

NSK

Multi Function Ultrasonic Scaler

Varios 560 LUX (Optic)

Varios 560 (Non-Optic)

OPERATION MANUAL

Please read this Operation Manual carefully before use, and file for future reference.



The EU directive 93/42/EEC was applied in the design and production of this medical device.

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Specifications are subject to change without notice.

*10.03.01

OM-E0248E 004



MADE IN JAPAN

0197

◆ **Original Operation Manual**




Thank you for purchasing the Varios Ultrasonic Scaler (Varios 560 LUX / Varios 560). This product is used in dental office only. This device generates ultrasonic waves intended for use in dental applications such as scaling, root canal treatment, periodontal and cavity preparation. Read this operation manual carefully before use, and keep it within user's reach.


■ Classifications of equipment

- Type of protection against electric shock :
 - Class II equipment 
- Degree of protection against electric shock :
 - Type BF applied part 
- Method of sterilization or disinfection recommended by the manufacture :
 - See 8. Sterilization
- Degree of protection against ingress of water as detailed in the current edition of IEC 60529 :
 - Foot Control . . . IPX1 (Protected against vertically falling water drops)
- Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide :
 - EQUIPMENT not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Mode of operation :
 - Continuous operation

 **Cautions for handling and operation**

- Read these cautions carefully and use only as intended or instructed.
- Safety instructions are intended to avoid potential hazards that could result in personal injury or damage to the device. Safety instructions are classified as follows in accordance with the seriousness of the risk.

Class	Degree of Risk
 WARNING	A hazard that could result in bodily injury or damage to the device if the safety instructions are not followed.
 CAUTION	A hazard that could result in light or moderate bodily injury or damage to the device if the safety instructions are not followed.
 NOTICE	General information needed to operate the device safely.

 WARNING
<ul style="list-style-type: none"> · Use by medical professional, such as doctor or dental hygienist, is intended. · Do not unplug the Power Cord with wet hands to avoid electric shock. · Be sure to prevent water on the Control Unit, because it may result in short circuit and electric shock. · Do not allow any impact on the Control Unit. Do not drop. This could result in electric shock. · Do not touch the handpiece backend, where electrical connections are attached to the cord. It might result in electric shock. · Do not disassemble or alter the handpiece/Control Unit. · Keep away from patients with cardiac pacemakers. · Keep away from explosive substances and flammable materials. Do not use for patients anesthetized under laughter gas. · Use the fuse of specified rating. ([FU201, FU202] 120V : T500mA/250V, 230V : T250mA/250V) · There is the judgment that applies this product to a patient in the user side. · This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information. · Portable and mobile RF communications equipment can affect this product.

- The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the product as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of it.
- This product should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, it should be observed to verify normal operation in the configuration in which it will be used.

⚠ CAUTION

- When operating the handpiece always consider the safety of the patient.
- The handpiece is designed only for dental clinical use.
- Check the vibration and overheating outside the patient's oral cavity before use. If any abnormalities are found, stop using immediately and contact your dealer.
- Should this products function abnormally, cease operation immediately and return it to the dealer for repair.
- Do not force or pull on Power Cord and/or Handpiece Cord. It could cause disconnection.
- Be sure to attach NSK genuine tips when using NSK Varios ultrasonic scaler (Varios 560 or Varios 560 LUX). The 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 the Non-NSK tips.
 - Vibration failure caused by using nonconformable screws
 - Patients' accidental ingestion of damaged tips
 - Damage of thread ridge of handpiece
- Do not exceed Maximum Power for Tips. It could damage tooth structure and Tips.
- Check if the damages, bending and rust before use. Use new one.
- Check the Irrigation Hole of the Tip can irrigate adequately water before use. It may not irrigate the water adequately because of the dirt.
- Check to see if dust does not stick on the screw of the tip before use. If not clean, tips will not generate enough vibration.
- Do not sharpen and/or bend the Tip. Tips may damage and not generate enough vibration during scaling.
- Do not mount or remove the Tip until the vibration completely stopped.
- Tips are consumables. Check the wear condition with the tip card periodically, and replace it with a new one in good time.
- Always use with pouring enough water, or it may damage tooth plane and overheat the handpiece.
- Always keep Tip connection area clean. Entry of debris into this area could cause Tip run-out or weak holding.
- Do not hit metal or prosthetic crown etc., except for removing them. Tips could break and fall into mouth.
- Do not hit gingiva, mucosa and/or skin directly. It could cause damage and burn.
- Be sure to firmly mount the tip with provided wrench, or the tip will not generate enough vibration.
- Be sure to turn the power switch after mounting the handpiece.
- Do not drop nor give an excessive shock to the control unit.
- Do not autoclave any parts other than those that can be subjected to autoclave sterilization.
- Do not sterilize by ultraviolet light. Handpiece could discolor.
- Remove the handpiece after tip is taken off.
- If chemical, solvent or antiseptic solution is deposited on this product, immediately wipe it away. Discoloration or deformation may occur if left as it is.
- Do not wipe with, or clean or immerse in, high acid water or sterilizing solutions.

⚠ NOTICE

- During vibration, the handpiece and the Handpiece Cord may affect computer and LAN cable. Noise could be heard during operation near a radio receiver.
- Be sure to turn off the Power Switch after use. Remove the Power Plug and water inside of the Control Unit if not used for a long time.
- Users are responsible for operational control, maintenance and inspection.
- When trouble is found, send to dealer.
- This product does not consider patient's age (except infants), gender, weight or nationality.
- No special training is required for this device.
- Applied parts for patient and/or operator are/ is tip and handpiece.

1. Features

- Lightweight and compact device.
- Three types of Power Mode, "G-mode (General)", "E-mode (Endo)", and "P-mode (Perio)" according to each Tip, and also allows adjusting freely within the recommended power.
- The Control Unit can simply be wiped off so spills are very easy to clean up, and the front control panel is extremely easy to read.
- This product can be preset operation into the System Memory.
- Handy and small handpiece can lighten user's fatigue.
- The Handpiece Ring Light is extremely bright for easy viewing of the operating area. (Varios 560 LUX)
- Light, durable, and slippy Handpiece Cord with unique Jacket.
- Tip Wrench has a torque-limiter mechanism to prevent Tips from over-tightening and lack of tightening.
- The Control Unit has provision to operate the handpiece with light or the one without.
- The handpiece is autoclavable at 135°C.

2. Component Names

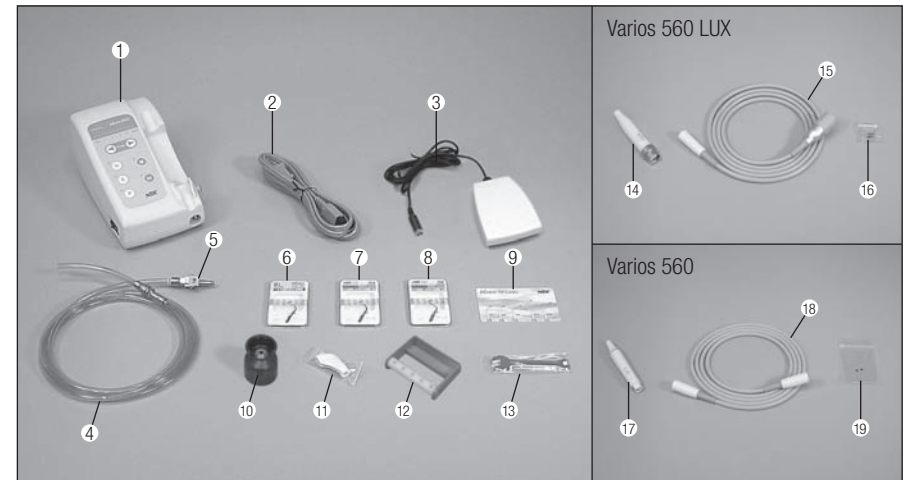


Fig. 1

- | | |
|--|--|
| ① Control Unit | ⑪ Tip Cover S |
| ② Power Cord | ⑫ Tip Holder |
| ③ Foot Control | ⑬ Spanner Wrench (5 X 8) 2 pcs |
| ④ Water Tube | ⑭ Handpiece (Optic) |
| ⑤ Water Supply Connector (AC120V Only) | ⑮ Handpiece Cord (Optic) |
| ⑥ Tip (G1) | ⑯ Lamp |
| ⑦ Tip (G4) | ⑰ Handpiece (Non-Optic) |
| ⑧ Tip (G6) | ⑱ Handpiece Cord (Non-Optic) |
| ⑨ Tip Card | ⑲ O-ring 2 pcs |
| ⑩ Tip Wrench | |

3. Installation and Assembly

(1) Water System Setup

- 1) Connect the Water Filter Case side of the Water Tube deep into the Water Connector on the Varios Control Unit. (Fig. 2)
- 2) Connect the Water Tube to the Water Outlet on the dental unit.

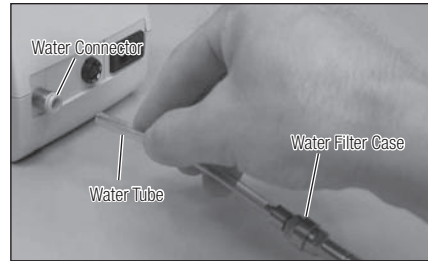


Fig. 2

CAUTION

- Insert the Water Tube deep into the connector on the Control Unit.
- If water has not been used at the water outlet of the dental unit for a long time, brownish water may come out but wait until clean water comes out, and make connection.

NOTICE

Pushing the White Ring, (the Quick Connector Release Ring) on the Water Connector, gently remove the tube. (Fig. 3)

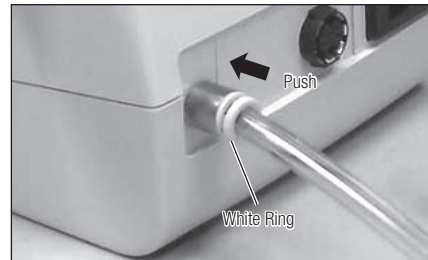


Fig. 3

(2) Foot Control Connection

Connect the Foot Control Plug to the Foot Control Connector at the back of the Control Unit, take care in properly align all the pins. Push the plug gently into the connector.

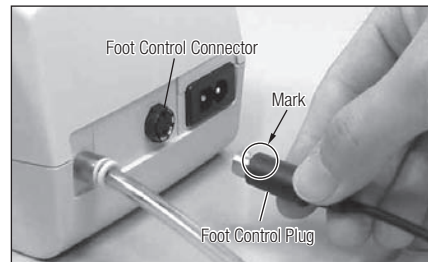


Fig. 4

(3) Power Cord Connection

Insert the Power Cord into the Inlet at the back of the Control Unit.

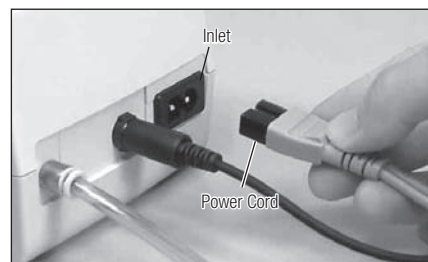


Fig. 5

(4) Handpiece Cord Connection

Align the marks on the Control Unit and the Handpiece Cord Plug. Gently push the Plug into the Connector.

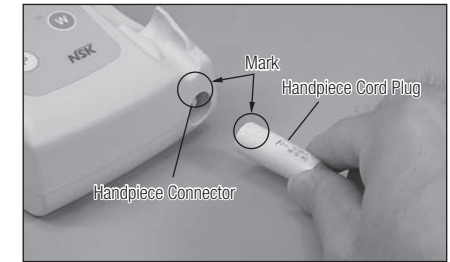


Fig. 6

(5) Handpiece Connection

Align the Marks on the handpiece and the Handpiece Cord Plug. Push straight inmost.
· When removing the handpiece, grip the Front and Rear of the handpiece firmly. Pull to separate.

WARNING

Do not touch the handpiece backend. (where Electrical Connections are made to the cord.)
It might result in electrical shock.

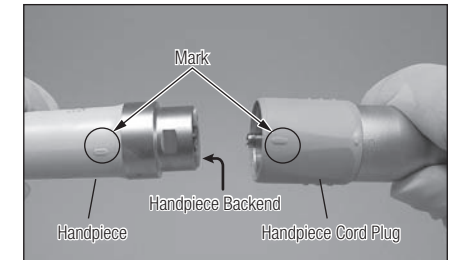


Fig. 7

* Picture shows Varios 560 LUX.

CAUTION

- Detach Tip before removing handpiece.
- Push handpiece against Handpiece Cord Plug inmost to connect.
- When removing the handpiece, grip the plug of the Handpiece Cord.

4. Operating Procedures

(1) Water System Setup

Carefully check all Water Supply Connections prior to starting procedure. Open the dental unit's water valve. Set water pressure between 0.1-0.5MPa (1.0-5.0kgf/cm²).

(2) Tip Connection

- 1) Mount the Tip by fastening it lightly by hand.

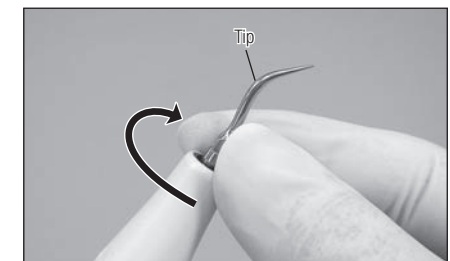


Fig. 8

2) Insert the Tip through the hole of the Tip Wrench, align the four cornered tip's base into the hole of the Tip Wrench. Turn it clockwise **until it clicks**.

- To remove the Tip, turn counterclockwise with the Tip Wrench.

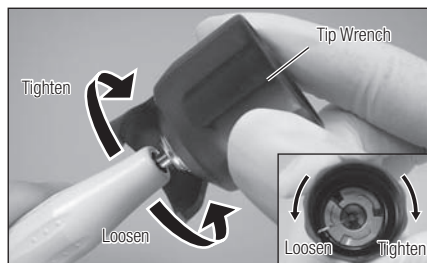


Fig. 9

CAUTION

- When mounting and/or removing the Tip, always use grooves.
- Tip, Tip Wrench, and Handpiece that have been sterilized.
- Tip Wrench is consumable. For reliable operation, replace annually.

(3) Power On

Connect the Power Cord to the wall outlet. Turn on the Power Switch of the Control Unit. Front Panel will light up.

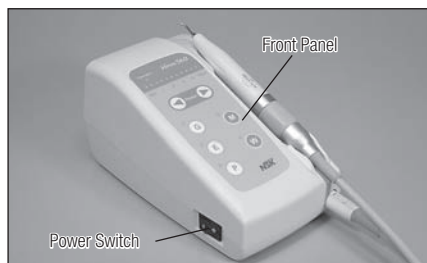


Fig. 10

CAUTION

Do not use any wall outlets other than those of AC120V±10% or AC230V±10%. There is a risk that the Power Cord could be damaged.

(4) Power Setting

CAUTION

Check the case the selected Tip came in for proper power. You can check Maximum Power on the Tip Case Label. Check your model.

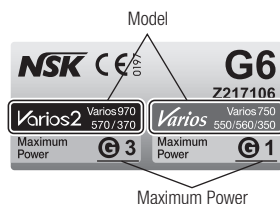
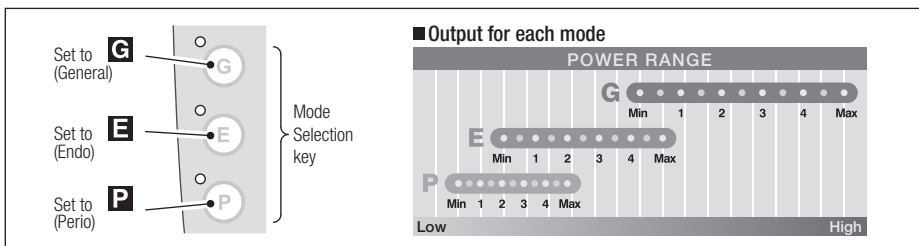


Fig. 11

1) Select the Operating Mode with the Mode Selection Keys on the Front Panel. The light over the selected mode will illuminate.



2) Set the Power Level with the Power Level Key on the Front Panel. The lamps in the Power Display Panel will indicate the selected power level. Check to make sure the Power Level is set in the appropriate range for the selected Tip.

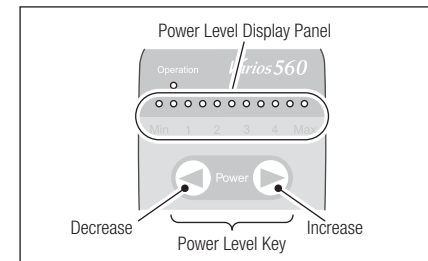


Fig. 12

NOTICE

- Continuous pushing of the Power Level Key will cause the Power Level Display to climb.
- When only water is desired without oscillating the Tip, keep pressing "Decrease" key to extinguish Power Display Panel Lamp.

(5) Water Mode Selection

Push the Water Key to select whether or not to supply water. (When the lamp illuminates, water supply becomes available.)

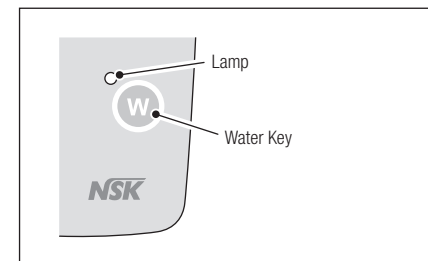


Fig. 13

CAUTION

Always use the water supply unless you are doing procedure requiring Dry Mode (No Irrigation Mode). If water supply is insufficient, handpiece will overheat patient's tooth surface can be injured.

(6) Operate Varios 560 LUX, Varios 560

- Depress the Foot Control. Tip will vibrate. (If the lamp stays illuminated by pushing the Water Key, water supply will also start.)
- The Operating Lamp stays illuminated while the Tip is vibrating. (Fig. 14) The handpiece ring light also illuminates. (Varios 560 LUX)
- Adjust the Power Level to the proper range.
- Turn the Water Adjustment Knob counterclockwise gradually to increase the supply volume. (Fig. 15)

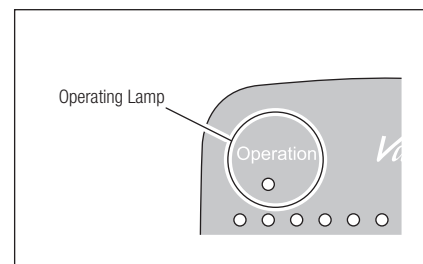


Fig. 14



Fig. 15

CAUTION

- Always use the water supply unless you are doing procedure requiring Dry Mode. If water supply is insufficient, handpiece will overheat patient's tooth surface can be injured.
- Prior to starting the procedure, verify that the water spray is clean and at adequate volume.

(7) When Treatment is Finished.

- Release the Foot Control and attach the handpiece to the handpiece holder. (Fig. 16)
- Turn off the Power Switch.
- Close the dental unit's water valve.
- Remove the Tip after use. (Refer. 4. (2) Tip Connection)



Fig. 16

NOTICE

When the Control Unit is shut down, the last mode settings in use are automatically retained in memory. When you power on the system for the next procedure, the system will reactivate in the same configuration as when shut down.

* Safety Function

- When the operating mode is set to G and the power setting is set to Max the Control Unit will automatically reduce power if operated at these settings for more than 10 minutes. (The output display moves 3 lamps from "Max" to "4".)

To reset the safety function....

Before a lapse of 10 minutes or when the power weakens after a lapse of 10 minutes, release the Foot Control. The above safety function is reset. Depressing the Foot Control again repeats the same operation.

- If the Power Switch is turned on while the Foot Control is depressed accidentally (by an object, etc.), beeping starts to call attention.

To reset the alarm....

Release the Foot Control (remove the object, etc.).

* Memory Function

The Control Unit can be preset for Water Mode, power setting and operating mode. To set the desired preset conditions into memory follow the procedure below.

- 1) Set the desired levels.
- 2) Push the Memory Key for about 2 seconds or more, the memory light will illuminate and the control unit will produce a beep. The memory is set. (Fig. 17)

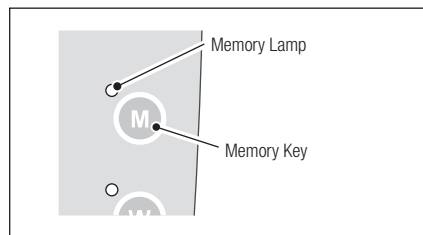


Fig. 17

To enter new settings....

After confirming the settings of Water Mode, Power Setting and Operating Mode, push the memory key for approx. 2 seconds. (The memory light will illuminate.) The old memory is cleared and new settings are programmed.

5. How to Use Tip Cover S

When the Tip is mounted to the handpiece, install the Tip Cover S for safety.

- Hold the Tip Cover S as shown and insert it all the way to the Tip-Handpiece joint.
- To remove, hold the Tip Cover S and the handpiece as shown and pull straight out.

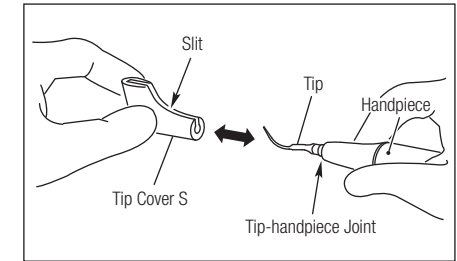
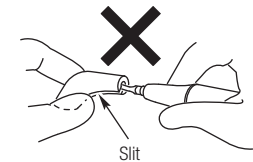


Fig. 18

WARNING

Carefully insert the tip into the Tip Cover S. Avoid injuring the fingers.



CAUTION

Do not use the Tip Cover S as a Tip change tool.

6. Tip Holder

- Use the tip holder for tips removed from the handpiece.
- The tip holder is autoclavable and can hold up to 5 types at once. To autoclave, tilt the tips in the direction of the arrow in fig.19.

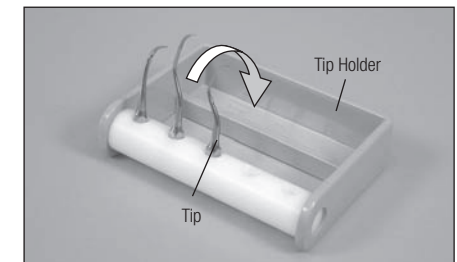


Fig. 19

7. Sterilization

- Autoclave sterilization is recommended.
- Sterilization is required first time you use and after each patient as noted below.
- The Tip, Handpiece, Tip Wrench, Tip Cover S, and Tip Holder can be autoclaved.

CAUTION

Do not autoclave any parts (the control unit, power cord, foot control, water tube, irrigation connector, handpiece cord including the cover, lamp, O-ring, tip card, and spanner wrench (5 X 8)) other than those that can be subjected to autoclave sterilization.

Autoclave Procedure

- 1) Remove the Tip after use. (Refer. 4. (2) Tip Connection)
- 2) Remove the handpiece from the Handpiece Cord. (Refer. 3. (5) Handpiece Connection)
- 3) Wipe off dirt and debris on the handpiece with an alcohol soaked cloth.
- 4) Insert into an autoclave pouch. Seal the pouch.
- 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 autoclave pouch to keep it clean until you us.

*Sterilization at 121°C for more than 15 minutes is recommended by EN13060 or EN ISO17665-1.

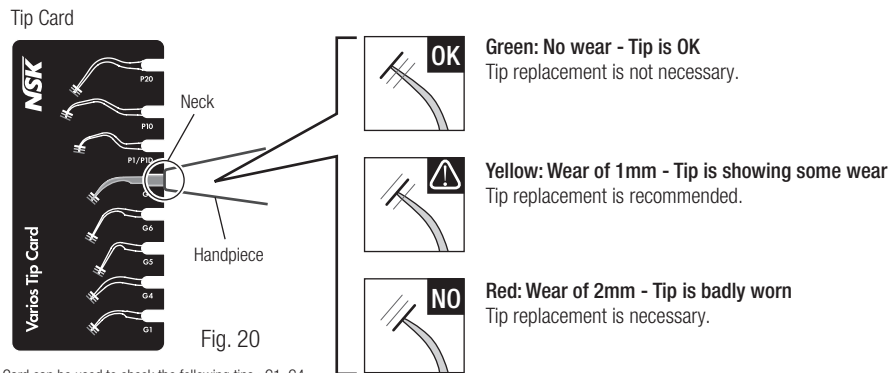
WARNING ON STERILIZATION

- This products can not be cleaned and disinfected with a Thermo-Disinfectant.
- Do not sterilize by ultraviolet ray. The handpiece could discolor.
- If autoclaved with other instruments stained with chemical solution, it could strip the plating and make the surface black.
- Since the bottom shelf of the sterilizer is close to the heat source, it can be too hot. Place instruments in the middle or top shelves.
- Do not autoclave any parts (the Control Unit, Power Cord, Foot Control, Water Tube, Water Connector, Handpiece Cord including the Cover, Lamp, O-ring, and Spanner Wrench (5 X 8)). Other than those that can be subjected to autoclave sterilization. Perform alcohol disinfection to the Control Unit, Power Cord, Foot Control, Handpiece Cord including with reference after every patient.
- Do not sterilize diamond coated Scaler Tips for the reason of single use.

8. Care and Maintenance

(1) How to use the Tip Card

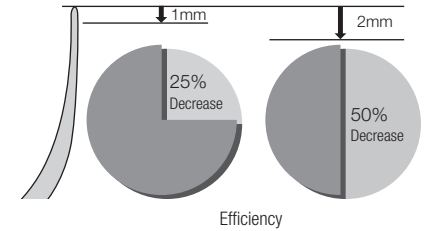
- 1) Place the neck of the Tip in the cut out.
- 2) Check wear of the Tip.
- 3) See the green, yellow and red line to check wear of the Tip. *See below what each color means. At NSK we recommend to replace a Tip when the Tip meets the yellow line (wear of 1mm) to guarantee safe and effective use.



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

CAUTION

Tips are consumables. The efficiency of dental scaling decreases approximately 25% when the top of the Tip wears 1 mm and approximately 50% when it wears 2 mm. In addition, the vibration condition changes owing to the wear, which may damage a patient's tooth surface. Check the Tip wear condition with the Tip Card periodically, and replace the Tip with a new one in good time.



(2) Changing Water Filter

- 1) Close the water valve of the dental unit to which Varios 560 LUX or Varios 560 is connected. Mount two Spanner Wrenches(5 X 8) as shown in Fig. 21, and turn in the directions shown.

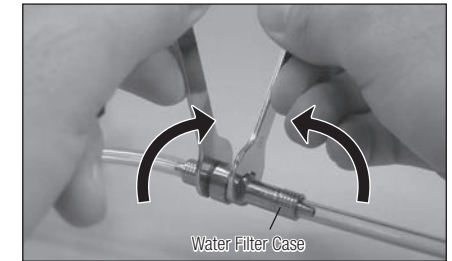


Fig. 21

NOTICE

When Water Tube is getting twisted by this, relieve the twist by turning it, as its end on the Control Unit side is free to turn.

- 2) When the Water Filter Case is separated, the Water Filter can be removed as shown in Fig. 22. Replace with a new one and reassemble the Filter in the reverse order.

* Optional Water Filter : Order No.U387042

CAUTION

When replacing the water filter, be careful about its direction. (Point the O-ring on the water filter toward the control unit side.) If it is assembled in the opposite direction, the effect of the water filter will be lost.

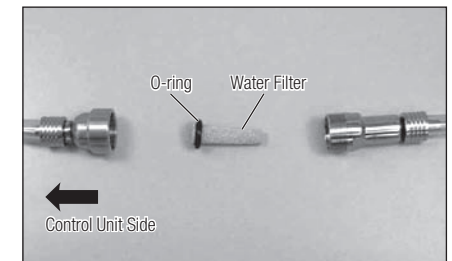


Fig. 22

(3) Cleaning of Donut-Shape Light (Varios 560 LUX)

Wipe the debris off the End Face Optic Fibers at the handpiece with alcohol soaked cotton swab.

CAUTION

Do not use any sharp pointed tools to clean the End Face Optic Fiber. In case the light becomes dim, contact your dealer.

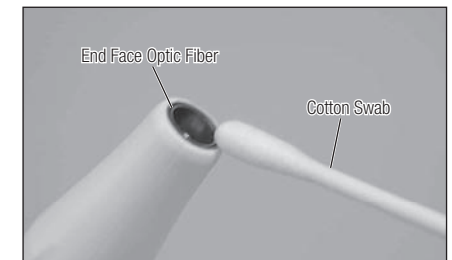


Fig. 23

(4) Changing Lamp (Varios 560 LUX)

- 1) Refer to 3. (5) Handpiece Connection. Disassemble the handpiece from the Handpiece Cord. Remove the cover. Use a precision screw driver and push lamp out.
- 2) Align the Lamp Pins of a new lamp with the holes, and push the lamp into.

* Optional Lamp : VA Bulb Set (A Set consist of 3 pieces) Order No. Y900107

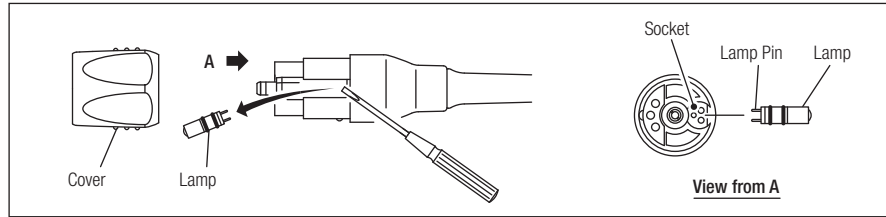


Fig. 24

- 3) Align the Mark on the cover with the same on the Handpiece Cord. Push the cover to the cord unit it clicks. Assemble the handpiece and the Handpiece Cord. (Refer. 3. (5) Handpiece Connection)

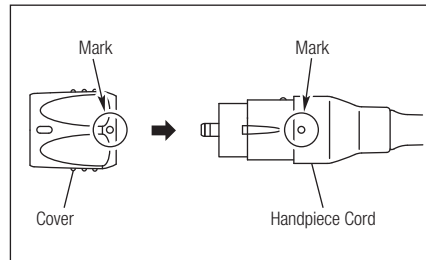


Fig. 25

CAUTION

- Make sure that the bulb is sufficient cooled, when it is replaced.
- Do not touch glass part of new lamp.
- Care needs to be excised when mounting a new lamp to avoid the O-ring off from the groove or being twisted.

(5) Maintenance of the Control Unit etc

If dirt sticks on the Control Unit, Foot Control, or Handpiece Cord, remove the Power Cord first. Then, soak a clean cloth in water and squeeze cloth tightly to drain water. Use the cloth to wipe away dirt. After that, wipe off with an alcohol soaked clean cloth.

9. Troubleshooting

When trouble is found, check the following items again before asking repairs. If none of these are applicable or the trouble is not remedied even after action has been taken, a failure of this product is suspected. Contact your dealer.

Problem	Probable Cause	Cause	Solution
No / Poor vibration.	The Power Lamp does not light, even if the Power Switch is ON.	The Power Cord or the Jack is disconnected.	Correctly insert the Power Cord or the Jack.
		The internal Fuse has burned out.	Contact your dealer.
	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 rotates freely with clicks.
		Worn Tip.	Replace the Tip.
		Output has not been correctly adjusted for the Tip.	Adjust the Power on the Tip Case. Do not exceed.
		The Foot Control is disconnected.	Connect the Foot Control correctly.
Failure of vibrator in the handpiece.	Contact your dealer.		
Failure of the Foot Control.	Contact your dealer.		
The tip is bent or broken.	—	Output has not been properly adjusted for the Tip.	Adjust the power on the Tip Case. Do not exceed.
The tip walks out.	—	The Tip is not tightened firmly.	Tighten the tip until the Tip Wrench rotates freely with clicks.
Noise from the handpiece.	—	Output has not been properly adjusted for the Tip.	Adjust the power on the Tip Case. Do not exceed.
		The Tip is not tightened firmly.	Tighten the Tip until the Tip Wrench rotates freely with clicks.
		Failure of vibration in the handpiece or the Control Unit.	Contact your dealer.
The handpiece is overheating.	—	Output has not been properly adjusted for the Tip.	Adjust the power on the Tip Case. Do not exceed.
		The Tip is not tightened firmly.	Tighten the tip until the Tip Wrench rotates freely with clicks.
		Failure of vibration in the handpiece or the Control Unit.	Contact your dealer.

Problem	Probable Cause	Cause	Solution
No / Poor water.	The water does not reach to the Control Unit.	—	Check the water circuitry and supply to the Control Unit. Water Pressure : 0.1-0.5MPa (1.0-5.0kgf/cm ²)
	Check to see if water reaches the Control Unit.	The Water Adjustment Dial is closed.	Turn the Water Adjustment Dial and adjust to the appropriate volume.
		Disconnected irrigation supply at low volume range. (less than 10cc/min.)	No problem. Turn the Water Adjustment Dial and increase the irrigation volume.
Water leakage.	Water is leaking from the joint between the Irrigation Tube and the Irrigation Connector.	The Irrigation Tube is not connected correctly.	Firmly insert the Irrigation Tube into the Irrigation Connector <u>inmost</u> .
	Water is leaking from the Control Unit.	The water circuitry in the Control Unit is damaged.	Contact your dealer.
Donut light does not illuminate. (Varios 560 LUX)	Tip oscillates, but donut light turns on and off.	The handpiece is not connected into the Handpiece Cord correctly.	Firmly insert the handpiece into the Handpiece Cord <u>inmost</u> .
	Tip oscillates, but light does not turn on.	The Lamp Pins are not correctly engaged in the socket.	Mount the lamp correctly and securely.
	Lamp is correctly and securely mounted in the socket, but light does not turn on.	Has the lamp burned out.	Replace with new lamp. (Refer. 8. (4) Changing Lamp (Varios 560 LUX))
Disconnection in the handpiece, or failure in the Control Unit.		Contact your dealer.	
Loss of power output without operation.	Power output is set at maximum at G mode.	Safety function is activated.	Power output will weaken automatically while continuous operation is over 10min at the setting of Maximum power at G mode. Releasing the foot from the Foot Control will reset the safety function. Stepping on the Foot Control then will resume the previous function. (Refer. 4. * Safety Function)
The operating lamp flashes.	- Continuous operation for a long time at high mode (G: General). - Operation in a high-temperature room.	Safety function is activated.	Turn off the Power Switch and leave until Control Unit becomes cool. Turn on the Power Switch after it cools off completely.
Beeping during operation, automatic mode change, or vibration stop.			
Start Beeping.	Beeping while power on.	Depress Foot Control.	Turn the Power Switch on after release of the Foot Control.
	Beeping while stopping vibration of Tips.	Abnormal heating of the Control Unit.	Stop the operation and leave until Control Unit becomes cool.

10. Warranty

Manufacturer warrants its products to the original purchaser against defects in material and workmanship under normal practices of installation, use and servicing. Such expendable items as O-rings and lamps are not covered by this warranty.

Specifications

Type	NE171
Power Source	AC120V10% 50/60Hz AC230V10% 50/60Hz
Vibration Frequency	28-32kHz
Maximum Output	8W
Power Consumption	Varios 560 LUX : Max.35VA Varios 560 : Max.30VA
Water Pressure	0.1-0.5MPa (1.0-5.0kgf/cm ²)
Lighting	Varios 560 LUX : Yes Varios 560 : No

Dimensions	W109 x D194 x H95mm (Control Unit)
Use Environment	Temperature 0-40°C (The liquid must not freeze up)
	Humidity 30-75 % Atmospheric pressure 700-1060 hPa
Store Environment Transport Environment	Temperature -10-60°C
	Humidity 10-85 % Atmospheric pressure 500-1060 hPa

Symbols



TUV Rhineland of North America is a Nationally Recognized Testing Laboratory (NRTL) in the United States and is accredited by the Standards Council of Canada to certify electro-medical products with Canadian National Standards.



Follow the waste of electric and electronic equipment (WEEE) Directive (2002/96/EC) to dispose of the product and accessories.



Consult operation instructions.



Manufacturer.



This conforms to CE European Directive of "Medical equipment directive 93/42/EEC."



Type BF applied part.



Authorized representative in the European community.



Protected against vertically falling water drops.



Class II equipment.



Autoclavable up to Max.135°C. *for detail see Sterilization.

Guidance and manufacturer's declaration - electromagnetic emissions		
The Varios560/Varios560LUX is intended for use in the electromagnetic environment specified below. The customer or the user of the Varios560/Varios560LUX should assure that is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11	Group 1	The Varios560/Varios560LUX uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	class B	
Harmonic emissions IEC61000-3-2	class A	The Varios560/Varios560LUX is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions IEC61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The Varios560 / Varios560LUX is intended for use in the electromagnetic environment specified below. The customer or the user of the Varios560 / Varios560LUX should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV 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 IEC61000-4-4	±2kV for power supply lines ±1kV for input/output	±2kV for power supply lines ±1kV for input/output	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1kV line(s) to line(s) ±2kV line(s) to earth	±1kV line(s) to line(s) ±2kV line(s) to earth	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 IEC61000-4-11	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 secs	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Varios560 / Varios560LUX requires continued operation during power mains interruptions, it is recommended that the Varios560 / Varios560LUX be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: Ut is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The Varios560 / Varios560LUX is intended for use in the electromagnetic environment specified below. The customer or the user of the Varios560 / Varios560LUX should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC61000-4-6	3Vrms 150 kHz to 80MHz	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Varios560 / Varios560LUX, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80MHz to 800MHz $d = 2.3 \sqrt{P}$ 800MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC61000-4-3	3V/m 80MHz to 2.5 GHz	3V/m	
NOTE 1 At 80MHz and 800MHz, 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 mobiles 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 RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Varios560 / Varios560LUX is used exceeds the applicable RF compliance level above, the Varios560 / Varios560LUX should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Varios560 / Varios560LUX.			
b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3 V/m.			

 Marking on the outside of Equipment or Equipment parts that include RF transmitters or that apply RF electromagnetic energy for diagnosis or treatment.

Cables and accessories	Maximum length	Shield	Complies with
Handpiece cord	2.0 m	Unshielded	RF emissions, CISPR11, Class B/ Group 1
Foot Controller	2.5 m	Unshielded	Harmonic emissions, IEC61000-3-2 Voltage fluctuations/ flicker emission, IEC61000-3-3 Electrostatic discharge (ESD) IEC61000-4-2 Electric fast transient / burst IEC61000-4-4 Surge IEC61000-4-5 Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11 Power frequency(50/60Hz) magnetic field IEC61000-4-8 Conducted RF IEC61000-4-6 Radiated RF IEC61000-4-3

Recommended separation distances between portable and mobile RF communications equipment and the Varios560 / Varios560LUX			
The Varios560 / Varios560LUX is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Varios560 / Varios560LUX can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Varios560 / Varios560LUX 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		
	150kHz to 80MHz $d = 1.2 \sqrt{P}$	80MHz to 800MHz $d = 1.2 \sqrt{P}$	800MHz to 2.5GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			