

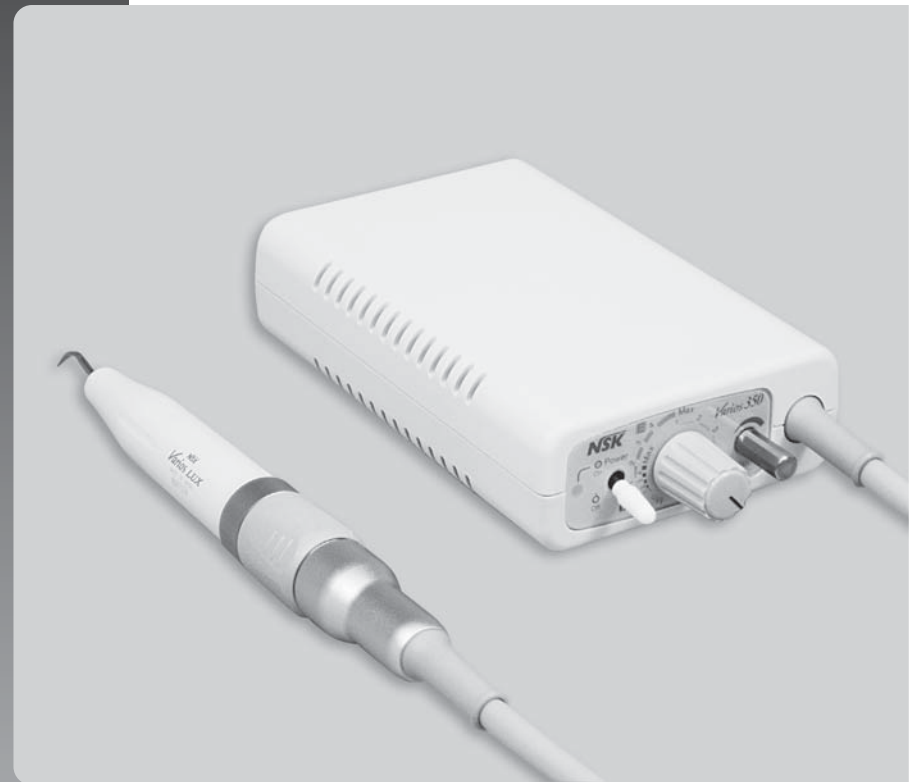
# NSK

Compact Multi Function Ultrasonic Scaler

## Varios 350 (Non-Optic)    Varios 350 LUX (Optic)

### OPERATION MANUAL

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



**NAKANISHI INC.**   
[www.nsk-inc.com](http://www.nsk-inc.com)

700 Shimochinata Kanuma-shi  
Tochigi 322-8666,  
Japan

**NSK Europe GmbH**    
[www.nsk-europe.de](http://www.nsk-europe.de)

Elly-Beinhorn-Strasse 8  
65760 Eschborn,  
Germany

**NSK United Kingdom Ltd**  
[www.nsk-uk.com](http://www.nsk-uk.com)

Office 5, Gateway1000,  
Arlington Business Park, Whittle Way,  
Stevenage, SG1 2FP, UK

**NSK America Corp**  
[www.nsk-inc.com](http://www.nsk-inc.com)

700 Cooper Court  
Schaumburg, IL 60173,  
USA

**NSK France SAS**  
[www.nsk.fr](http://www.nsk.fr)

19 avenue de Villiers  
75017 Paris,  
France

**NSK Dental Spain SA**  
[www.nsk-spain.es](http://www.nsk-spain.es)

C/ Mòdena, 43 El Soho - Európolis  
28232 Las Rozas, Madrid,  
Spain

**NSK Oceania Pty Ltd**  
[www.nsk-inc.com](http://www.nsk-inc.com)

Unit 22, 198-222 Young St.  
Waterloo, Sydney,  
NSW 2017, Australia

**NSK Middle East**  
[www.nsk-inc.com](http://www.nsk-inc.com)

Room 6EA-701, 7th Floor, East Wing No.6  
Dubai Airport Free Zone,  
PO Box 54316 Dubai, UAE

**NSK Asia**  
[www.nsk-inc.com](http://www.nsk-inc.com)

1 Maritime Square,  
#09-33 HarbourFront Centre,  
Singapore 099233

Specifications are subject to change without notice.

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◆ **Original Operation Manual**




Thank you for purchasing the Ultrasonic Scaler Varios 350 / Varios 350 LUX. This device generates ultrasonic waves intended for use only in Professional dental application such as scaling, root planning, root canal treatment, periodontal and cavity preparation. Please read this operation manual carefully before use, and keep on file for future reference.


■ 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 11. 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 anaesthetic 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 and 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
 <b>WARNING</b>	Existence of a hazard that could result in personal injury or damage to the device, if the safety instructions are not followed.
 <b>CAUTION</b>	Explains where the possibility for minor to medium personal injury, or damage to the device, may occur.
 <b>NOTICE</b>	General information to operate the device safely.

 <b>WARNING</b>
<ul style="list-style-type: none"> <li>· Use by medical professional, such as doctor or dental hygienist, is intended.</li> <li>· Do not unplug the Power Cord with wet hands to avoid electric shock.</li> <li>· Be sure to prevent water on the Control Unit, because it may result in short circuit and electric shock.</li> <li>· Do not give a strong impact to the handpiece/Control Unit, nor drop onto a hard surface. This could result in electric shock.</li> <li>· Do not touch the handpiece backend, where electrical connections are attached to the cord. It might result in electric shock.</li> <li>· Do not disassemble or alter the handpiece/Control Unit.</li> <li>· Keep away from patients with cardiac pacemakers.</li> <li>· Keep away from explosive substances and flammable materials. Do not use for patients anesthetized under laughter gas.</li> <li>· There is the judgment that applies this product to a patient in the user side.</li> <li>· This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information.</li> <li>· Portable and mobile RF communications equipment can affect this product.</li> <li>· 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.</li> </ul>

· 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.
- Check the vibration outside the patient's oral cavity before use. If any abnormalities are found, stop using immediately and contact your dealer.
- Be sure to attach NSK genuine Tips when using Varios Ultrasonic Scaler (Varios 350 or Varios 350 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 failuer 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.
- Should this product function abnormally, cease operation immediately and return it to the dealer for repair.
- Do not force or pull on Power Cord and Handpiece Cord. It could cause disconnection.
- Do not exceed Maximum Power Level for Tips. It could damage tooth structure and Tips.
- Always use with pouring enough water, or it may damage tooth plane and overheat the handpiece.
- Do not hit metal or prosthetic crown etc., except for removing them. Tips could break and fall into mouth.
- Do not sharpen and/or bend the Tip. Tips may damage and not generate enough vibration during scaling.
- Do not hit gingiva, mucosa and/or skin directly. It could cause damage and burn.
- The Tip will wear down. If using worn tip makes power down, replace the Tip.
- Be sure to firmly mount the Tip with provided Wrench, or the Tip will not generate enough vibration.
- 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.
- Be sure to turn on the Power Switch after mounting the handpiece.
- Do not use the device with radiator breather of Control Unit downward.
- Do not sterilize by ultraviolet light. Handpiece could discolor.
- Remove the handpiece after the Tip is taken off.
- If you are using corrosive or harsh solutions, clean the Control Unit, handpiece, immediately after use. Those may result in damage to the equipment or color changes of the case.

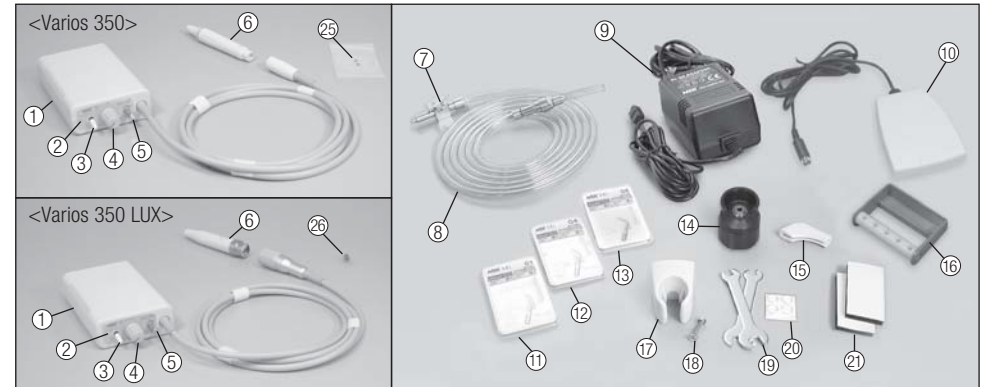
### NOTICE

- 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.
- 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

- The power adjustment dial allows selection of three power modes G-Mode (General), E-Mode (Endo), and P-Mode (Perio). Simply adjust the dial to the power mode required.
- The Water Adjustment Dial Functions as both the ON/OFF for water supply, plus as water volume adjustment.
- Light weight, compact and portable Control Unit equipped with multiple functions.
- Ergonomic handpiece is designed for hand comfort during extended operation. The handpiece can be autoclaved repeatedly.
- The Circular Optic emission brightly illuminates the field of operation for excellent visibility. (Varios 350 LUX)
- Light and durable handpiece tubing with unique jacket.
- The Tip Wrench has an automatic Torque Limiter Mechanism to assure that every Tip is correctly tightened.

## 2. Component Names



- |   |                              |
|---|------------------------------|
| ① Control Unit                          | ⑭ Tip Wrench                 |
| ② Pilot Lamp                            | ⑮ Tip Cover S                |
| ③ Power Switch                          | ⑯ Tip Holder                 |
| ④ Output Adjustment Dial                | ⑰ Handpiece Holder           |
| ⑤ Water Adjustment Dial                 | ⑱ Set Screw                  |
| ⑥ Handpiece                             | ⑲ 2 pc. Spanner Wrench (5x8) |
| ⑦ Water Supply Connector (AC120 V only) | ⑳ 4 pc. Rubber Pad           |
| ⑧ VA350 Water Supply Tube               | ㉑ 2 set Velcro               |
| ⑨ AC Adaptor                            | ㉒ Connector for Water        |
| ⑩ Foot Control                          | ㉓ Connector for Foot Control |
| ⑪ Tip G1                                | ㉔ Connector for AC Adaptor   |
| ⑫ Tip G4                                | ㉕ 2 pc. O-rings              |
| ⑬ Tip G6                                | ㉖ VA Bulb                    |

Fig. 1

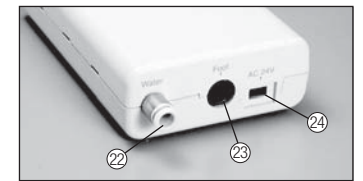


Fig. 2

## 3. Installation for Control Unit

The Control Unit may be installed in 3 ways

### (1) Bench Top Installation Using Rubber Pad

To be certain that the Control Unit is stable on the bench top we suggest that the 4 rubber pads are adhered to the bottom surface of the Control Unit as shown in Fig. 3. (Make sure that the surface is clean before placing the Rubber Pads)

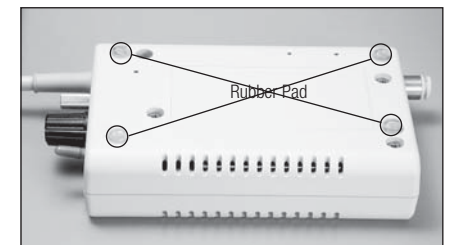


Fig. 3

### (2) Vertical Mount

To securely mount the Control Unit on a vertical location adhere two sets of Velcro to the Control Unit and the vertical surface (Fig. 4) (Make sure that the surface is clean before placing the Velcro)

### CAUTION

Do not mount the Control Unit with the vent section facing downward.

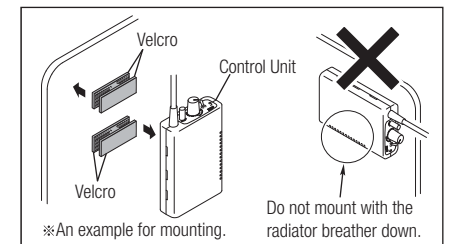


Fig. 4

### (3) Using the Unit Holder (Option)

Use the Unit Holder (Option), when installing the Control Unit beneath a Bench Top.

1. Adhere the Velcro to the Control Unit. (Make sure the surface is clean) (Fig. 5)

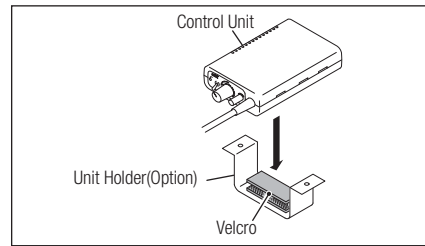


Fig. 5

2. Make two 4.2~4.5 mm holes in the mounting surface. Insert the screw with Spring Washer (Option) in the hole from the holder side and secure it with the nut. (Option) (Fig. 6)

\*Optional Unit Holder : Order No. Z253

[Spring Washer and Nut is provided together with this kit.]

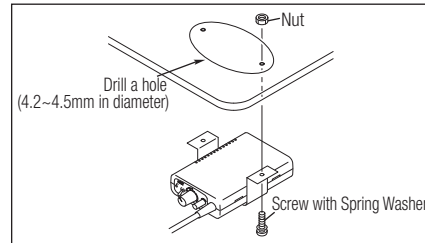


Fig. 6

## 4. Installation for Each Part

### (1) Connecting Water Supply Tube

Insert the Water Supply Tube into the water inlet part of the dental unit. Check that clean water is delivered from the dental unit. (Refer to CAUTION for Connecting Water TUBE) Connect Water Tube (Filter side) to Connector for Water at the rear of the Varios 350 / Varios 350 LUX Control Unit. (Fig. 7)

To remove, pull Water Tube with pushing White Ring of Connector for Water.

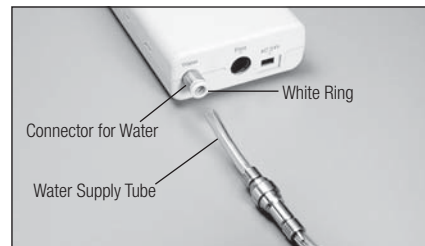


Fig. 7

### ⚠ CAUTION for Connecting Water Tube

If the dental unit water delivery outlet has been inactive the water may be discolored. Before connecting the Water Tube, first run the water until it becomes clean. Only connect the Varios 350 / Varios 350 LUX water tube after the water is clean.

### (2) Connecting the Foot Control

Insert the Foot Control Plug into the Connector for Foot Control at the rear of the Control Unit. (Fig. 8)

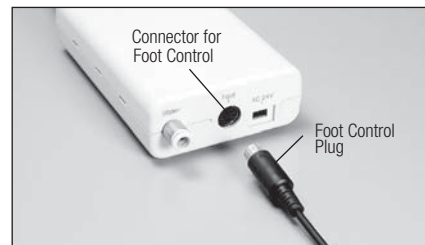


Fig. 8

### (3) Connecting AC Adaptor

Make sure that the Main Power is OFF. Insert the AC Adaptor Cord into the Connector for AC Adaptor at the rear of the Control Unit, and then plug the AC Adaptor into mains power supply (120/230 VAC). (Fig. 9)



Fig. 9

### (4) Mounting the Handpiece Holder on a vertical surface

To mount the Handpiece Holder on a vertical surface follow the procedures below. Note that the holder should be mounted with the NSK mark facing upward.

1. Make a 3 mm hole in the Double-coated tape behind the screw hole in handpiece holder. (Fig. 10)
2. On the vertical surface make a 3.2~3.5 mm hole in the plate where the holder will be mounted. Aligned to the screw hole of the holder. Make certain the surface is clean then adhere the holder to the plate, and attach. Insert the Set Screw through the two holes of the holder and the plate. Fasten the Set Screw with the Nut from the rear of the plate. (Fig. 11)

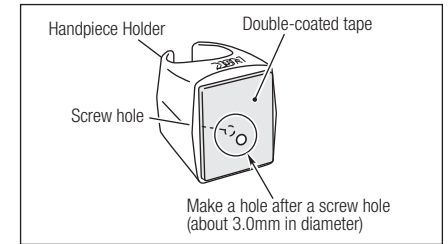


Fig. 10

### (5) Using the Tip Cover S

Grip the Tip Cover S and insert it all the way to where the Tip is connected to the handpiece. To remove the Tip Cover, grip the Tip Cover S and the handpiece (Fig 12) gently pull the Tip Cover out.

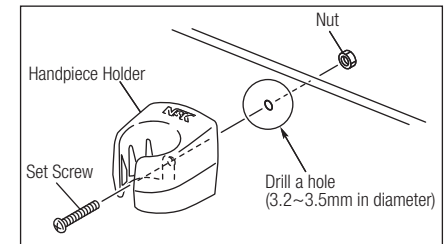
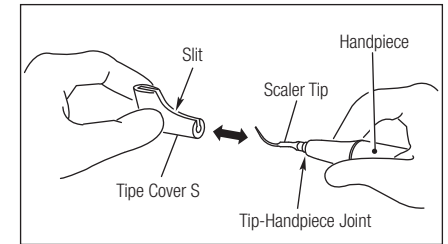
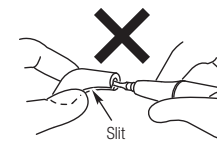


Fig. 11

### ⚠ WARNING

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



\* Figure shows Varios 350.

Fig. 12

### ⚠ CAUTION

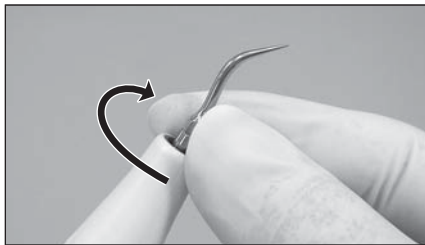
The Tip Cover S is not designed for use as a Tip changing tool.

## 5. Attaching and Removing Tips

Attach the Tip and tighten it lightly by hand. Screwing it clockwise. (Fig. 13)

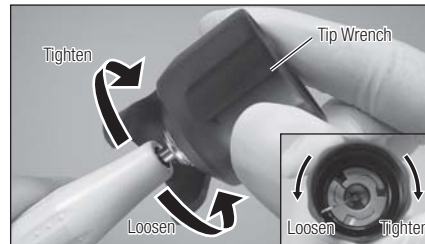
Insert the Wrench shown as Fig14. (Do not stop it halfway) Turn the Wrench clockwise until it clicks. (Fig. 14)

To remove the Tip, turn the Tip counterclockwise with Tip Wrench. (Fig. 14)



\* Picture shows Varios 350 LUX

Fig. 13



\* Picture shows Varios 350 LUX

Fig. 14

### CAUTION

- When attaching the Tip, always use gloves.
- The Tips, Tip Wrench, Scaler Handpiece, Tip Holder, Tip Cover S are all autoclavable.
- Tip Wrench is consumable For reliable operation replace annually.

## 6. Mounting and Removing the Handpiece

To connect the handpiece, first align the Locating Marks on the handpiece to coupling on the handpiece Cord. Push the handpiece firmly into place.

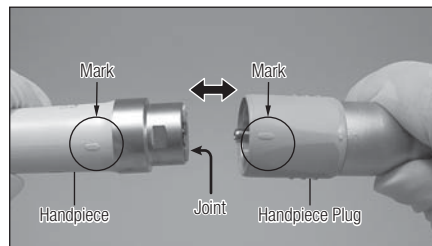
To remove the handpiece grip the handpiece and coupling section of the cord and gently pull the handpiece out. (Fig. 15)

### WARNING

Do not touch the electrical connections at the handpiece backend. It might result in electrical shock.

### CAUTION

- To avoid personal injury always remove the Tip before removing the handpiece.
- When removing the handpiece, always grip the connector section of the handpiece cord. (Fig 15)



\* Picture shows Varios 350 LUX

Fig. 15

## 7. Operating Procedures

### (1) Water Volume Adjustment Dial

Turn (counterclockwise) the Water Adjustment Dial to the lowest position.

### (2) Output Adjustment Dial

Turn Output Adjustment Dial to the lowest (Min) in advance.

### (3) Mains Power Switch

When the mains Power Supply is active the Pilot Lamp will be illuminated.

### (4) Selecting the Power

For each Tip, select the Power Output Level to within the Power Output Level exhibited on each individual Tip case. (Fig. 16)

The Output Adjustment Dial indicates G-mode, E-mode, and P-mode.

The Tip vibration, it has to start from the lowest Level to maximum. Power which write on the Tip Case.

### CAUTION

Do not exceed Maximum Power for Tips. It could damage tooth structure and Tips.  
You can check Maximum Power on the Tip Case Label. Check your Model.

#### Output for each mode

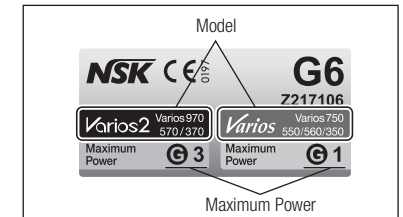
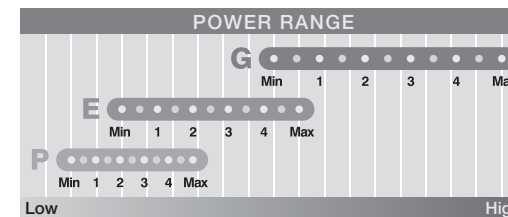


Fig. 16

### (5) Operation and adjusting Water Volume

Depress the Foot Control and the Tip will oscillate, Optic Illumination will turned on for LUX model, then select the required water volume by turning the Water Adjustment Dial in the clockwise direction.

### CAUTION

- Before uses make sure that the water supply to the Varios 350 Control Unit is clean.
- Operate the scaler handpiece only when water is connected.

## 8. Provided Scaler Tips

### Tip G1



This Tip is designed for removing tartar on the neck of tooth (the tooth plane), in the inter proximal region and below the gum margin. Adjust the Power Output Level to Max. G3.

Removing tartar on the neck of tooth ..... Apply the top of the Tip to the tooth plane and move it sideways along the neck of tooth. (Fig. 17)

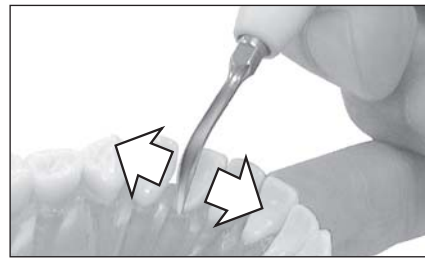


Fig. 17

Removing tartar on the tooth plane ..... Place the side of the Tip parallel with the tooth plane and move it up and down. (Fig. 18)

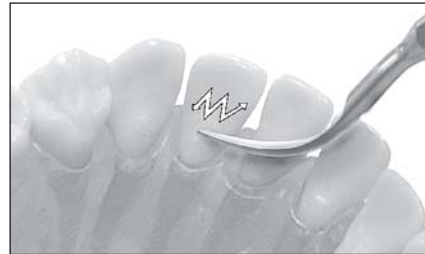


Fig. 18

Removing interdentally calculus ..... Insert the Tip between the teeth vertically and move it slightly. Make sure the Tip is in contact with the tooth surface.

### Tip G4



This Tip is designed for removing tartar on the neck of tooth (sub gingival) and interdentally calculus. Adjust the Power Output Level to Max. G3.

Apply the top of the Tip to the tooth plane and move it sideways in the same manner as the G1 Tip. (Fig. 19)



Fig. 19

### Tip G6



This Tip designed for removing sub gingival calculus and cleaning periodontal pockets. Adjust the Power Output Level to Max.G1.

Insert the top of the Tip into the periodontal pocket and move it slowly. The top of the Tip is designed to be sharp so that tartar on long corona and retracted gingival may be removed. (Fig. 20)



Fig. 20

\*When cleaning periodontal pockets adjust the Power Output Level to Max P2.

## ◆ 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.

Tip Card

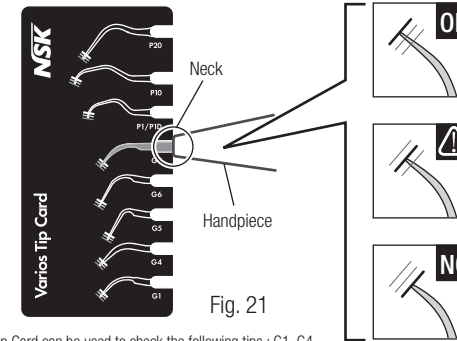


Fig. 21

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

**Green: No wear - Tip is OK**  
Tip replacement is not necessary.

**Yellow: Wear of 1mm - Tip is showing some wear**  
Tip replacement is recommended.

**Red: Wear of 2mm - Tip is badly worn**  
Tip replacement is necessary.

## ⚠ 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.

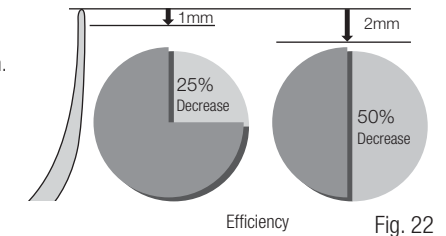


Fig. 22

## 9. Tip Holder

- Use the Tip Holder for Tip storage.
- The Tip Holder is autoclavable and can hold up to 5 tips at once. To autoclave, tilt the tips in the direction of the arrow in Fig.23.

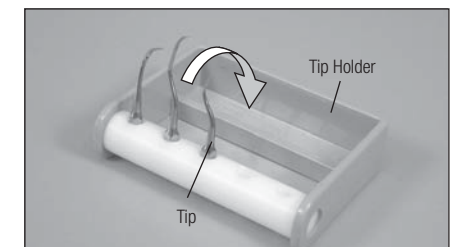


Fig. 23

## 10. Care and Maintenance

### (1) Changing the handpiece O-Ring (Varios 350)

An O-Ring is located at the rear of the handpiece where it connects to the Handpiece Cord Connector. Use a pointed tool to remove the O-Ring and insert the replacement O-Ring in the groove. (Fig. 24)

\* Optional O-ring : Order No. 0312012100

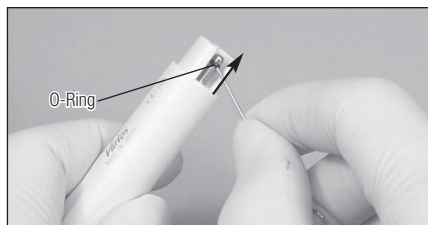


Fig. 24

### (2) Changing the Water Filter

1. Close the water supply valve of the dental unit to which Varios 350 or Varios 350 LUX is connected. Use two Spanner Wrench (5 x 8) and turn in the directions shown in Fig.25. If the water supply tube becomes twisted, relieve the twist by turning it at the Control Unit end.
2. When the Water Filter housing is separated, the Water Filter can be removed as shown in Fig.26. Replace with the new Water Filter and reassemble the filter in the reverse order per the above instructions.

\* Optional Water Filter : Order No. U387042



Fig. 25

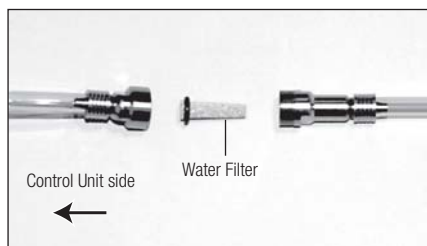


Fig. 26



#### CAUTION

Make sure that the Water Filter is always assembled in the correct direction as shown in Fig. 27.

### (3) Cleaning of optic illumination emission area (Varios 350 LUX)

Use an alcohol dampened cotton swab to wipe all debris from the donut shaped illumination emission area. (Fig. 27)



#### CAUTION

Never use a sharp object to clean the illumination as this may damage or dim the optic illumination.

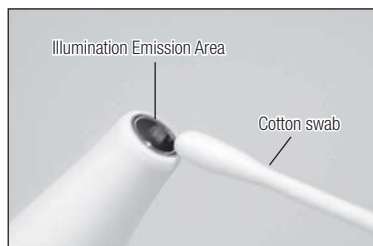


Fig. 27

### (4) Changing the Optic Illumination Lamp (Varios 350 LUX)

Disconnect the handpiece - Refer to 6 Connecting & Removing the Scaler Handpiece.

Remove the cover. Use a Precision Screwdriver. to push out the lamp. Align the replacement lamp pins with the lamp socket holes, and push the lamp into place. (Fig. 28) Align the alignment mark on the cover with the same on the Handpiece Cord, and push the cover onto the cord until it clicks. (Fig. 29) Reassemble the handpiece and the Handpiece Cord.

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

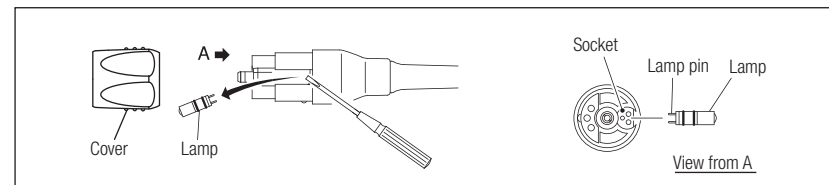


Fig. 28

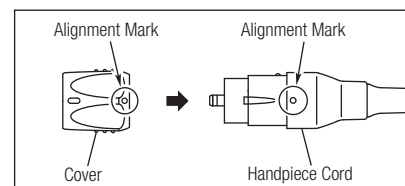


Fig. 29



#### CAUTION

- Do not directly touch or impact the glass part of the new lamp.
- Care needs to be exercised when inserting the replacement new lamp to avoid dislocating the O-Ring off the groove or causing it to become twisted.

## 11. 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.

#### ■ Autoclave Procedure

- 1) Remove the Tip after use. (Refer to 5. Attaching and Removing Tips)
- 2) Remove Handpiece from the Handpiece Cord. (Refer to 6. Connecting and Removing the Scaler Handpiece)
- 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 handpiece in the autoclave pouch to keep it clean until you use it.

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



#### WARNING ON STERILIZATION

- This system can not be cleaned and disinfected with a Thermo-Disinfector.
- Do not sterilize by ultraviolet ray. The handpiece could discoloration.
- If autoclaved with other instruments stained with chemical solution, it could strip the plating and make the surface black.

## 12. Troubleshooting

When trouble is found, check the following again before consulting your dealer. If none of these is 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 AC Jack is disconnected.	Correctly insert the Power Cord or the AC Jack.
		The Fuse in AC Adaptor is burnt out.	Contact dealer.
	The Tip does not generate vibration, in spite of depressing the Foot Control.	The Tip is not tightened firmly.	Tighten the Tip until its clicks by Tip Wrench.
		Worn Tip.	Replace the Tip.
		Output has not been correctly adjusted for the Tip.	Adjust the Power level less than Max. Power on the Tip Case.
		Failure of vibrator in the handpiece.	Connect the Foot Control correctly.
Failure of internal components of the Foot Control.	Contact dealer.		
The Foot Control Plug is Disconnected.	Contact dealer.		
The Tip is bent or broken.	—	Output has not been properly adjusted for the Tip.	Adjust the Power level less than Max. Power on the Tip Case.
The Tip walks out.	—	The Tip is not tightened firmly.	Tighten the Tip until its clicks by Tip Wrench.
Noise from the handpiece.	—	Output has not been properly adjusted for the Tip.	Adjust the Power level less than Max. Power on the Tip Case.
		The Tip is not tightened firmly.	Tighten the Tip until its clicks by Tip Wrench.
		Failure of vibration in the handpiece or the Control Unit.	Contact dealer.
The handpiece has overheating.	—	Output has not been properly adjusted for the Tip.	Adjust the Power level less than Max. Power on the Tip Case.
		The Tip is not tightened firmly.	Tighten the Tip until its clicks by Tip Wrench.
		Failure of vibration in the handpiece or the Control Unit.	Contact dealer.

Problem	Probable Cause	Cause	Solution
No / Poor water.	Check if the water reaches to the Control Unit.	The water does not reach to the Control Unit.	Check the water circuitry and supply the water to the Control Unit. Water pressure: 0.1-0.5MPa (1-5kgf/cm <sup>2</sup> ).
		The Water Adjustment Dial is closed.	Turn the Water Adjustment Dial and adjust to the appropriate volume.
		The Water Filter is clogged.	Refer to "10.(2) Changing Water Filter".
Water leakage.	Water is leaking from the joint between the handpiece and the Cord.	O-ring at the back of the handpiece is worn or damaged.	Refer to "10. (1) Changing O-ring (Varios 350)".
		Water is leaking from the Control Unit.	The water circuitry in the Control Unit is damaged. Contact dealer.
Donut light does not illuminate. (Varios 350 LUX)	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 lamp does not turn on.	Has the lamp burned. Replace the lamp. (Refer to "10.(4) Changing Lamp (Varios 350 LUX) ")
		Discontinuity in the Handpiece Cord, or failure in the Control Unit.	Contact dealer.

## 13. Disposing product

Consult with dealer from whom you purchased it about waste disposal.

## 14. Warranty

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



## Specifications

<Control Unit>

Type	Varios 350 :NE133 Varios 350 LUX :NE149
Power Source	AC24 V 50/60 Hz
Vibration Frequency	28-32 kHz
Maximum Output	8 W (G mode)
Power Consumption	Max. 30 VA
Water Pressure	0.1-0.5 MPa (1-5 kgf/cm <sup>2</sup> )
Lighting	Varios 350 :Not Available Varios 350 LUX :Donut-shape lighting
Dimensions	W 80 x D 125 x H 32 mm

Use Environment	Temperature 0 - 40 °C (The liquid must not freeze up)
	Humidity 10 - 85 % Atmospheric pressure 700 - 1060 hPa
Store Environment	Temperature -10 - 60 °C
	Humidity 10 - 85 % Atmospheric pressure 500 - 1060 hPa

<AC Adaptor>

Type	NE138
Input	AC120 V 50/60 Hz AC230 V 50/60 Hz
Output	AC24 V 1.6 A
Dimensions	W 70 x D 102 x H 56.5 mm

## 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/CE) 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.



Authorised representative in the European community.



Protected against vertically falling water drops.



Class II equipment.




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



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

Guidance and manufacturer's declaration - electromagnetic emissions		
The Varios350/Varios350LUX is intended for use in the electromagnetic environment specified below. The customer or the user of the Varios350/Varios350LUX should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11	Group 1	The Varios350/Varios350LUX 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	The Varios350/Varios350LUX 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.
Harmonic emissions IEC61000-3-2	class A	
Voltage fluctuations/flicker emissions IEC61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The Varios350/Varios350LUX is intended for use in the electromagnetic environment specified below. The customer or the user of the Varios350/Varios350LUX 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 Varios350/Varios350LUX requires continued operation during power mains interruptions, it is recommended that the Varios350/Varios350LUX 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.
<b>NOTE :</b> Ut is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The Varios350/Varios350LUX is intended for use in the electromagnetic environment specified below. The customer or the user of the Varios350/Varios350LUX 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 Varios350/Varios350LUX, 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	
<b>NOTE 1</b> At 80MHz and 800MHz, the higher frequency range applies.			
<b>NOTE 2</b> 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 Varios350/Varios350LUX is used exceeds the applicable RF compliance level above, the Varios350/Varios350LUX should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Varios350/Varios350LUX.			
b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3 V/m.			

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 Varios350/Varios350LUX			
The Varios350/Varios350LUX is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Varios350/Varios350LUX can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Varios350/Varios350LUX 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.			
<b>NOTE 1</b> At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
<b>NOTE 2</b> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			