless motor Ti-Max NLX-nano

Short description: brushless micro-motor (100-40.000 r/min.) with light, type **ISO E** with internal water. Only instruments with **ISO E-type fitting** can be used.

For further information please refer to annex C (Motor).

Safety guidelines



Caution!

- Please always consider the safety of the patient when operating the motor (20).
- The motor is only provided for dental application by qualified personnel.
- The motor only works in conjunction with the control panel (21)
- Do not try to disassemble or manipulate the motor.
- The user is responsible for regular maintenance and inspection of the motor.
- Check the motor outside the mouth for vibration, noises and overheating before commencing treatment. If any irregularities occur, immediately interrupt the application and contact your NSK-dealer.
- In case of abnormal function of the motor immediately interrupt the application and send it for repair to your NSK-dealer or NSK service partner.
- Do not expose the housing to mechanical impacts. Do not drop the motor. This can lead to a malfunction.
- Do not connect/ remove the motor cable or instrument as long as the motor drive has not come to a complete standstill.
- Do not use the motor under full load for extended periods of time as this will cause it to overheat.
- The time for continuous use should be not more than 3 minutes.
- Do not exceed the motor speed recommended by the instrument (Option) manufacturers.
- Ensure that the correct speed is set on the control panel.
- Before use, always ensure that the instrument is securely located on the motor.
- Do not connect / disconnect the instruments during operation.
- The motor does not require lubrication
- After lubrication leave the handpiece at a suitable location for a certain time. Only place on the motor when excessive oil has completely drained off. If oil gets into the motor, this leads to malfunctions of the motor.
- Do not autoclave the motor cord (or sterilize with another high temperature procedure).
- Do not wipe off, clean or immerse the motor with a disinfectant solution or acid water!

8.6.3 Ultrasonic scaler VARIOS 170 LUX

For further information see the operating instructions of the Ultrasonic Scaler (19) In Annex B.



Safety instructions

- Thoroughly read through these safety guidelines before use and use the instrument only for their intended purpose and in accordance with the operating instructions.
- These displays allow a safe use of the instrument and prevent danger and damages for you and other persons.

Indicating dangerous situations



Warning!

- Do not touch the connections at the end of the scaler cord. This can cause an electric shock.
- If you feel any abnormality such as vibration, heat generation, abnormal noise, etc., prior or during use, stop immediately.
- The Electromagnetic Compatibility (EMC) is described in the operating instructions, section 4.
- Portable and mobile RF communications equipment can affect Electrical Medical equipment. Do not use RF equipment in close proximity to the product.
- USE ONLY NSK genuine tips when using NSK Varios Ultrasonic Scaler (Varios 170 LUX) problems such as damage, failure and accident of Handpieces resulting from use of Non-NSK Tips are not included in the warranty. The following are the possible failure that could happen when using non-NSK tips:
 - Vibration failure caused by using incompatible tips.E311.
 - Accidental ingestion of broken tips by the patient.
 - Damage of thread ridge of handpiece.



Warning!

- When operating the product always consider safety of the patient.
- The scaler is only to be used by qualified personnel
- Before using check the vibration of the instrument outside the oral cavity of the patient. If you determine abnormalities, immediately interrupt the use and contact your NSK-dealer or authorised service partner.
- Avoid hard impacts on the handpiece or dropping the instrument and tips on hard surfaces.
- Always work with sufficient coolant water in order to avoid damages of the tooth or an overheating of the instrument itself.
- Tips and Handpiece cannot be cleaned and disinfected with a Thermo-Disinfector.
- Sterilize the Tip, Handpiece, and Tip Wrench by autoclaving. Wipe the Handpiece Cord including the connectors. Disinfect handpiece cable according to the instructions after each treatment with a **VAH*** listed, no protein-fixing and Aldehyde-free disinfectants.
- If chemical, solvent or antiseptic solution is deposited on this product, immediately wipe it away. Discoloration or deformation may occur if left.
- Do not disassemble or change the handpiece. **DO NOT USE** on patients with a pacemaker.
- **DO NOT** use near explosive substances or combustible materials. **DO NOT** use the instrument on patients anesthetized with nitrous oxide.



Caution!

- The instrument may only be used by qualified personnel.
- Patient safety **MUST ALWAYS** have the highest priority.
- Before using check the vibration of the instrument outside the oral. If you determine abnormalities, immediately interrupt the use and contact your NSK-dealer or an authorised service partner
- Do not exceed the recommended performance area for the applied tools, because it could not only damage the tooth but also the tip.
- Do not contact ceramic prostheses during the treatment, because it could damage the prostheses and/or tip.
- **DO NOT** contact ceramic or metal crowns except when removing. The tip could break and fall out.
- Never sharpen or bend tips. Tips could be damaged and not generate sufficient vibrations. Use tip guide to check tip is fit for purpose.
- Do not directly use the tip on the gums, mucous membrane or skin. This implies the danger of injuries or combustions.
- The tip is subject to general wear and tear and natural material fatigue, which will result in reduced performance. In this case the tip should be replaced.
- . Tips **MUST NOT** be changed while the scaler is in operation.
- Always use NSK tip wrench to carefully attach the tip Otherwise only a reduced vibration could be produced.
- Before use check the screw thread of the tip for potential contaminations and clean if contaminated.
- Use only NSK scaler tips, because scaler performance may be affected or handpiece may be damaged by using tips **NOT** made by NSK. For more information refer to annex B, section B5 and B6.
- Do not sterilize the instrument with ultraviolet radiation, because the handpiece may change colour due to this.
- Unplug the handpiece at the hose coupling only after the tip has been removed. (Risk of injury)



Caution!

- The user is responsible for a constant functional supervision, maintenance and inspection of the scaler
- For the storage of the instrument the following limits apply: air temperature -10...60°C humidity 10...85% and atmospheric pressure 500...1060hPa
Air **MUST** be free of any contamination, sulphur dioxide or salt.
- To disconnect the handpiece from the handpiece cord for sterilization and/or cleaning, pull gently apart by holding the handpiece body in hand and the connector on the handpiece cord in the other hand. Pull along the long axis of the handpiece and **DO NOT** twist.

* Association for Applied Hygiene (VAH)

Warning! DO NOT touch the connections at the end of the scaler cord as this can cause an electric shock.

Caution! Make sure that the scaler tip is removed, before you disconnect the handpiece to avoid injury.
To disconnect the handpiece from the handpiece cord, pull gently apart by holding the handpiece body in hand and the connector on the handpiece cord in the other hand.

8.6.4 Multifunction syringe

Short description

The Multifunction syringe (22) is a device exclusively designed for the dental sector. It serves to blow in air and water, individually or as spray, in order to clean and dry the operating field.

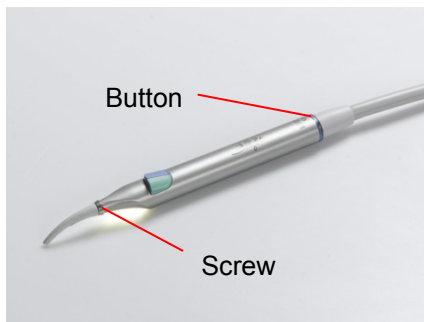


fig.14

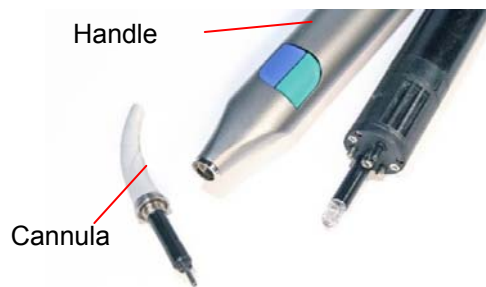


fig.15

Characteristic features

Ergonomic aspects were decisive for the choice of this Multifunction syringe for Dentalone.

This Multifunction syringe is easy to use, simple to clean and sterilize.

An LED-light positioned in the grip sleeve improves the visibility in the treatment area. Both the Cannula and the handle are easy to dismantle, perfect to disinfect and sterilize in an autoclave at 135 ° C i.e. NSK iClave.

Use

- For water only press the left key
- For air only press the right key
- For water-air mixture/spray press both keys at the same time
- The LED light is automatically activated when you take the syringe out of the holder.

Cleaning and sterilization

To constantly guarantee maximum hygiene, you should clean and sterilize the multifunction syringe tip after each treatment. To take the syringe apart, please follow these instructions:

- Remove the syringe cannula by loosening the screw (fig.14)
- To remove the complete syringe handle, push the button at the lower end of the handle in axial direction upwards. (fig.14)
- Wipe off potential contaminations with a clean cloth.
- The parts have to be sterilized in a steam autoclave at 134°C at least 3 minutes i.e. NSK iClave

Maintenance

Except the described cleaning and sterilization no additional maintenance is required for the syringe. DO NOT lubricate the multifunction syringe as this will cause irreparable damage.

8.6.5 Suction

The suction system offers the prerequisite for relaxed and ergonomic working without permanent interruptions due to the swallowing reflex of the patient.

The saliva ejector (23) allows the use of interchangeable flexible saliva ejector tips (consumable material) or autoclavable tips (size 6 mm or 1/4").

The suction is automatically switched on as soon as the suction hose is taken from the instrument holder and vice versa the suction is switched off, when the suction hose is put back in the in the holder.



Please note the position of the lever on the suction handpiece.

Lever position forwards	= closed
Lever position backwards	= open

The suction is automatically switched off, as well, when the waste water reservoir (12) is full and has to be emptied.

The waste reservoir has a maximum volume of 1 litre It is located on the front of the unit. (See section 8.1 – fig.7)

Cleaning:

- Before disconnecting the reservoir the saliva ejector has to be emptied, by holding the saliva ejector as high as possible and by doing so slightly stretching the suction tubing to allow any residual liquid to drain out of the tubing into the reservoir.
- Pull out the plug of the filling level sensor socket! (fig.16).
- After that the reservoir has to be released from the connector by pressing the release lever.



Connector "Level-Sensor"

unlocking lever on quick release connector

suction tube connector

fig.16

After that the reservoir can be removed from the connector and be emptied. To remove lid unscrew from the reservoir and empty content into an amalgam separator, waster container or sewer system in accordance with applicable regulations. Additional waste water reservoir containers with lids are available as an accessory.

Before reuse the reservoir should be cleaned (see also section 9).

After cleaning and screwing the lid back on the reservoir can be placed back on the quick release connector ready to be used again. Please make sure it is securely held in place by listening out for noticeable locking click indicating that it is securely in place.

ALWAYS check the safe and secure fastening of the reservoir before use

Re-insert the plug of the level sensor in the contact socket (level sensor).



A filter is installed in the front part of the saliva ejector. This is accessible by careful removing the rubber adapter for the suction nozzle.

Clogging the strainer may cause a malfunction or power reduction of extraction. Therefore, the strainer should be checked after each treatment and daily cleaned.

9. Cleaning, maintenance, disinfection and sterilization

9.1. General

- When cleaning the Dentalone protective gloves MUST be worn at all times for health and safety compliance.
- Objects which cannot be sterilized and disinfected MUST NOT be handled with the same gloves. When interrupting cleaning process the gloves have to be taken off.



A treatment area is defined as an area where the recommendations regarding the hygiene requirements in the reprocessing of medical devices of the **Division of Hospital Hygiene, Infection Prevention and Control of the Robert Koch-Institute** and **The Federal Institute for Drugs and Medical Devices** apply.

Cleaning intervals:

Between patients

- Rinse the water tank and fill with fresh drinking quality water
- Connect suction hose and saliva ejector to the waste container and then rinse by sucking approximately 0.2 litre drinking water.
- Change the saliva ejector cannula consumables), the multi-function syringe tip (Autoclavable) and scaler including scaler tip.
- Disinfection of all parts, which were touched during the treatment or came into contact with the patient.
These include especially
hose, coupling piece and saliva handpiece, console upper part with instrument holder, multifunction syringe, scaler, motor, patient chair.

At the end of the working day

- All of the aforementioned items as between patients
- Sterilisation of the water tank (the water tank cap only to clean and disinfect!).
- Clean and disinfect suction handpiece, suction hose and waste water collection tank including cap with disinfectant solutions in accordance with the manufacturer's instructions.
- Disassemble saliva ejector and suction hose attachment, wash and lay in disinfection solution overnight.
- Clean sieve of suction hose.
- Cleaning and disinfection of the unit

Once per week

- All of the aforementioned steps as per the end of the working day procedures
- Autoclaving of the water tanks and the waste water collection container (clean and disinfect the caps – as the caps are not autoclavable!)

9.2. Disinfection, cleaning and sterilization of instruments and handpieces

- Contaminated instruments have to be changed between patients to be cleaned, disinfected and sterilized in accordance with applicable guidelines following the manufacturer's instructions.

For disinfection and sterilization the selected procedure MUST be suitable for the respective instrument, you will find relevant information also in the detailed operating instructions for the micro-motor, contra-angles, handpieces and ultrasonic scaler in annex B und C.

- Before the first use and immediately after each use rotating instruments have to be cleaned and sterilized. Until the first use the storage has to be conducted in the original package at room temperature in a dust- und humidity-protected manner.
- Rotating instruments should be stored on hygienically maintained stands, autoclaving pouches or other suitable containers. The same applies to sterilized instruments and instruments in sterile packaging. The storage has to be in a dust-, humidity- and recontamination-protected environment.
- In case of non-corrosion protected instruments disinfection and cleaning agents with corrosion protection have to be applied.
- The contact with H₂O₂ (hydrogen peroxide) has to be avoided as this will attack and damage hard metal working components invalidate the product warranty and shorten the product life.
- Avoid temperature over 180°C as this will reduce the product's life.
- Rotating instruments out of hard metal and non rust-proof instruments are attacked by the thermo-disinfector. This leads to discoloration and a short lifetime.
- Always refer to manufacturer's instructions before using any cleaning or disinfecting solutions.

9.3. Cleaning and sterilization of drills and abrasive tools

Drills and abrasive tools have to be cleaned, disinfected and sterilized professionally. Suitable cleaning and disinfection agents can be obtained from specialist dental suppliers. Instructions for use have to be strictly followed.

9.4. Cleaning of surfaces which cannot be sterilized

(Unit, trays, etc.)

General procedure:

Disinfect by wiping with a cloth which is soaked in disinfectant solution. Mechanical wiping movement with a wet, however not dripping cloth is essential. Do not wipe with a dry cloth afterwards.

Painted surfaces and all metal parts can be wiped with mild cleaning and disinfection agents. Please only use ammonium chloride-free agents, because ammonium chloride would destroy the paintwork in the long run!

9.5. Water pipes and water tank

- After longer periods when the unit has not been used (especially in the morning before first use) all tubings, pipes and hoses of the unit.
- The water tank (without screw cap) has to be autoclaved at 121°C once a day.
- The lid of the water tank should be disinfected with VAH listed disinfectants because it cannot be autoclaved.
- For disinfection and to prevent the formation of organic film it is recommended to flush all tubings, pipes and hoses regularly with suitable solutions (Please refer to section 9.7)
- Afterwards rinse thoroughly by running each instrument twice for at least 20 seconds with the water spray function activated. The spray controls (13) and (14) have to be turned on maximum flow. Thus, the remains of cleaning and disinfectant are rinsed from the hoses.



Remember that the cap of the water tank **MUST NOT** be autoclaved!

9.6. Suction system

- Wipe suction hose between patients with a disinfectant wipe.
To avoid blockages flush hose especially following procedures with bleeding with cold water but at least 4 to 6 times per day Attach suction hose to the waste water container (12) and rinse.
- At the end of the day's sessions flush suction hose as per manufacturer's instructions.
- The waste water collection reservoir (wide neck glass bottle) has to be thoroughly cleaned after emptying and, if necessary, to be autoclaved at 121 °C (except the screw cap which is NOT autoclavable).



The lid of the waste water reservoir MUST NOT be autoclaved!

9.7. Recommended disinfection and cleaning agent

BILPRON	Agent for operating water disinfection
ALPRON	Agent for water treatment
BIOTEST plus	Agent to verify the bacterial load of liquids and surfaces
AlproJet-DD or -D	Highly effective concentrate for daily cleaning of suction systems
AlproJet-W	Highly effective concentrate for the weekly cleaning of suction systems

Always follow the instructions of the manufacturer of disinfectants and cleaning solutions.

10. Maintenance

It is recommended to maintain the DENTALONE according to the suggested intervals (see below). Maintenance and repair may only be carried out by authorized personnel by an appointed dealer or the manufacturer.

It is not permitted under any circumstances for unauthorized persons to open and interfere with the device.

Changes and repairs carried out by unauthorized persons invalidate the manufacturer's warranty and liability.

In addition to the inspection and functional examination during regular maintenance of the device an examination according to DIN VDE 0702/0751 has to be carried out.

All parts subject to normal wear and tear have to be replaced as required and are not covered by the warranty.



Advice: For the disposal of packaging, accessories and also the device you MUST COMPLY with applicable regulations!

10.1. Regular maintenance works

Scope and intervals of the safety-technical checks should be in accordance with country-specific regulations.

Recommended are:

At least once every 12 months the below mentioned safety-technical checks have to be carried out under consideration of DIN VDE 0750 and DIN VDE 0751:

- Visual control of the device and accessories, examination of the protective earthing according to DIN VDE 0751, equivalent leakage current measurement according to DIN VDE 0751.
- Functional checks of the device under consideration of accompanying documents.

It is recommended to keep a log book, in which the examination results of the safety-technical checks are documented.

Clean liquid container regularly, if necessary, de-scale and autoclave at 121°C.

10.2. Maintenance intervals

Daily maintenance (by the user)

The fulfilment of requirements for hygiene and the maintenance of efficiency of the device is guaranteed by carefully observing the information for disinfection, cleaning and maintenance of the instruments.

- Before the first treatment flush all tubings and hoses pipes for approximately 30 seconds by operating all outlets. While doing this, the spray controls (9) and (10) for motor and scaler have to be adjusted on maximum flow.
- Clean and maintain handpieces and contra-angles in accordance with manufacturer's guidelines.
Important: observe exactly the maintenance instructions of the instruments under section 8.6 and 9.



Instrument tubings CANNOT be cleaned in the thermo disinfectant and MUST NOT be exposed to temperatures exceeding 40 °C maximum.

Annual maintenance (by authorised personnel)

Basic cleaning of the water lines:

A basic cleaning of the water lines to remove biofilm is necessary for the treatment unit which has been in operation for more than one year. This has to be carried out by an authorised service technician. Remove instruments from micro-motor and scaler handpiece, so that the water channels in these instruments do not get blocked as a result of the cleaning process.

Control:

Within the examination of the treatment unit it has to be inspected:

- control of function and performance
- examination of delivery volume of the water
- Visual Control
 - Integrity of the housing
 - Integrity of hoses, fuses and the power connection cable
 - Labels, symbols, indicator lamps
 - tightness of water and air channels
 - Instrument wear
 - Existence of the operation manual

10.3. Maintenance works at the compressed air reservoir

The compressed air filter (7) is located on the left side next to the water tank. In regular intervals during cleaning and maintenance drain condensate which may have accumulated in the filter.

The drain valve MUST ONLY be operated when the unit is turned OFF, (fig.17) Start by placing an absorbent cloth under the drainage valve and wipe the housing thoroughly dry afterwards.



fig.. 17

10.4. Replacing the hand piece cords

Should the exchange of one of the motor- or hand piece cords be required, please follow the below steps:

- Switch off the unit on the main switch.
- After that, release any remaining pressure in the water tank by pushing the release vent. (fig. 12) and remove the tank..
- Unscrew the defective hose from the unit below the console and then disconnect it carefully (gently pulling downwards).
- It is possible that some remaining fluids may drip from the connections. (please keep an absorbent cloth for drying to hand)
- For disconnecting the cord on the scaler or micro-motor please refer to the related sections in annex B and C.



- When replacing the multifunction syringe, any remaining pressure and water in the system will escape from the open hose. (please keep an absorbent cloth for drying to hand)
The multi-function syringe together with the hose can be separated from the unit and completely replaced together with the hose or separately



The unit may only be put into operation if all outlets are properly connected.

Please check that the connectors are tight after they have been changed.

In case of any leaks please liaise with manufacturer appointed dealer or the manufacturer.

11. Malfunctions and trouble-shooting

11.1. Fault diagnosis

Please see below information for help should you come across any issues. In case problems cannot be resolved please contact manufacturer appointed dealer or the manufacturer.

Malfunction	Search for problem	Cause	Measures
Device does not work	Main switch does not light-up	No power from mains electricity	Please check power cable connection / check device fuses / if necessary, check socket
	Main switch light works but no display in the operating part	Possibly power supply defect, internal device fault	Send device for repair, no self-help possible
Micro-motor does not work, when taken from the holder	Control panel displays fault code – see operating instructions, annex A	Motor is not connected	Check connection of the handpiece to the device
		Foot pedal not connected or defective	Connect or check footswitch
		Faulty contra-angle or handpiece (blocked or ceased up)	Check the handpiece/contra-angle and the chuck locking system
	Control panel displays still in the previous status	Optical detection sensor in holder is dirty	Clean the optical sensors with a cotton swab
		Defect of electronics	Send device to repair, no self-help possible
Spray function does not work	Check filling level of the water tank	No water	Fill water tank
	Check the spray switch	Spray switch not activated	Switch on spray selector switch
	Check by activating the vent valve, if air escapes at activation	No pressure built-up in the water tank, because either screw cap is not closed tightly or seal is missing	Screw the cap tightly on the water tank and/or clean the seal
	Check Spray adjuster	Spray adjuster was closed	Adjust to the desired volume
Suction does not work or only with restricted performance	Check the lever on the suction handpiece	Lever at "closed" position	Move lever to "open" position
	Check Sieve	Sieve is clogged	clean, or replace if necessary
	Check the screw cap	Lid isn't tightly screwed on; or missing seal. Effect: vacuum is not building up	Check the seal ring, clean and screw the cap tightly.
	Check the O-ring seals on the coupling plug from the tank and the suction hose	Seals missing or damaged	Replace the seals
	Check filling level of the waste container	Waste container full	Empty waste container
	missing signal from the filling level sensor	filling level sensor isn't connected on the unit	Check the connection (fig. 15)
	Check the floating body of the filling level sensor	floating body sluggish and remains in the upper position	Clean the guiding surfaces and check for smooth operation

Electric unlocking of console does not work		Locking mechanism jammed	Relieve the plunger of the locking mechanism by slightly lifting the console during activation of the unlocking button
		Only one of the unlocking switches (one side of the console) is activated	De-press the unlocking button on both sides of the console
		Internal electric functional disturbance	Use manual emergency unlocking (section 11.4), send device for repair to NSK service partner
	Main switch does not light	No voltage	Please check power cable connection

11.2. Fault signals

Signal	Description	Measure
Acoustic signal permanent	Device temperature < 10 °C (outside of the limits)	Move the machine into a warmer environment
Acoustic signal alternate	Device temperature > 70 °C (outside of the limits)	Move the machine into a cooler environment (treatment break)
Error code on the Control Panel	Refer to instruction of use for the control panel in annex A	Refer to instruction of use for the control panel in annex A

11.3. Change of fuse



Attention! Only carry out change of fuse while unit is disconnected from the mains electricity supply. Hazard of electric shock! Hazard of electric shock!

The fuse box is located at the side of the power inlet between the main switch and the power socket. Before changing the fuse always disconnect the power cable from the power socket!
For opening the fuse box you require a flat screwdriver by which you carefully take out the link.



Attention! Only use fuses with the correct rating. After that push back the fuse in the holder until it is securely held.

11.4 Manual unlocking the console

⚠ Attention! Please only use this mechanical unlocking option of the console in case of defect or power failure.

For manual emergency unlocking remove the cover cap at the housing. (fig.18)

Then turn the slotted screw with a screwdriver by approximately ¼ turn clockwise until the console is unlocked (fig.19), while a second person gently pushes the console downwards.

The locking in the transport position is automatically carried out.



fig.18



fig.19

12. Disposal advices

The device and its packaging were made from materials which can be recycled. This reduces the waste and protects the environment.

Discard the packaging separately for recycling in accordance with local recycling options.



Devices that are marked with this symbol must not be disposed as household waste! You are legally obliged to dispose old devices separately from the household waste. (European Directive 2002/96/EC) Get free information about the disposal of your product from your NSK dealer.

WEEE-Reg.-No. DE 72356056

13. Technical data

Mechanical data	
Dimensions including cover: (Heightxwidthxdept)	580 x 415 x 365 mm
Dimension without cover in operating position: (Heightxwidthxdept)	770 x 405 x 350
Weight: (including cover)	19,5 Kg
Protection type (covered):	IP32 nach EN 60529
Protection type without cover:	IP30 nach EN 60529
Electrical data	
Nominal voltage:	100 - 240 V~ 50/60 Hz
Power consumption:	max. 400 VA on 230 VAC
Device fuse:	2x T4,0 AL / 250 V
Protection in the installation:	16 A idle (e.g. circuit breaker with B-character)
Protection class:	I according DIN EN 61140
Classification according to MDD 93/42/EWG annex IX:	IIa
Operating data	
Operation mode	continuous
Noise level	< 58 dB
Capacity of Water Tank	500 ml
Capacity of Waste Container	1000 ml
Suction power of vacuum pump (max.)	11 l/min air; 78% vacuum
Compressor– air pressure (max.)	3,0 bar
Water consumption for spray	>50 ml / min
Cooling air for Motor	>6,5NI / min
Motor speed	1000 – 40000 min ⁻¹
Motor torque	Max. 3,4 N cm
Operating temperature	+15 ... +40 °C
Life time	5 years
Storage and transport conditions	
Temperature area	-10 ...+60 °C
Relative air humidity, non-condensing, no tropical protection	10...85%
Air pressure	500 – 1060 mbar

KONFORMITÄTSERKLÄRUNG DECLARATION OF CONFORMITY

Wir
We

Hersteller / Manufacturer:
NSK WT GmbH
Portitzer Straße 69 d
D-04425 Taucha
Germany

erklären in eigener Verantwortung, dass das Medizinprodukt
declare on our own responsibility that the medical device

Dentalone

Artikel-Nr. / Article number: 9070

**allen relevanten Anforderungen der Richtlinie 93/42/EWG und
der Richtlinie 2006/42/EG entspricht.**

meets all the provisions of the Directive 93/42/EEC and Directive 2006/42/EC which apply to him

Angewendete Normen

Applied standards

(Liste der Angewendeten Normen / List of applied standards)

Gesetz über Medizinprodukte (Medizinproduktegesetz MPG)

EN 60601-1 (Gerätesicherheit)

EN 60601-1-2 (EMV)

EN 60601-1-6 (Gebrauchstauglichkeit, Ergonomie)

DIN EN ISO 14971 (Risikomanagement)

Benannte Stelle

Notified Body

BSI Group Deutschland GmbH
Eastgate
Hanauer Landstraße 115
60314 Frankfurt



Kenn-Nummer / Registration Number.

CE 595189

Konformitätsbewertungsverfahren

Anhang II.3 93/42/EWG

**Diese Erklärung gilt für alle oben genannten Produkte, die während des Jahres 2014 und 2015
hergestellt sind und für die eine interne Freigabe vorliegt.**

This declaration applies to all above mentioned devices manufactured in 2014 and 2015 for which an internal release was given.

Die Technischen Unterlagen werden beim Hersteller aufbewahrt.

The technical data are kept by the manufacturer.

Taucha, den

Unterschrift und Angabe der Funktion

Signature and function of the signing person



Dieter Bauch
General Manager NSK WT GmbH

Annex A

Operation manual Multi-control panel

Please read this Operation Manual carefully before use.

A1. General information



Precautions for the handling and operation

- Read these safety cautions thoroughly before use and operate for their intended purpose according to this manual.
- Connect only NLXnano-Motors. Do not connect any other motor!
- These indicators will show you how to operate the product safely and prevent danger to you or others. They are classified by degree and/or severity of danger. All contents relating to safety should be observed.

Classification

Degree and severity of danger or damage



Danger

Provides an instruction where death or the instructions may occur.



Warning

Provides an instruction where personal injury or physical damage may occur.



Caution

Provides an instruction where minor to medium injury or physical damage may occur.



Notice

Provides an instruction that should be observed for safety reasons.



Danger

- Do not attempt to disassemble the product or tamper with the mechanism, it may cause an electric shock or fire.



Warning

- Do not use the product for implant surgery.
- The product is designed only for clinical dental use by qualified personnel.



Caution

- The multi-control panel is not water proof and should not be exposed to water.
- Do not use the multi-control panel as a handle when you want to move the dental unit.
- Do not pull the instrument cords and suction tubing with an excessive force.
- Be sure to press the buttons with a finger.
- When operating always consider the safety of the patient.
- Should the product function abnormally, cancel the operation immediately and send it to your NSK-dealer for repair.
- Care should be taken not to place the motor cord near a gas burner. Never attempt to repair a burnt motor cord. Always replace damaged cords with a new one.
- Do not exceed the drive motor speed recommended the bur/file manufacturers.
- Ensure the gear ratio on the display and gear ratio of the handpiece match.
- Please ensure that rotation speed range is set correctly.
- Don't use or leave the product in a high-temperature environment such as under strong direct sunlight, by a fire or near a radiator as this may cause a malfunction for inner circuit or sudden heat generation.

Summary of user setting menu

Motor

The following menus will be displayed on the LCD screen:

1. Language	▶	English
2. Gear ratio		Espanol
3. Lamp		Italiano
4. Endo mode		Francais
5. Air		Deutsch
6. Endo alert		
7. Others		
8. Version		

1. Language	▶		
2. Gear ratio		Gear ratio 1	▶ 1 – 20 : 1 – 5 *
3. Lamp		Gear ratio 2	▶ 1 – 20 : 1 – 5 *
4. Endo mode			
5. Air			
6. Endo alert			
7. Others			
8. Version			

* Adjustable range

1. Language			
2. Gear ratio			
3. Lamp	▶	On / Off	▶ On / Off
4. Endo mode		Intensity	▶ 1.6 – 3.6 V *
5. Air		Delay timer	▶ 1.0 – 5.0 sec *
6. Endo alert			
7. Others			
8. Version			

* Adjustable range

1. Language			
2. Gear ratio			
3. Lamp			
4. Endo mode	▶	Display setting	▶ Ncm
5. Air			mm
6. Endo alert			%
7. Others		Auto REV time	▶ 0.3 – 1.0 sec *
8. Version		Auto FWD time	▶ 1.0 – 3.0 sec *

* Adjustable range

“Endo mode” setting is not reflected in the case of the NLX nano motor

1. Language			
2. Gear ratio			
3. Lamp			
4. Endo mode			
5. Air	▶	Display setting	▶ psi
6. Endo alert			bar
7. Others			MPa
8. Version		Motor MIN pressure	▶ 0.03 – 0.10 MPa *
		Motor MAX pressure	▶ 0.20 – 0.40 MPa *

1. Language
2. Gear ratio
3. Lamp
4. Endo mode
5. Air
6. Endo alert
7. Others
8. Version

|

Endo mode alert	▶	On / Off
Alert setting 1	▶	40 – 80 %*
Alert setting 2	▶	80 – 100 % *
REV alert	▶	On / Off

* Adjustable range

“Endo mode” setting is not reflected in the case of the NLXnano motor

1. Language
2. Gear ratio
3. Lamp
4. Endo mode
5. Air
6. Endo alert
7. Others
8. Version

|

LCD contrast	▶	-2, -1, 0, +1, +2
Backlight timer	▶	1 – 30 min or ∞ *
Acceleration time	▶	0.5 – 3.0 sec *
Default setting	▶	No / Yes

* Adjustable range

1. Language
2. Gear ratio
3. Lamp
4. Endo mode
5. Air
6. Endo alert
7. Others
8. Version

|

LCD XXXX
NLX XXXX
VA170 XXXX

Scaler

In the case of connected to the Varios 170 this menu is displayed at the setup:

1. Version

LCD XXXX
VA170 XXXX
NLX XXXX

A2. Features

- Integrated System of Electric Micromotor (NLX BF) and Multi Function Ultrasonic Scaler (Varios 170) can be controlled with the multi-control panel.
- User settings are achieved via the LCD graphical user interface.
- Visual identification of graphics on the multi-control display is possible even during operation of the handpiece.
- The multi-control panel allows up to 8 custom programs for your exacting needs (motor only).
- The multi-control panel supports 5 languages (English, Espanol, Italiano, Francais and Deutsch).

A3. Description of the user interface



A4. Start-up

When turning the power ON, the name of connected instruments will be displayed for about 3 seconds along with a beep tone. Then, the LCD display will switch to operating screen automatically.



When turning the power on and simultaneously push the foot control, the display of the multi-control display will show the error message with „Release Foot Pedal“ until a beep is heard. The error message will disappear when foot controls is released.

A5. Description of the display

A5.1. MOTOR



Fig.1 Normal display when using micromotor

While the display shows the fig.1, you can control a motor by pressing the foot control pedal.

- Rotation display (fig.1):
 - When the motor is stopping, the display shows the maximum rotation speed. When the Motor is rotating, the display shows the actual rotation speed.
 - When the motor stops, the display shows "0" on the display then turn to the maximum rotation speed originally selected.



Forward Mode: Motor turns clockwise



Reverse Mode: Motor turns counter clockwise.

- Rotation speed display (fig.1)



The display shows rotation speed you selected. While the motor is rotating, the actual rotation speed will show on the display

SET VALUE display:



The pre-programmed maximum rotation speed is indicated on the display. The icon will go off while the motor is rotating. While the motor is rotating the speed icon appears for 1 second.

- Program number display: (fig.1)



The program number you selected will be displayed. For detailed program setting, refer to section A7 „Useful functions“.

- Gear ratio display: (fig.1)



The preset gear ratio is displayed. A total of 10 different gear ratios can be selected.

8 gear ratios are default and cannot be changed.

2 gear ratios are for customized setting by users. For detailed gear ratio setting, refer to section A6. „Settings“.

A5.2. SCALER

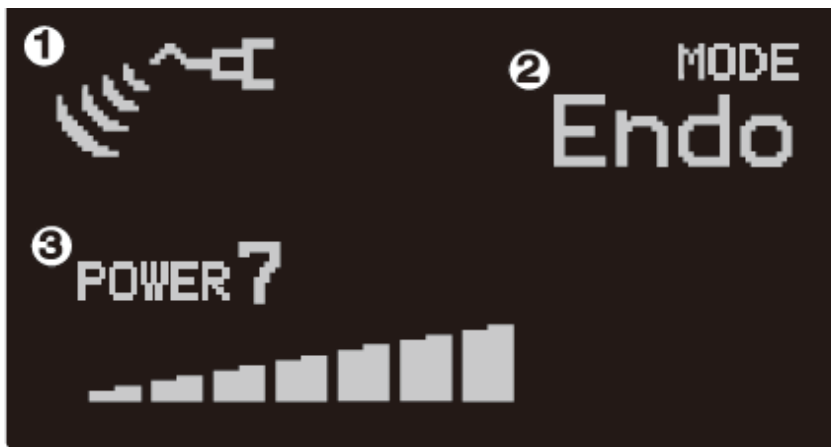


Fig.2 Normal display when using scaler

While the display shows the fig. 2, you can control the ultrasonic scaler by pressing the foot control.

- Ultrasonic Vibration display: (fig.2)



When the scaler is vibrating, vibration icon will be displayed.

- Vibration Mode display: (fig.2)



Selected ultrasonic mode is displayed. (Perio, Endo or General)

- Power Level display: (fig.2)



Selected ultrasonic power level is displayed. (POWER 0 – 10)

A5.3. Selection of the instrument

The selection of the instrument is done automatically by removing the respective instrument (scaler or motor) out of the instrument holder.

A6. Settings

A6.1. MOTOR

Functions you can set while the motor is rotating: Maximum rotation speed, rotation direction.
 Functions you can set while the motor is stopping: maximum rotation speed, rotation direction, gear ratio, program (PRG).

- Speed setting
 Press the ▲ / ▼ key to set your desired speed in the motor function display.
 Speed Range: 1,000 – 40,000 min⁻¹



Notice

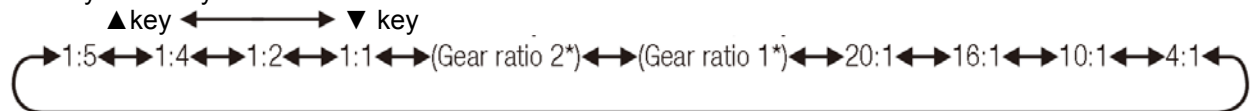
Speed display changes faster as you press and hold the ▲/▼ key

- Gear ratio setting
 A maximum of 10 different gear ratios can be set.
 8 are fixed default settings, 2 are for free settings.
 - Press SELECT key until 'Gear ratio' on the display blinks at the normal display.
 - Press ▲ / ▼ keys to choose an appropriate Gear ratio.
 - Press and hold **ENT/SAVE** key for 3 seconds or longer to save the set Gear ratio.



Notice

The turn by ▲/▼ key is shown below



*Gear ratio 1 und 2 only displayed, when you set them in user setting menu. For user setting menu, refer to section A9. „Other Settings“.

- Rotation Direction setting
 To select the motor forward rotation, press **FWD/REV** key, until “F” appears at the normal display.
 To select the motor reverse rotation, press **FWD/REV** key, until “R” appears at the normal display.

A6.2. SCALER

- Treatment mode setting:
 Use **MODE** key to select the different treatment modes at the ultrasonic scaler display.
 Press **MODE** key, “Perio”, “Endo” and “General” modes will be displayed as you press the key.
- Power level setting:
 Use ▲ / ▼ key to select the power level at the normal display.
 Press ▲ key for increase, press ▼ key for decrease.(Power 0 to 10).

A7. Useful functions

A7.1. MOTOR

Up to 8 customized settings are available with the following selections:

- Maximum rotation speed
- Rotation direction
- Gear ratio
- Program selection

:

- 1) Press **SELECT** key, until program number is displayed blinks at the motor function display.
- 2) Press ▲ / ▼ key to select the program number that you want to use.
- 3) Press **ENT/SAVE** key for 3 seconds or longer, the selection is completed.



Notice

When the program you selected is modified, the colour of „PRG“ will inverse



A8. Error-Codes

A8.1. MOTOR

The system incorporates an automatic diagnosis feature that can help to diagnose the cause of a problem in the event of failure mode. When the system has failed, the display will show the “E-**” code and message. Details of each error code are listed below.

Error Code	Error Message	Cause	Solution
E-00	Over setting torque value	Too much torque is loaded	Remove the load from motor
E-01	Over current (Soft1)	Too much torque is loaded	Release the foot control
E-02	Over current (Soft2)	Abnormal electric current applied to motor and circuit	Release the foot control
E-03	Fault error	Motor driver is over current	Contact NSK dealer
E-04	Overheat	Motor is overused	Leave the motor until it has cooled down
E-05	Over input voltage	Excess voltage	Contact NSK dealer
E-06	Over lamp voltage	Lamp circuit over voltage	Contact NSK dealer
E-07	Residual voltage error	Output circuit error	Contact NSK dealer
E-08	Over load error	The state of the load that exceeded the limits continued during the fixed time	Remove the load from motor/handpiece and release foot control
E-09	Motor start is failure	Handpiece/motor cord disconnected	Check if the handpiece cord has been connected properly on motor and device
	?????	Electric circuit may fail	Contact NSK dealer
E-10	Lamp under voltage	Lamp circuit under voltage	Contact NSK dealer
E-13	Over control range	Over motor control range	Remove the load from motor/handpiece and release foot control
E-14	EEPROM error	Memory read/write data error	Contact NSK dealer

A8.2. SCALER

Error Code	Error Message	Cause	Solution
E-09	Poor tool	Handpiece cord disconnection	Check the handpiece cord is connected to handpiece properly
E-01	Over current (Soft1)	Program error	Contact NSK dealer

A9. Other settings

For each setting, follow the process below.

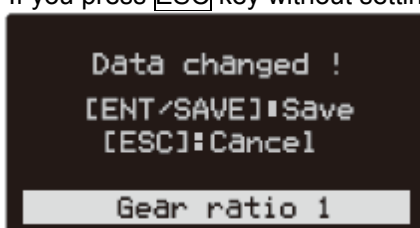
- 1) Ensure the Motor and the Scaler are completely stopped.
- 2) For normal display, press and hold SET UP key for 3 seconds or longer, then “User setting menu” will be displayed.
- 3) Use ▲ / ▼ key to select the item you wish to change.
- 4) Press ENT/SAVE key. Then, straight away select the item. (Perform this process, in order to decide change after a setup “it indicates from 9-1 to 9-2”).
- 5) Press and hold **[ENT/SAVE]** key for 3 seconds or longer to save the program.



Notice

At the setting mode, to move back to the previous screen press the **[ESC]** key.

If you press **[ESC]** key without setting, the menu below will appear. Follow the instruction on the display.



A9-1 Motor settings

A9-1-1 [1.Language]: Setting the display language.

1. Language	▶	English
2. Gear ratio		Espanol
3. Lamp		Italiano
4. Endo mode		Francais
5. Air		Deutsch
6. Endo alert		
7. Others		
8. Version		

A9-1-2 [2.Gear ratio]:

2 of 10 gear ratio settings can be set for customized settings.

To move the cursor, press the **[SELECT]** key.

The gear ratio can be set [20 to 1:1] or [1: 1 to 5].

The right side or the left side should be 1.

1. Language	▶		
2. Gear ratio		Gear ratio 1	▶ [1 – 20 : 1] or [1 : 1 – 5]*
3. Lamp		Gear ratio 2	▶ [1 – 20 : 1] or [1 : 1 – 5]*
4. Endo mode			
5. Air			
6. Endo alert			
7. Others			
8. Version			

*Adjustable range

A9-1-3 [3.Lamp]: For setting the function of the LED.

At setup mode, select “Lamp” on the screen. Then you will see the next selection shown below diagram.

- ON/OFF:
Setting the Motor Lamp on/off.
- Intensity:
Setting the intensity of the motor lamp (1.6 V – 3.6 V). Default is 3.5 V.
- Delay timer:
Setting the time delay of lighting after the motor has been used. (1.0 – 5.0 seconds) Default is 3.0 sec.

1. Language			
2. Gear ratio			
3. Lamp	▶	On / Off	▶ On / Off
4. Endo mode		Intensity	▶ 1.6 – 3.6 V *
5. Air		Delay timer	▶ 1.0 – 5.0 sec *
6. Endo alert			
7. Others			
8. Version			

* Adjustable range



Notice

The setting items of „Intensity“ and „Delay timer“ will be displayed only the when it is „ON“.

A9-1-4 [4.Endo mode]: Endo (endodontics) mode setting.



This setting is not applicable to the NLX nano motor and Dentalone

A9-1-5 [5.Air]: Calibration for air driven foot control



This setting is not applicable to the Dentalone

A9-1-6 [6.Endo alert]: Settings the alarm in Endo (Endodontics) mode.



These settings are not reflected in the case of the NLX nano motor.

A9-1-7 [7.Others] : Other settings

At setup mode, select “Others” on the screen. Then you will see the next screen shown below.

- LCD contrast:
Setting the contrast of the LCD display.
Select the LCD contrast that you want to use, “- 2”, “- 1”, “0”, “+ 1”, “+ 2”. Default is “0”.
- Backlight timer:
Setting the timer up to ‘OFF’ of the backlight of the LCD display.
Select the ‘Backlight timer’ that you want to use, 1 minute to 30 minutes or infinite.
Default is 10 min.
- Motor acceleration time:
Setting the time for the motor rotation speed to arrive at the maximum speed value.
Select the acceleration time that you want to use, 0.5 seconds to 3.0 seconds. Default is 0.5 sec.
- Default setting:
Back NLX BF to the factory default setting.
When you select “Default setting” by pressing **ENT/SAVE** key, you will see the menu of Reconfirmation screen.
Use ▲/ ▼ key to move to “Yes”, then **ENT/SAVE** key for 3 seconds. Then the all settings are initialized.

1. Language
2. Gear ratio
3. Lamp
4. Endo mode
5. Air
6. Endo alert
7. Others
8. Version

LCD contrast	▶	-2, -1, 0, +1, +2
Backlight timer	▶	1 – 30 min or ∞ *
Acceleration time	▶	0.5 – 3.0 sec *
Default setting	▶	No / Yes

* Adjustable range

A9-1-8 [8.Version]: Display product information

LCD: Software Version
VA170: Software Version
NLX: Software Version

1. Language
2. Gear ratio
3. Lamp
4. Endo mode
5. Air
6. Endo alert
7. Others

8. Version

LCD XXXX
NLX XXXX
VA170 XXXX



A9-2. SCALER SETTINGS

9-2-1 [1.Version]: Display product information

LCD: Software Version

VA170: Software Version

NLX: Software Version

1.Version



LCD XXXX
VA170 XXXX
NLX XXXX

Annex B

Operation manual Ultrasonic Scaler Varios 170

Please read this Operation Manual carefully before use.





B1 General information

Intended use

This product is designed only for dental clinic / dental office use. This device generates ultrasonic waves intended for use in dental applications such as scaling, root canal treatment, periodontal and cavity preparation.

Precautions for the handling and operation

- Read these safety cautions thoroughly before use and operate for their intended purpose according to this manual.
- These indicators will show you how to operate the product safely and prevent danger to you or others. They are classified by degree and/or severity of danger. All contents relating to safety should be observed.

Classification	Degree and severity of danger or damage
 Danger	Provides an instruction where death or the instructions may occur.
 Warning	Provides an instruction where personal injury or physical damage may occur.
 Caution	Provides an instruction where minor to medium injury or physical damage may occur.
 Notice	Provides an instruction that should be observed for safety reasons.

Warning

- TO PREVENT ELECTRIC SHOCK - Do not touch the electrical connector pins at the rear of the Varios handpiece and the Varios scaler cord!
- If you feel any abnormality such as vibration, heat generation, abnormal noise, etc., prior to or during use, stop using it immediately.
- This product is an electrical Medical Device. The Electromagnetic Compatibility (EMC) is described in the operating instructions, section 4.
- Portable and mobile RF communications equipment can affect electrical medical equipment. Do not use RF equipment in close proximity to the product.
- Use ONLY genuine NSK tips when using NSK Varios ultrasonic scaler (Varios 170 LUX). Problems such as damage and, failure and accidents of scaler handpiece resulting from use of non-NSK Tips are not included in the warranty. The following describes possible failures that could happen when using the Non-NSK tips;
 - Vibration failure caused by using non-conforming tip threads.
 - Accidental ingestion of broken tips by the patient.
 - Damage of thread ridge of handpiece.
 - You must use the tip within the power range described on the Tip-Power Guide. If you use it out of the power range, the tip might break or damage an operative site.
- When operating the product always consider the safety of the patient.
- Only use by dental professionals, such as dentists, therapists or dental hygienist, is intended.
- Check the vibration outside the patient's oral cavity before use. If any abnormalities are found, stop using immediately and contact your NSK-dealer.
- Do not drop or exert an excessive shock to the scaler handpiece and cord.
- To prevent possible tooth plane damage and handpiece overheating, always use with sufficient water.
- Do not sterilize with ultraviolet light as handpiece could be discoloured.
- Sterilize the scaler tip, Varios handpiece, and tip wrench by autoclaving. Wipe the handpiece cord including the cover. Disinfect the hand piece cable according to the instructions after each treatment with a VAH listed disinfectants
- If chemical, solvent or antiseptic solution is deposited on this product, immediately wipe it away.

Discoloration or deformation may occur if left.

- Do not disassemble or alter the handpiece.
- DO NOT USE on patients with cardiac pacemakers.
- Keep away from explosive substances and flammable materials. Do not use for patients anesthetized with Nitrous Oxide
- This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information.
- The use of ACCESSORIES and cables other than those specified may result in increased EMISSIONS or decreased IMMUNITY of this product.
- If any water drops remain on the handpiece after autoclaving, wipe them off. Staining may result if left.
- This device must not be used by the patients themselves.



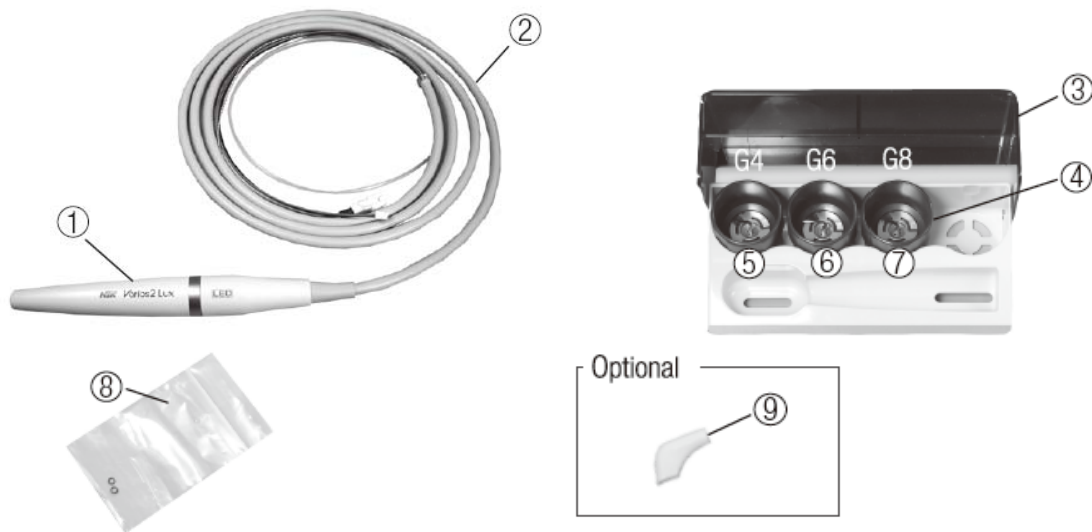
Caution

- During operation, high frequency oscillations in the handpiece and handpiece cord may affect computer and LAN cables. Noise may be heard during operation near a radio receiver.
- Users are responsible for operational control, maintenance and inspection.
- Clean/sterilize the product immediately after use before you store it. Leaving it non-sterile might lead to failure.
- When you have not used the product for a long time and use it again, check the operation before use.
- Eye damage may result if the LED is shone directly into the eyes. Do not look into or turn it to the eyes of the patient.
- This product's use is not restricted by patient's age (except infants), gender, weight or race.
- No special training is required for this device but it may only be used by qualified personnel.
- Applied parts for patient and/or operator are/is Tip and handpiece.

B2 Technical data

Use Environment:	Temperature:	+15 – 40 °C
	Humidity:	30 – 75 %
	Atmospheric pressure:	700 – 1060 hPa
Storage Environment:	Temperature:	-10 – 60 °C
	Humidity:	10 – 85 %
	Atmospheric pressure:	500 – 1060 hPa

B3 Description of the components



No.	Description	Quantity
1	Varios2 LUX handpiece (optic)	1
2	Handpiece Cord (optic)	1
3	Sterilization Cassette	1
4	Tip Wrench	3
5	Tip Type G4	1
6	Tip Type G6	1
7	Tip Type G8	1
8	O-Ring	2
9	Tip Cover S (Option)	1

Operation principle

The sinusoidal electrical signal, at ultrasonic frequency ($f > 20$ kHz) is generated by the generator. This signal is applied to the piezoelectric ceramic, located inside the transducer. The piezoelectric ceramic converts this signal into mechanical vibrations. These vibrations are at the same ultrasonic frequency as the electrical signal. The mechanical vibrations are propagated towards the distal end of the transducer. The „Tip“ insert, which is attached at the distal end of the transducer, vibrates at ultrasonic frequencies and makes it possible to achieve the aimed purpose.

B4 Assembling or disassembling of the handpiece

Align the dots on the handpiece and the handpiece cord. Push the handpiece into the connector.

To remove the handpiece, grip the handpiece and handpiece cord and pull to separate handpiece and cord. (fig.1)

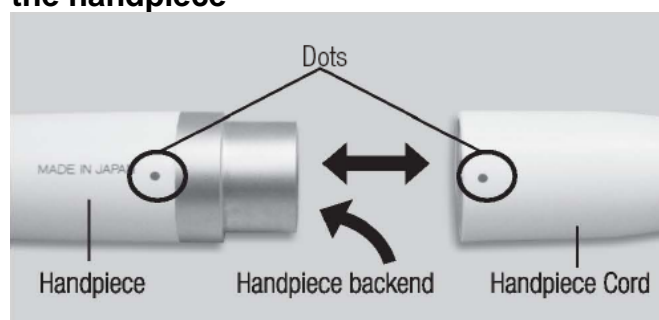


fig.1

Warning

To avoid electrical shock do not touch the electrical connector pins at the rear of the Varios handpiece

and the Varios scaler cord! **Caution**

- Always ensure that the handpiece is properly connected and securely held in place.
- Do not connect or use non-NSK scaler handpieces

B5 Attaching or removing a scaler tip

- 1) Place tip inside tip wrench. Tip is placed in tip wrench from bottom. (fig. 2)
- 2) Align tip thread and handpiece thread and turn it clockwise until the Wrench clicks. (fig. 3) Do not twist the handpiece cord always hold on to handpiece body.

⚠️ Pay attention to the top of tip as some extend beyond the tip wrench and may cause injury.

To remove the tip, place tip wrench over tip and turn counter-clockwise with the tip wrench until tip and handpiece are separated

Tip Wrench



fig.2

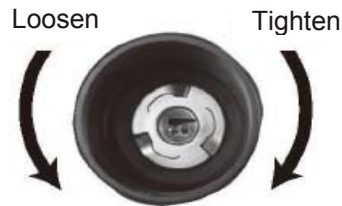
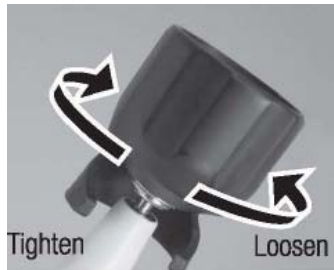


fig.3

⚠️ Caution for Tip Usage

- Check the tip before use. (Dirt, Damage, Bending or Rust)
- Do not exceed Maximum Power Level for tip as this may damage the tooth structure and/or tip.
- Do not hit ceramic prosthesis with tip during scaling as this may damage the restoration and/or the tip
- Do not touch metal or prosthetic crowns, except for removing them, as tip could break and fall into patient's mouth and could be inhaled.
- Do not touch gingival, mucosa and/or skin as. It could cause damage and/or burn injury.
- Do not sharpen and/or bend the tip. Tip may damage and not generate enough vibration during scaling.
- During use, tip will gradually wear away. As the tip wears the tip movement will change and decrease operating efficiency. When performance level drops too far change the Tip(Use tip guide check card for reference)
- DO ENSURE when securing tip to use the tip trench as supplied to avoid inefficient performance.
- DO ENSURE before attaching tip, cleanliness of the tip thread to avoid inefficient performance.
- To avoid personal injury DO ENSURE tip is removed prior to disconnecting the handpiece.
- If you feel the tip is not vibrating, remove it from the operative site and press the foot control again. If this does not improve the condition, Ensure the Tip is secure, turn the power off and restart it.
- When attaching a tip, always use gloves and NSK tip wrench as supplied.
- Ensure that water volume on the adjuster of the unit must be "0", when you use a tip which does not require irrigation.
- The tip wrench is a consumable item. For reliable operation replace it annually.

Provided Scaler Tips

G4



The end of the Tip is thin and for supragingival fine scaling and interdental scaling. The round cross-section allows tooth surfaces to be finished without causing damage. Set the level less than "Power 5" at G mode.

Apply the top of the Tip on the tooth surface and gently move it sideways in the same way as G8 Tip. (fig.4)



fig.4

G6



Removal of supra and subgingival calculus. It provides easy access to interdental spaces and narrow pockets. Set the level less than "Power 5" at G mode.

Insert the top of the tip into the periodontal pocket and move it slowly and gently. The top of the tip is sharp so that it could remove tartar on long crowns and retracted gingival. (fig.5)
Clean periodontal pocket at low power. (Set the level less than "Power 5" at P mode.)



fig.5

G8



Removal of supragingival and interdental calculus. This tip can be used in all quadrants and is very useful for the removal of hard calculus. Set the level less than "Power 7" at G mode.

Apply the top of the tip on the tooth plane and move it sideways finely along the neck of tooth. (fig.6)

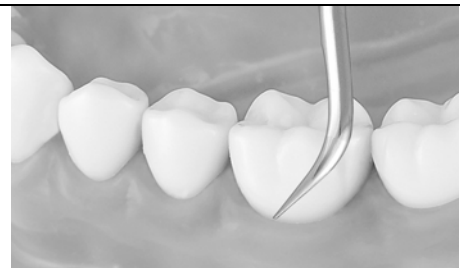


fig.6

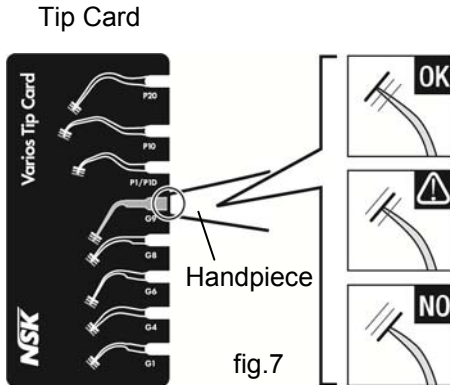


Caution

Tips are consumable products and subject to wear and tear. We recommend periodical replacement. Please use the Varios Tip Card to check when tips need to be replaced.

B6 How to use the “Varios Tip Card“

- 1) Place the neck of the tip in the cut out.
- 2) Check wear of the tip.
- 3) See the green, yellow and red line to check wear of the tip. *See below what each colour means. To guarantee effective and safe used we recommended to replace tips when they meet the yellow line (wear of 1 mm)



Green: No wear – Tip is OK
Tip replacement is not necessary

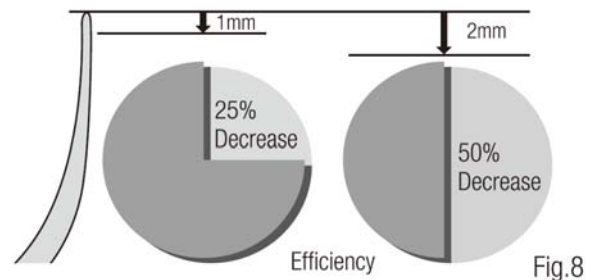
Yellow: Wear of 1 mm – Tip is showing some wear
Tip replacement is recommended

Red: Wear of 2 mm – Tip is badly worn
Tip replacement is necessary

* The Varios Tip Card can be used to check the following tips:
G1, G4, G5, G6, G8, P1/P1D, P10 and P20

Caution

Tips are consumable products. The efficiency of dental scaling decreases approximately 25%, when the top of the Tip wears 1 mm and approximately 50%, when it is has worn 2 mm. In addition, the vibration condition changes owing to the wear, which may damage tooth surfaces. Check the tip wear condition with the Varios Tip Card periodically and replace tips frequently.

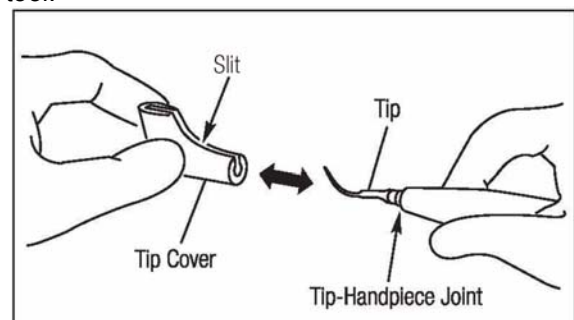


B7 Use of the optional tip cover S

Grip the tip cover S and put it over the tip.
To remove, grip the tip cover S and the handpiece and pull gently apart. (fig.9)
*The tip cover S is not designed for use as a tip changing tool.

Caution

Carefully put the tip cover S over the tip Pay particular attention to avoid injuring fingers.



B8 Care and Maintenance

B8.1 Cleaning of Optic Outlets (Varios 170)

Wipe the debris off the end of the Optic Outlets at the handpiece with alcohol soaked cotton swab. (fig.10)

In case the light degradation, contact your NSK-dealer.



Caution

Do not use any sharp pointy tools to clean the Optic Outlets.

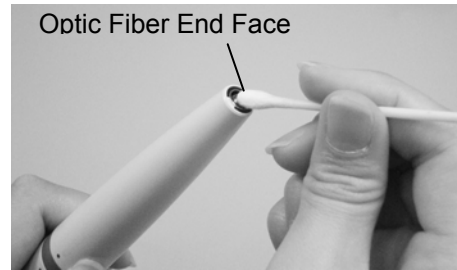


fig.10

B8.2 Changing the O-Ring

An O-ring is located in the Handpiece Cord Connector. Use a pointed tool to remove and mount a new one into the groove. (fig. 11).

*Optional O-Ring: Order No. 0311020080



fig.11

B9 Sterilization

- Autoclave sterilization is recommended.
- Autoclave sterilization required prior to first time of use and after each patient as noted below. Take handpiece out of the packaging before sterilization.
- **ONLY** the tip, Arios handpiece and tip wrench can be autoclaved.

Autoclave procedure

- 1) Clean and remove the Tip after use. (Refer to section B4)
- 2) Wipe dirt and debris from the products and wipe clean with alcohol-immersed cotton swab or cloth. Do not use a wire brush.
- 3) Place items into the sterilization cassette or an autoclave pouch. Seal the pouch.
- 4) Autoclavable up to max. 135°C.
Ex.) Autoclave for 20 min. at 121°C, or 15 min. at 132°C
- 5) Keep the products in the sterilization cassette or autoclave pouch to keep it clean until you use it.

* Sterilization at 121°C for more than 15 minutes is recommended by ISO17664 and ISO17665-1.



Caution

- Tip and Handpiece can not be cleaned and disinfected with a Thermo-Disinfector.
- Do not sterilize by ultraviolet ray. The handpiece could be discoloured.
- If autoclaved with other instruments stained with chemical solution, it could strip the plating and make the surface black.
- Do not wipe with, or clean or immerse in, high acid water or sterilizing solutions.
- Clean and disinfect the handpiece cord with alcohol after every treatment.

Sterilization cassette

The Varios handpiece, tip and tip wrench can be sterilized together using the sterilization cassette. (Fig.12)

- 1) Remove the tip from the Varios handpiece by using tip wrench.
- 2) Place the tip wrench with the tip inside into the sterilization cassette. (You can put up to four tip wrenches with tips inside the cassette).
- 3) Disconnect Varios handpiece from the handpiece cord (refer to section B3), and clean (refer to section 8),
- 4) Place the handpiece into the sterilization cassette.
- 5) Autoclavable up to max. 135°C.
ex.) Autoclave for 20 min. at 121°C, or 15 min. at 132°C
- 6) Keep the products in the sterilization cassette or autoclave pouch to keep them clean until you use it.



fig.12

B10 Troubleshooting

In case of any functional problems please verify to following points before you contact your NSK Dealer:

Problem	Term to check	Cause	Solution
No / Poor vibration	The tip does not generate vibration, in spite of depressing the Foot Control	The tip is not tightened firmly	Tighten the tip until the tip wrench clicks.
		Worn tip	Replace the tip
		Power setting has not been correctly adjusted for the tip.	Adjust the power setting according to the power guide or tip case label. Do not exceed maximum power
		Failure of vibrator in the handpiece	Contact your NSK-dealer
The tip is bent or broken	—	Power has not been properly adjusted for the tip	Adjust the power level the power guide or tip case label. Do not exceed.
The tip is flying away.	—	The tip is not tightened firmly	Tighten the tip until the tip wrench clicks
Noise from the handpiece	—	Power has not been properly adjusted for the tip	Adjust the power level the power guide or tip case label. Do not exceed.
		The tip is not tightened firmly	Tighten the tip until the tip wrench clicks
		Failure of vibration in the handpiece or the module	Contact your NSK-dealer
The handpiece is overheating	—	Power has not been correctly adjusted for the tip	Adjust the power level the power guide or tip case label. Do not exceed.
		The tip is not tightened firmly	Tighten the tip until the tip wrench clicks
		Failure of vibration in the handpiece or the module	Contact your NSK-dealer
No / Weak water	The water does not reach to the handpiece	—	Check the water circuitry and supply to the unit
	Remove the handpiece from the handpiece cord. Water does not comes out or weak from handpiece cord	The water adjustment dial is closed	Turn the water adjustment dial and set it to an appropriate water volume
		The water filter is clogged.	Contact your NSK-dealer
	No / weak water from the handpiece	There may be exogenous material in the internal water line	Blow out with the appliance such as syringes from the rear of the handpiece; If it is still unsolved, contact dealer
Water leakage	Water is leaking from the joint between the handpiece and the cord	O-r at the handpiece cord is worn or damaged	Replace with new O-Ring (Refer to section A6.6-2) (Changing O-Ring)
Handpiece LED does not illuminate (Varios 170Lux)	Tip oscillate, but Handpiece LED doesn't turn on and off	The handpiece is not connected into the handpiece cord correctly.	Firmly insert the handpiece into the handpiece cord
	Tip oscillate, but Handpiece LED turns on and off	Disconnection in the Handpiece Cord, or failure in Module	Contact your NSK-dealer

B11 Spare parts

Model	Product	Order code
Sterilization cassette	 	Z1035001
Tip Wrench (CR-10)	 	Z221080
Tip Holder	 	Z221080
O-Ring		0311020080
Tip Cover S	 	Z217851



Autoclavable at 135°C max.

Annex C

Operation manual Micromotor NLXnano

Please read this Operation Manual carefully before use!

C1 General information



Precautions for the handling and operation

- Read these safety cautions thoroughly before use and operate for their intended purpose according to this manual.
- These indicators will show you how to operate the product safely and prevent danger to you or others. They are classified by degree and/or severity of danger. All contents relating to safety should be observed.

Classification

Degree and severity of danger or damage



Danger

Provides an instruction where death or the instructions may occur.



Warning

Provides an instruction where personal injury or physical damage may occur.



Caution

Provides an instruction where minor to medium injury or physical damage may occur.



Notice

Provides an instruction that should be observed for safety reasons.



Caution

- When operating this system always consider the safety of the patient and operator.
- The motor is designed only for dental use by qualified personnel.
- This product can't be operated without the exclusive Dentalone control-panel.
- Do not allow any impact on the motor and do not drop it as this may cause a malfunction.
- Check for vibration, noise and overheating outside the patient's oral cavity before use. If any abnormalities are found, stop using the motor immediately and contact authorized NSK-dealer.
- Do not exceed the motor speed over recommended speed for the handpiece (Option).
- Prior to use, always check the handpiece tightness, vibration, noise and overheating. If any abnormalities are detected, stop using immediately and contact authorized NSK-dealer.
- Do not use the motor under heavy load for extended periods of time as this will cause overheating
- The time for continuous use should be not more than 3 minutes.
- Do not connect or disconnect the cord until the motor has completely stopped.
- Do not connect / disconnect the handpiece from the motor during operation.
- Air Requirements: dry, free from contamination and oil. Use a compressor with a dry air system. Install an air filter if necessary. (This point is not applicable for the Dentalone, because there is an internal air supply)
- Do not autoclave the motor cord (or any other high temperature sterilization).
- The user shall be responsible for operation and maintenance
- The operator is responsible for correct operational control, maintenance and inspection.

C2 Technical data

Model	NLXnano
Max. Rotation Speed	1,000 - 40,000 min ⁻¹
Max. Torque	3.4 N·cm

C3 Connecting / Disconnecting the Motor and Handpiece ^{*)}

C3.1 Connecting / Disconnecting the Motor and the Motor Cord

Align and insert firmly the motor pin into the pin holes of the Motor Cord Connector, and fasten the Motor Cord Nut securely.(fig.1)

To remove the motor cord from the Motor, unscrew and detach the motor cord nut, and gently pull out the motor cord connector.

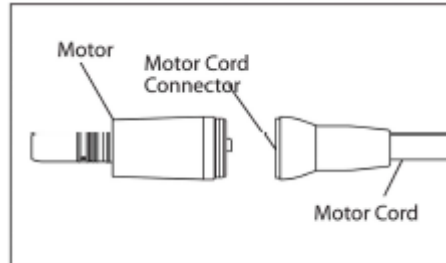


Fig.1

C3.2 Connecting / Disconnecting the motor and the handpiece *

To attach the E-type instrument to the Motor , align handpiece and motor, then turn until it clicks to align light source and light conductor in case of fibre optic handpieces. (Positioning locator pin is aligned) (fig.2)

To remove the handpiece, gently pull motor and instrument apart

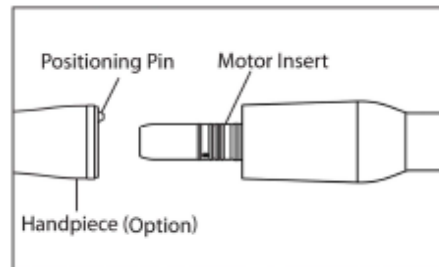


Fig.2

* Handpiece is not included.



Caution

- Care should be taken when using instruments which require lubrication (E-Type Micromotor). Following lubrication stand the handpiece vertically to allow the excess lubricant to drain away. Wipe the instrument before you attach it to the Micromotor.
- Do not connect or disconnect the handpiece until the motor has completely stopped.

C4 Sterilization

- For the sterilization method, we recommend the autoclave sterilization method.
- Sterilization is required before first time of use and after each patient as noted below.

Steps for autoclaving

- 1) Turn off the power.
- 2) Detach the motor from the Motor Cord. (Refer to section C3.1)
- 3) Clean the surface of the Motor with brush. Do not use a metal brush and wipe it with the cotton moistened with disinfecting alcohol.
- 4) Screw the Motor Cap on to the Motor. Put the Autoclave plug on to the E-type joint of the motor.
- 5) Insert into an autoclave pouch. Seal the pouch.
- 6) Autoclavable up to max. 135°C.
ex.) Autoclave for 20 min. at 121°C, or 15 min. at 132°C.
- 7) Keep the Motor in the autoclave pouch to keep it clean during storage.

*Sterilization at 121°C for more than 15 minutes is recommended by EN 13060.

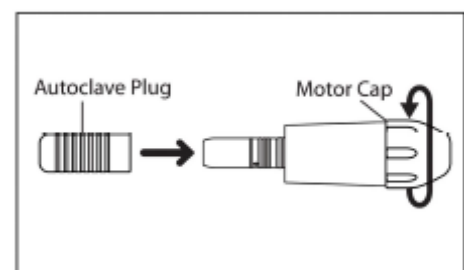


Fig.3



Caution

- Do not autoclave (or any other high temperature Sterilization) motor cord.
- Do not lubricate the motor.
- Do not wipe nor immerse the motor in acidic water or acidic solutions.
- Store the motor until the first use in the original packaging in suitable conditions as defined in section 5 of the manual in a dust- und humidity-protected manner and not in salty or sulphurous air.
- Don't sterilize with dirt on the surface as this may cause corrosion.
- Keep the autoclave plug for E-type joint and autoclave screw cap for motor base in a safe place, so that they don't get lost.
- Don't hold the motor by the autoclave plug/cover as they may be loose and you may drop the motor
- Don't touch the motor after autoclaving as it can be very hot.
- We discourage plasma sterilization or EOG sterilization.

C5 Maintenance

If the O-Ring have worn to it becomes difficult to connect instruments or air or water might leak, replace the O-Ring. Remove the O-Ring from the E-type joint with a pointy tool, and replace with new O-Rings in the grooves.

- O-Ring (Blue) : 0313-084070
- O-Ring (Black): 0312-074080
- O-Ring (Autoclave plug) 0312-457102

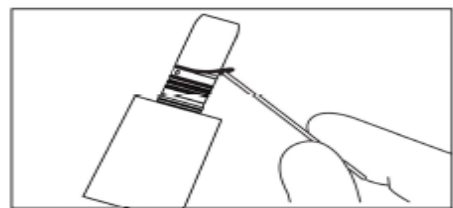
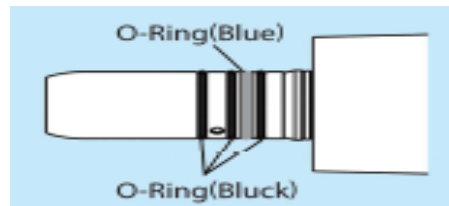


Fig.4



Caution

- There are 4 O-Rings on the E-type joint. The blue o-ring is thinner than the other 3 o-rings. Make sure you order and replace the correct o-rings. Never use the autoclave plug without the correct o-ring in place. Missing o-ring can lead to water and steam ingress during autoclave cycle and damage the motor beyond repair. If the O-ring is damaged, replace it immediately.
- Missing or damaged O-rings can lead to:
 - Air/Water leak
 - Air/Water spray does work properly
 - Vibration
 - Difficult to connect/disconnect instruments



C6 Troubleshooting

If the motor stops due to an abnormality such as a malfunction, overload, break or incorrect usage, it automatically checks the state of the Multifunction control panel and detects the cause of the malfunction and displays an error code on the display. If an error code is displayed, turn on the power again and check whether the same error code is displayed. If the same error code is displayed, take action by referring to the instructions provided in the "Check/Remedy" column in the following table:

Check/Remedy	Cause	Solution
Motor does not run	Motor Cord is not connected correctly	Check the connection.
LED does not illuminate.	Reached the end of life expectancy.	Contact your NSK-dealer.
Water leakage	Motor Cord is not connected correctly.	Contact your NSK-dealer.
	Water is leaking from the motor.	Replace with new O-ring.