

OPERATION MANUAL

Varios Handpiece

NSK

CE
0197

MADE IN JAPAN

1 Preface

1-1 User and intended purpose

In this operation manual, VA2-HP Ti, VA2-LUX-HP Ti, VA2-HP, VA2-LUX-HP are called "ultrasonic handpiece".

User: Qualified professionals (dentists, oral surgeons, hygienist)

Intended purpose:

The dental device is intended for the following application(s):

Removal of accretions and deposits from the surface of teeth and dental restorations (fillings and prostheses, etc.), finishing (preparation, adjustment, and polishing), removal and cleaning of infected dental tissues, enlargement and preparation of root canal, filling of root canal filling materials and removal of foreign body in root canal.

1-2 Related manuals

For proper use with the combined items, refer to the following operation manuals:

Manual title	Operation manual No.
Varios Combi Pro OPERATION MANUAL	OM-E0841E
Varios Combi Pro2 OPERATION MANUAL	OM-DE1002MA
Varios 970 OPERATION MANUAL	OM-E0847E
Varios 370 OPERATION MANUAL	OM-E0506E
Varios 170 OPERATION MANUAL	OM-E0840E
CLA-10 OPERATION MANUAL	OM-DE0982MA
Varios Tips OPERATION MANUAL	OM-Z0314E
Varios Tips VarioSurg Tips OPERATION MANUAL	OM-Z0288E
TIP POWER GUIDE	OM-DE0905MA
POWER GUIDE	R0000043

1-3 Precautions for handling and operation



- This product is not intended for use on newborn (neonate) and infant (<2 years old) patient populations.



- Be sure to always carefully read the operation manual for the Ultrasonic System before use to understand the usage and performance of the instrument.
- Do not use in rooms with a risk of explosion or near flammable substances. Also, do not use on or near patients under flammable anesthesia (nitrous oxide).
- Before unpacking this product, make sure that the packaging has not been opened, tampered with, or damaged. If it has been opened or damaged, there may be a risk of malfunction or contamination. Stop use and contact your authorized NSK dealer.
- Always use irrigation in normal use (except for dry tips, which do not require coolant water). If there is insufficient irrigation, the product will overheat and may injure the tooth surface.
- Do not aim the light of the ultrasonic handpiece or handpiece cord at the eye of the patient, operator, or assistant. Doing so may damage eyesight.
- Report all serious events, related to the product immediately to the manufacturer and the responsible national authority.
- Qualified professionals must use this device by fully complying with their respective country's regulations, accident prevention measures, and strictly follow these instructions for use. Users are responsible for operational control, maintenance, and inspection.
- When operating the product, always consider the safety of the patient.
- The user shall be responsible for any judgment that relates to the application of this product to a patient.
- Should the product function abnormally, stop using the product immediately and contact your authorized NSK dealer.



- The product surface may reach the following temperature when using a dry tip continuously for 23 minutes in a room temperature of 26°C. If the product becomes hot, stop use and leave it for approximately 10 minutes until it cools down. (Tip: 29°C, Titanium handpiece (VA2-HP Ti, VA2-LUX-HP Ti): 41.2°C, Resin handpiece (VA2-HP, VA2-LUX-HP):50.2°C).
- The product surface may reach the following temperature when using the product under the NSK specified conditions (40°C, G8 tip, G mode, power 10, continuous load for a long time). If the handpiece becomes hot, stop use and leave it for approximately 10 minutes until it cools down. (Tip: 56°C, Titanium handpiece (VA2-HP Ti, VA2-LUX-HP Ti): 45°C, Resin handpiece (VA2-HP, VA2-LUX-HP):46°C)
- Use or store this handpiece in a location that meets the requirements for the use environment, storage and does not produce condensation. Otherwise, it may cause malfunction.

- The use of non-NSK tips may cause the following faults or unexpected accidents:
 - Inappropriate vibration caused by incompatible threads.
 - Accidental ingestion or aspiration of a broken tip by the patient.
 - Damage or premature wear of the ultrasonic Handpiece threads.
- The glass rod of the ultrasonic handpiece can deteriorate as a result of a long term use over the lifetime of the device.
- Hold the connector part when pulling out the handpiece cord. Pulling the cord may cause a broken wire or damage.
- If water droplets, chemicals, solvents, or liquid disinfectant come into contact with this product (including each part and each connection part), wipe them off immediately. Failure to do so may result in discoloration or deformation.
- Clean, disinfect, and sterilize it following the instructions in this manual before use.
- The effectiveness of sterilization methods other than autoclave sterilization is not verified.
- The ultrasonic handpiece must only be used by a qualified personnel in accordance with the intended purpose and the directions for use stated in the operation manual of the ultrasonic system of NSK and this operation manual. Do not use it for any other purpose.
- The ultrasonic handpiece is consumable. To ensure proper function and safe use of the medical device, perform periodical maintenance checks in accordance with the operation manual of the ultrasonic system.
- This product is for indoor use only.
- Do not drop, hit, or subject to excessive shock. Glass rod and ultrasonic handpiece may be damaged.
- For information related to the EMC of this product, refer to the operation manual of the ultrasonic system used.
- Push the handpiece securely and fully onto the handpiece cord when connecting.
- Before connecting the products, make sure that there is no dirt or foreign object adhered to each connection part. If there is any dirt or foreign object, clean it off.
- Read this operation manual before use to fully understand the product functions and file for future reference.
- Be sure to perform inspection by operating the product with each connecting part mounted before use.
- If any abnormal condition is detected, stop using the product and contact your authorized NSK dealer.
- If the product has not been used for a long period, check that it is functioning correctly and safely before using on a patient.
- Do not bend the handpiece cord at excessive angles. This may result in a decrease in the amount of irrigation.
- Immediately after using on a patient, clean, disinfect, and sterilize this product with the correct method.
- Do not attempt to disassemble the product or tamper with the mechanism except as recommended by NSK in this manual.
- To avoid clinical downtime, it is recommended that a spare be kept on hand in case of a breakdown during operation.
- Be sure to conduct periodical maintenance check on the device and parts.
- This product can be safely used in the treatment of children, pregnant or breastfeeding women, or other patient groups considered particularly vulnerable to such substances.
- Check that clean water is sprayed adequately before use.

NOTICE

- Substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council, or substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5 of Regulation (EU) No 528/2012 of the European Parliament and the Council, in accordance with the criteria that are relevant to human health amongst the criteria established therein: lead (Pb), cobalt (Co).



- No special training is required for this device.

2 Applicable product

Products that can be used in combination with the device.

	VA2-HP Ti	VA2-LUX-HP Ti	VA2-HP	VA2-LUX-HP
Varios Combi Pro	—	—	—	✓
Varios Combi Pro2	—	✓	—	—
Varios 970	✓	✓	✓	✓
Varios 370	—	—	✓	✓
Varios 170	✓	✓	✓	✓
Varios Tip	✓	✓	✓	✓

3 Preparation for Use

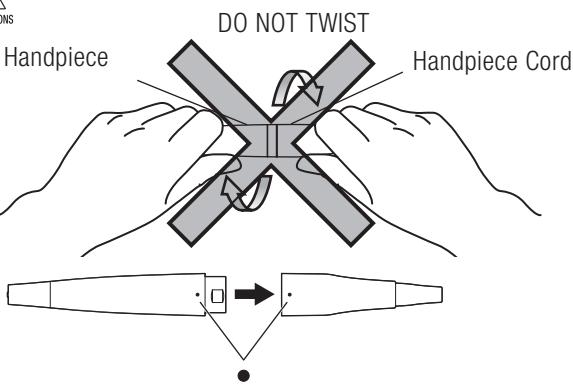
3-1 Mounting the handpiece



- Never touch the terminal (electrical contacts) of the handpiece cord. Doing so may cause an electric shock.



- Before connecting, make sure that dust or moisture does not adhere to the electrical contacts of the handpiece cord.
- Before connecting the handpiece cord to the ultrasonic handpiece, check the end face part by facing the handpiece side connector toward light. If the light transmitted by the illumination part at the end face part on the handpiece side connector is uniformly bright, it is functioning normally. If a part or all is dark, the illumination part may be cracked or broken.



3-2 Removing the handpiece



3-3 Attaching tip

Refer to the operation manual of the tip listed in Related manuals for the method of mounting and removing.

4 Post-use Maintenance



WARNINGS

- The product lifetime and product's ability to operate correctly are mainly determined by mechanical stresses during use and the chemical influences due to processing. If you detect any abnormality such as center heat generation, vibration or noise, or if the exterior markings (serial number or model number) have become unreadable before or during use, stop using the product immediately and request your nearest NSK dealer, or one of the NSK branches for a periodic inspection*.

Disappearance of exterior markings is not covered under warranty for repair.

When the product has been reprocessed 250 times or has been in use for one year, it is recommended that a periodic inspection be performed by an authorized NSK service*.

*Refer to the link below:

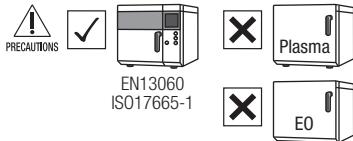


- Failure to properly maintain the products may cause infection, product failure, or overheating and injuries. Be sure to clean and disinfect the products immediately (within 30 minutes) after use to remove residue.

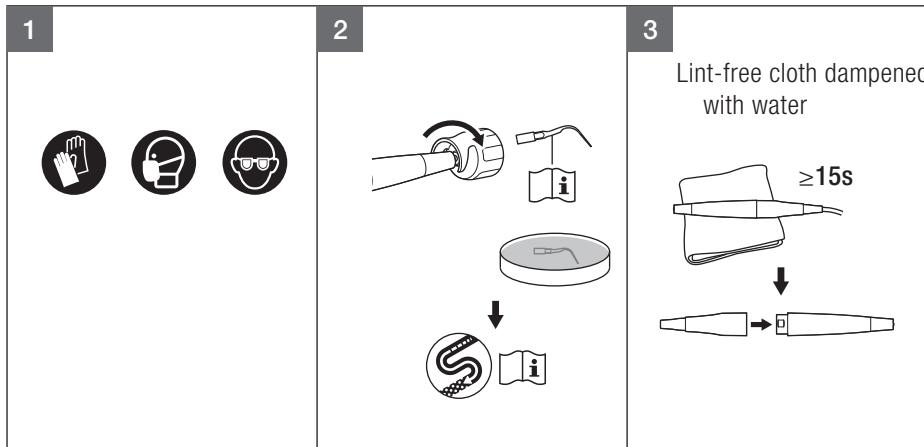


PRECAUTIONS

- Wear eye protection, protective mask, and gloves for safety and infection prevention before starting the maintenance.
- Do not use solvents such as electrolyzed-oxidizing water (strong acidic water or super acidic water), strong acidic or alkaline chemical, chlorine-containing solvent, benzine and thinner when cleaning, immersing, or wiping of the product.
- Ultrasonic handpiece is delivered in a non-sterile condition and requires reprocessing prior to first use and after each patient.
- Clean the ultrasonic handpiece prior to disinfection. If blood remains on the internal surface it can become clotted and cause product failure.
- Use only cleaning disinfectant products listed in this manual.
- Always obey the local directives, standards, guidelines, etc., as to the cleaning, disinfection, and sterilization of the product.
- Do not heat or cool the product too quickly. Rapid change in temperature could cause damage to the handpiece.
- Do not clean an ultrasonic handpiece with an ultrasonic cleaner.
- Use clean and dry compressed air for drying.
- After the thermo disinfection, take the product out of the washer-disinfector immediately (within an hour). Failure to do so causes corrosion.
- After using the washer-disinfector, dry the product completely, because remaining moisture may cause internal corrosion, etc.
- Do not sterilize by ultraviolet ray. The ultrasonic handpiece could discolor.
- This product requires reprocessing after each patient treatment.



4-1 Pre-cleaning

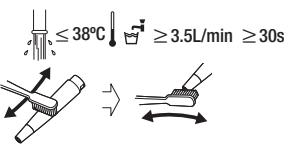
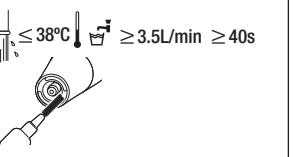
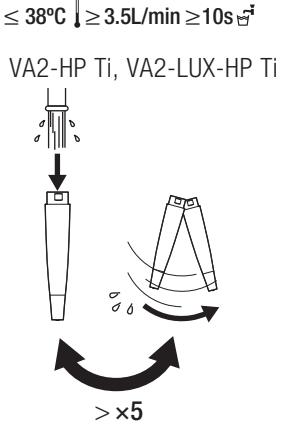
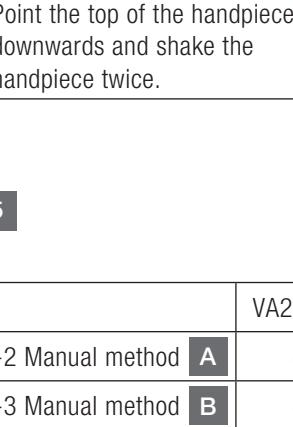
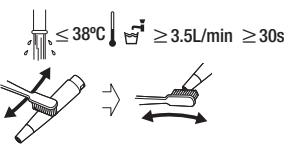
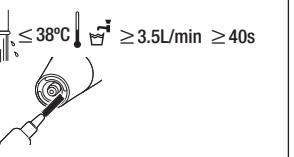
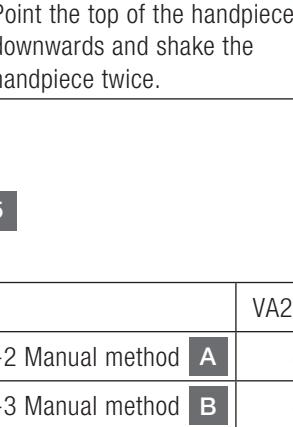


When using Varios Combi Pro / Varios Combi Pro2 / Varios 970:

Perform auto-cleaning according to the Operation manual of the ultrasonic system you are using.

When using other models:

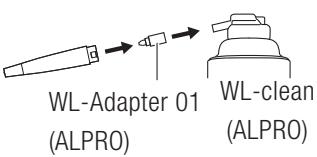
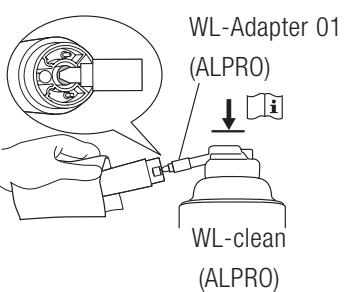
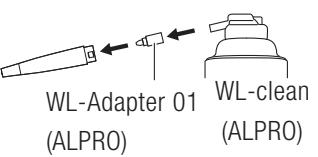
The auto-cleaning function is not available. Please proceed to **4**.

4	Lint-free cloth dampened with water	5		6	
7	$\leq 38^\circ\text{C}$ $\geq 3.5\text{L/min}$ $\geq 10\text{s}$	$\leq 38^\circ\text{C}$ $\geq 3.5\text{L/min}$ $\geq 10\text{s}$		VA2-HP, VA2-LUX-HP	VA2-HP Ti, VA2-LUX-HP Ti
					
	Point the top of the handpiece downwards and shake the handpiece twice.	Point the top of the handpiece downwards and shake the handpiece twice.			
8			5		
					

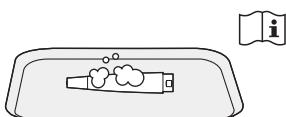
4-2 Manual method

A VA2-HP Ti, VA2-LUX-HP Ti, VA2-HP, VA2-LUX-HP

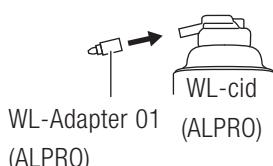
Cleaning and disinfection method using spray.
ALPRO products are not available in some regions.

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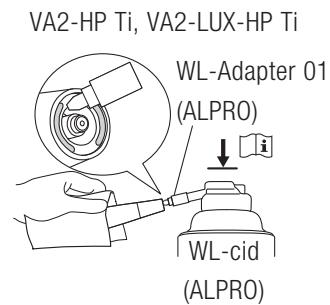
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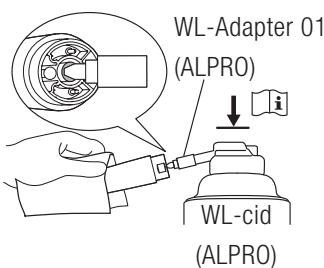


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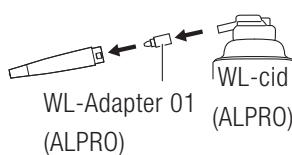


Contact the nozzle to the top of the handpiece and spray.

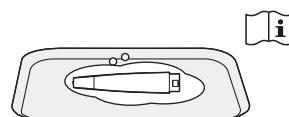
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8



9

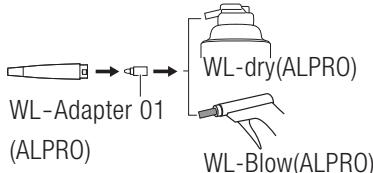
10 $\geq 2\text{min}$ 

Lint-free cloth dampened with disinfectant alcohol

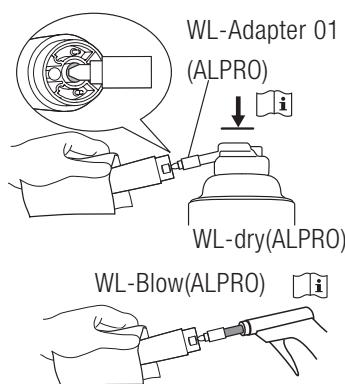


For cleaning and disinfection, use disinfectant ethanol or disinfectant isopropanol that does not contain any additives (any quaternary ammonium salts). Use of other disinfectants may cause discoloration or cracking. * For details, contact the manufacturer of the disinfectant. * In this operation manual, disinfectant ethanol or disinfectant isopropanol that does not contain any additives (any quaternary ammonium salts) is called by "disinfectant alcohol".

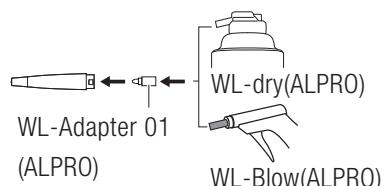
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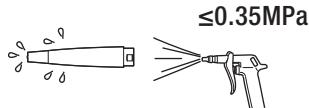
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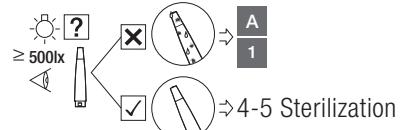


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4-2 Manual method



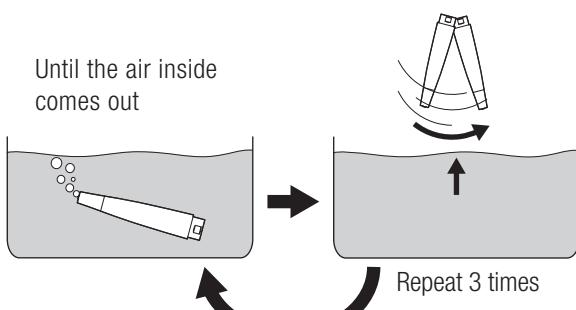
4-3 Manual Method

B VA2-HP Ti, VA2-LUX-HP Ti

Cleaning and disinfection method using detergent.

1

Until the air inside comes out



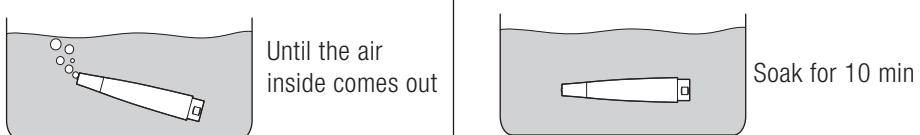
Point the top of the handpiece downwards and shake the handpiece twice.



Water quality	Detergent
Distilled water	Getinge Clean Enzymatic Detergent (pH 7.7-7.9)

2

Until the air inside comes out

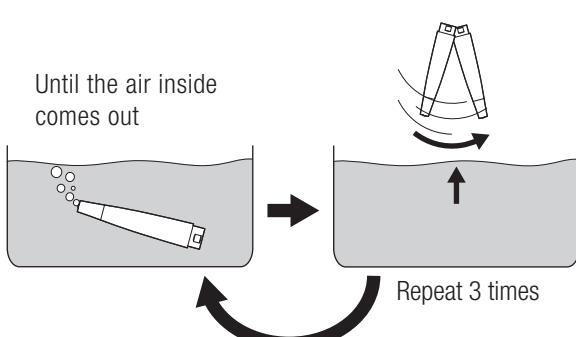


3

Soak for 10 min

4

Until the air inside comes out



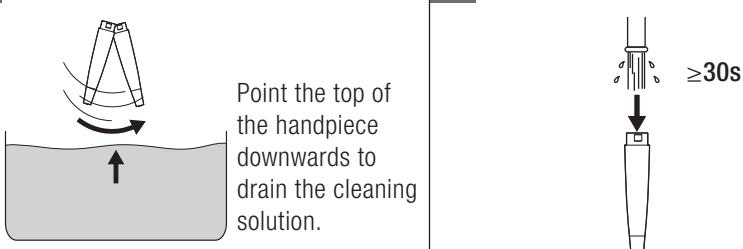
Point the top of the handpiece downwards and shake the handpiece twice.



Water quality	Detergent
Distilled water	Getinge Clean Enzymatic Detergent (pH 7.7-7.9)

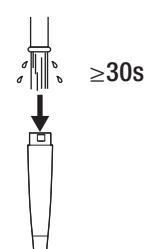
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Point the top of the handpiece downwards to drain the cleaning solution.



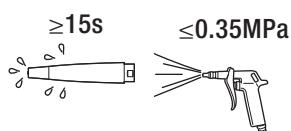
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$\geq 30s$

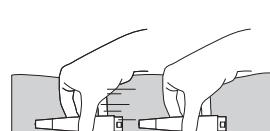


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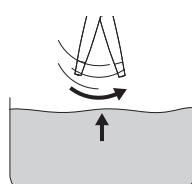
$\geq 15s$



$\leq 0.35MPa$

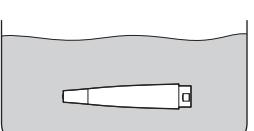


Repeat 2 times



8

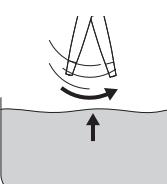
Disinfectant alcohol



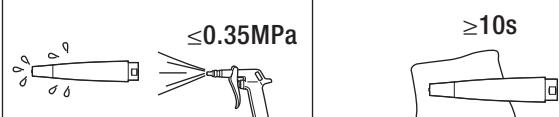
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Soak for 10 min

10



11

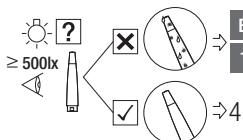


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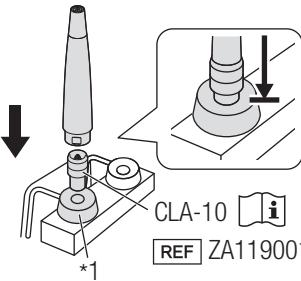
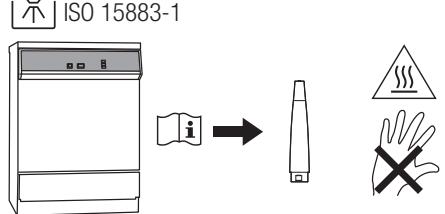
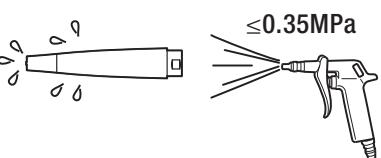
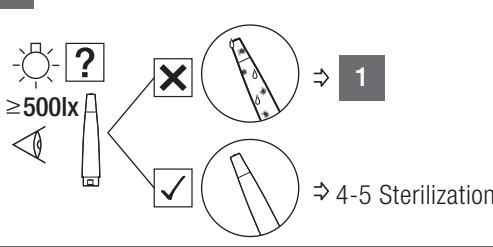


13

4-3 Manual method



4-4 Automated method

<p>1</p>  <p>CLA-10 </p> <p>REF ZA11900102</p> <p>*1</p>	<p>2</p>  <p>ISO 15883-1</p>																										
<p>References for washer-disinfector gasket (*1)</p> <table border="1"> <thead> <tr> <th></th> <th>REF</th> <th>Connection ø</th> <th>Color</th> </tr> </thead> <tbody> <tr> <td>Miele</td> <td>ADS</td> <td>16mm</td> <td>Green</td> </tr> <tr> <td>MELAG</td> <td>63500</td> <td>16mm</td> <td>Green</td> </tr> <tr> <td>GETINGE</td> <td>502887400</td> <td>16mm</td> <td>Black</td> </tr> </tbody> </table> <p>Due to the variation in cleaning/disinfection cycles and cleaning agents available from the various manufacturers, NSK has validated the Miele washer-disinfector PG8581 Cycle Vario TD (Refer to the table below) for automatic processing/reprocessing of the products. Only validated procedures must be used for cleaning and sterilization. When using reprocessing procedures that are different from those described in this manual, those procedures must be validated by the respective practice or hospital using washer-disinfector that conforms to EN ISO 15883-1.</p> <table border="1"> <tr> <td>Step1</td> <td>Precleaning with cold tap water for 1 minute.</td> </tr> <tr> <td>Step2</td> <td>Cleaning for 5 minutes using demineralized water mixed with 0.5% cleaner at 55 °C.</td> </tr> <tr> <td>Step3</td> <td>Rinsing with demineralized water for 1 minute. (twice)</td> </tr> <tr> <td>Step4</td> <td>Thermodisinfection with demineralized water at 93 °C for 5 minutes.</td> </tr> <tr> <td>Step5</td> <td>Dry the products for 40 minutes at 100 °C.</td> </tr> </table>			REF	Connection ø	Color	Miele	ADS	16mm	Green	MELAG	63500	16mm	Green	GETINGE	502887400	16mm	Black	Step1	Precleaning with cold tap water for 1 minute.	Step2	Cleaning for 5 minutes using demineralized water mixed with 0.5% cleaner at 55 °C.	Step3	Rinsing with demineralized water for 1 minute. (twice)	Step4	Thermodisinfection with demineralized water at 93 °C for 5 minutes.	Step5	Dry the products for 40 minutes at 100 °C.
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<p>3</p>  <p>$\leq 0.35 \text{ MPa}$</p>	<p>4</p>  <p>$\geq 500 \text{ lx}$</p> <p>1</p> <p>4-5 Sterilization</p>																										

4-5 Sterilization



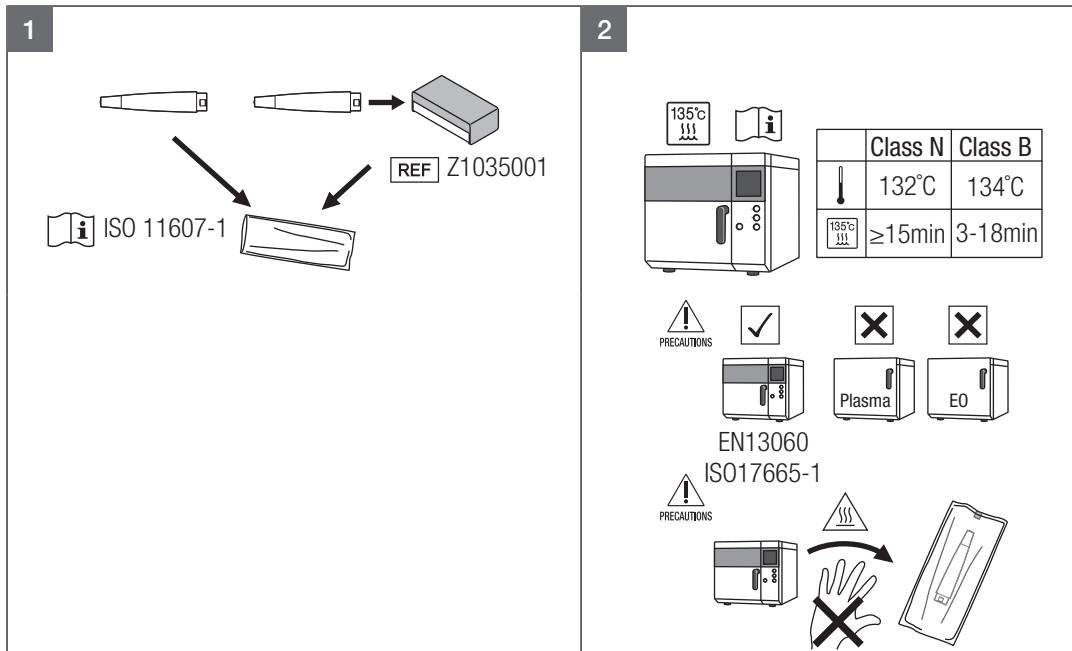
PRECAUTIONS

- Do not autoclave the ultrasonic handpiece with other instruments even when it is in a sterilization pouches. This is to prevent possible discoloration and damage to the product from chemical residue on other instruments.
- Be sure to use sterilizers that can perform sterilization up to 135 °C. In some sterilizers, the chamber temperature may exceed 135 °C. Contact the sterilizer manufacturer for detailed information about cycle temperatures.
- Do not use sterilization pouches containing water-soluble adhesive components such as PVA (polyvinyl alcohol). Adhesive components washed out during sterilization may enter the product, causing problems such as malfunction, sticking and failure to operate correctly.
- Immediately after sterilization is complete (within 1 hour), remove the ultrasonic handpiece from the sterilizer. Failure to do so may cause corrosion.
- Repeated autoclaving may cause the ultrasonic handpiece to become discolored due to heat. However, this is due to properties of the product and is not problem in terms of quality.
- Use a sterilization pouch that complies with ISO 11607-1.

- Do not put other instruments together with the items of this product in a sterilization pouch to perform the autoclave sterilization. Doing so discolors the product surface and affects internal parts. In addition, pay attention not to let chemicals enter the product during the autoclave process.
- Do not use a sterilizer that exceeds 135 °C during the dry cycle. It causes a failure of the product. For details, consult the manufacturer of the sterilizer.
- Do not heat or cool the product rapidly during the sterilization. Rapid changes in the temperature deteriorate the product.
- Do not touch the product just after the sterilization because it is hot.
- Do not sterilize using ultraviolet light. Doing so may result in discoloration.
- For this product, the effectiveness of sterilization methods (such as the plasma sterilization and EO sterilization) other than autoclave sterilization is not verified.
- After sterilization is completed, take the product out of the sterilizer within an hour. Failure to do so may cause corrosion.
- If water drops remain on the handpiece after sterilization, be sure to wipe them up. Failure to do so may result in discoloration.

NOTICE

- We recommend the class B sterilizer stipulated in EN13060. For details, refer to the operation manual issued by the manufacturer of the sterilizer.



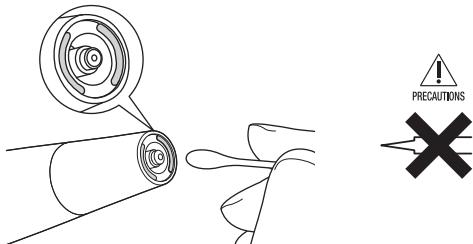
⇒ 4-6 Storage

4-6 Storage



5 Maintenance

5-1 Cleaning glass rod optic end



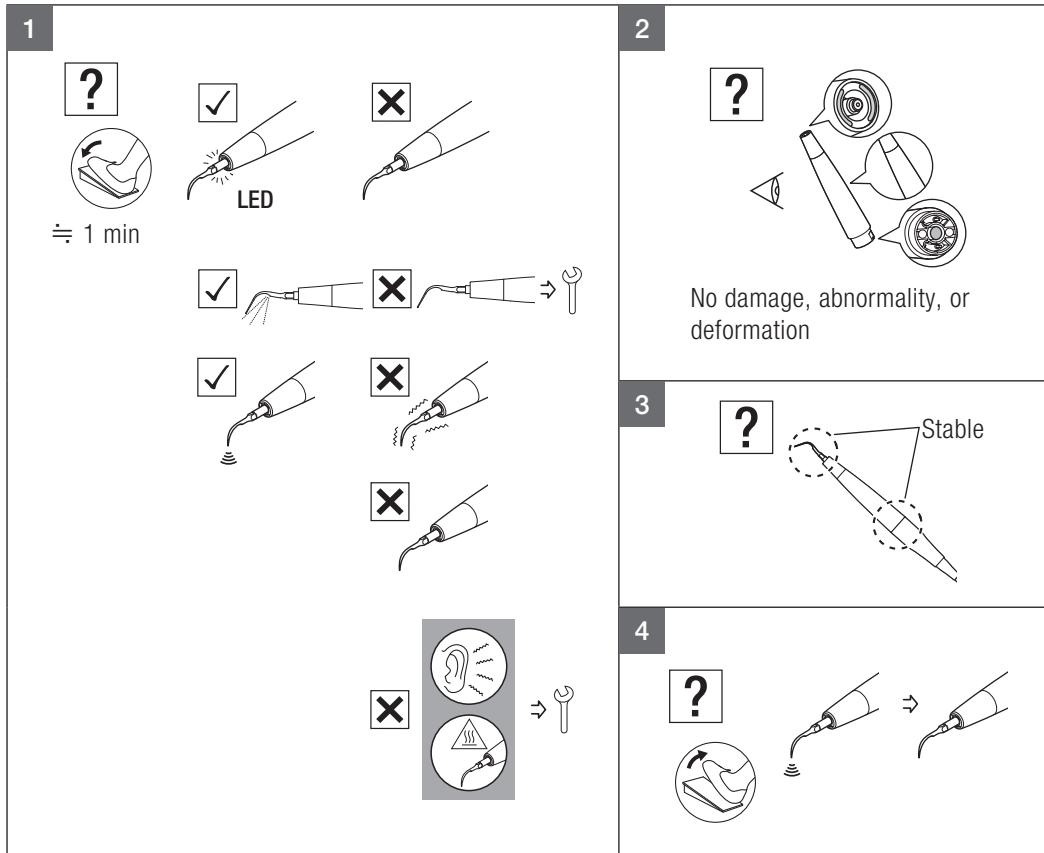
If dust or debris adheres to the glass rod,
carefully wipe it off using a cotton swab
dampened with disinfectant alcohol.

6 Check before treatment / Periodical Maintenance Checks

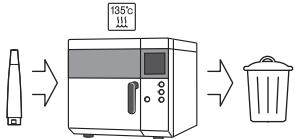
Checking the Handpiece Before Each Use Periodical Maintenance Checks (Every 3 months)

1

2 3 4



7 Disposing of products



When your medical device has reached the end of its service life, it must be disposed of via a specialist collection, removal, recycling or destruction channel. Prior to do so, in order to avoid the health risks to operators handling the disposal of medical equipment, as well as the risks of environmental contamination caused thereof, you need to confirm the equipment is decontaminated.

Therefore contact your nearest NSK dealer, or one of the NSK branches to find out how to proceed.

Refer to the link below:



8 Warranty

NSK products are warranted against manufacturing errors and defects in materials. NSK reserves the right to analyze and determine the cause of any problem. Warranty is voided should the product be not used correctly or for the intended purpose or has been tampered with by unqualified personnel or has had non NSK parts installed. Replacement parts are available for seven years beyond discontinuation of the model. Contact an authorized NSK dealer if repairs are necessary.

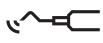
9 Troubleshooting

* Cannot be fixed at dental clinics. Be sure to contact your authorized NSK dealer.

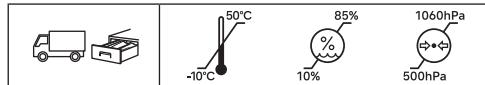
Problem	Cause	Remedy
There is no vibration or the vibration is poor.	The threads of the ultrasonic handpiece and tip are not clean.	Wipe them clean.
	The threads of the ultrasonic handpiece are worn out as a result of long term use.	Contact your authorized NSK dealer*.
	Failure of the vibration device in the ultrasonic handpiece.	
The ultrasonic handpiece produces a loud noise.	Power has not been correctly adjusted for the tip.	Adjust the power so that it does not exceed the set maximum power level mentioned in the supplied operation manual of the tip. =>"1-2 Related manuals"
	The tip is not tightened firmly.	Re-tighten the tip with the tip wrench by rotating the tip wrench until it makes a click sound and cannot rotate any further. If the problem still persists, replace the tip wrench as it may be worn out.
	Failure of the ultrasonic handpiece's vibration device or control unit's internal components.	Contact your authorized NSK dealer*.
The ultrasonic handpiece is overheating.	Power has not been correctly adjusted for the tip.	Adjust the power so that it does not exceed the set maximum power level mentioned in the supplied operation manual of the tip. =>"1-2 Related manuals"
	The tip is not tightened firmly.	Re-tighten the tip with the tip wrench by rotating the tip wrench until it makes a click sound and cannot rotate any further. If the problem still persists, replace the tip wrench as it may be worn out.
	The threads of the ultrasonic handpiece and tip are not clean.	Wipe them clean.
	Failure of the ultrasonic handpiece's vibration device or control unit's internal components.	Contact your authorized NSK dealer*.
Damage to the appearance or metal parts of the ultrasonic handpiece.	The ultrasonic handpiece has been dropped or deteriorated, or unspecified chemicals have been used.	Contact your authorized NSK dealer*.

10 Specification

Model	VA2-HP Ti	VA2-LUX-HP Ti	VA2-HP	VA2-LUX-HP
Optic	-	White LED	-	White LED
Drive frequency		28-32 kHz		
Dimensions	Ø17.6 mm×100 mm	Ø20 mm×103 mm	Ø17.6 mm×100 mm	Ø20 mm×103 mm
Weight	50 g	58 g	43 g	54 g



Refer to the operation manual of the ultrasonic system.



Use outside of these limits may cause malfunction.

Avoid any risk of freezing of irrigation solution. When operated outside the use environment, there is a risk of failure.

10-1 Classification of equipment

- Type of protection against electric shock: Refer to the operation manual of the ultrasonic system.
- Degree of protection against electric shock: Refer to the operation manual of the ultrasonic system.
- Method of sterilization or disinfection recommended by the manufacturer:
 - Autoclave sterilization
- 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: Refer to the operation manual of the ultrasonic system.

10-2 Operation principle

Electric signals supplied from the control unit are converted into ultrasonic vibrations by the ultrasonic transducer built into the ultrasonic handpiece. These ultrasonic vibrations are transmitted to various tips attached to the end of the ultrasonic handpiece. During treatment, water for cooling and cleaning is supplied from the control unit, delivered through the ultrasonic handpiece and various tips, and used in conjunction with the ultrasonic vibrations.

11 Symbol



CONTRA-INDICATIONS: Specific medical reason for not using the device : i.e. health condition of the patient.



WARNINGS: Failure to follow the warning could result in death or serious injury.



PRECAUTIONS: Means that, in case the precaution is not taken, it may cause minor or moderate injury.

NOTICE NOTICE: General product specification information highlighted to avoid product malfunction and performance reduction.

	Use Environment		Move in the direction indicated.		Move fully to the stop, in the direction indicated.
	Prohibited / Process NOT permitted / Wrong		Do the step / Process permitted / Correct		If...(Hypothetical situation)
	Wear protective gloves		Wear a face mask		Wear eye protection
	Temperature		The instrument can be used with a washer-disinfector for thermal disinfection.		This product can be sterilized in a steam sterilizer at 135°C.
	Lamp / lighting / illumination		Drinking water		Visual check
	Hand operated		Caution, hot surface		Consult operation instructions
	Specifications		Conforms to European "Medical Device Regulation"		Manufacturer
	Importer		Authorized representative in the European Community		Authorised representative for Switzerland
	Medical Device		Catalog number (Order code)		Serial No.
	Date of manufacture		Unique Device Identifier		GS1 DataMatrix for Unique Device Identifier.
	Contains hazardous substances		Transportation and Storage Environment		Temperature limitation
	Humidity limitation		Atmospheric pressure limitation		Keep away from sunlight
	Keep dry		Auto Cleaning		

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