NSK

Ultrasonic Bone Surgery System

VarioSurg

OPERATION MANUAL

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

Powerful Partners®

OM-E0559E

MADE IN JAPAN

CE 0197

English

Thank you for purchasing VarioSurg. This product is for use by dentists and oral surgeons.
Implant site preparation, Bone harvesting, Sinus surgery, Osteoplasty, Osteotomy, General oral surgery, Tooth extraction, Syndesmotomy, Tooth avulsion, Periodontal surgery, Cyst surgery.
Read this Operation Manual carefully before use for operation instructions and care and maintenance guidelines. Keep this Operation Manual for future reference.

■ Classification of Devices
- Classification by type of protection against electric shock:
  — Class I devices.
- Classification by degree of protection against electric shock:
  — Applied part type BF.
- Classification by sterilization or disinfection method allowed by the manufacturer:
  — Refer to Sterilization.
- Classification by degree of protection against harmful intrusion of liquid based on IEC60529:
  — Foot Control ··· IPX8 (protected against immersion)
- Classification by safety level of use in air, flammable anesthetic gas or dinitrogen monoxide (laughing gas), flammable anesthetic gas:
  — Not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous dioxide (Without Foot Control)
- Classification by mode of operation:
  — Continuously operating device.

⚠ Safety Precautions and Indications of Dangerous Items

■ We recommend that prior to using the device; you read carefully the safety precautions in order to operate it correctly.
■ Indications of Dangerous Items is designed so that you can use the product safely, thus obviating any safety hazard or damage to you or others. They are classified according to their magnitude and emergency degree of safety hazard or damages. As each and every item concerns safety, observe them.

Classification	Degree of Danger or Danger and Seriousness
⚠ WARNING	Explains an instruction where personal injury or physical damage may occur.
⚠ CAUTION	Explains an instruction where minor to medium injury or physical damage may occur.
⚠ NOTICE	Explains an instruction that should be observed for safety reasons.

1. Safety precautions prior to use

⚠ WARNING

- Do not plug or unplug the AC Power Cord with wet hands. This could cause electric shock.
- Do not use in a room where an explosion might occur. Do not use in the vicinity of flammable materials. Do not use in the vicinity of a patient who has been administered anesthesia (laughing gas).
- Be careful not to get water or liquid disinfectant on the Control Unit. This could cause short circuits and lead to a fire and/or electric shock. Should any water or liquid disinfectant get on the Control Unit, wipe it off immediately.
- Be careful not to give strong shock (dropping, in particular) to a Handpiece. This might break the optics (Optic Handpiece only) or give you an electric shock.
- Never touch the connecting part (electric pins) for the Handpiece and Handpiece Cord.
- Never attempt to take apart or reconfigure the Control Unit/Handpiece in any method not described in the manual.
- Keep away from patients with cardiac pacemakers (There is danger that it may affect the pacemaker).

⚠ WARNING

- Do not flick the Main Power Switch ON and OFF repeatedly. There is danger that it will blow a fuse.
- Turn off the Control Unit if there are any abnormal vibrations, heat generation, abnormal noise, etc., before or during use.
- Do not place anything within 10 centimeters around the Control Unit.

⚠ CAUTION

- This product should be used only by physicians, dental hygienists, dental technicians and others with professional training. It should be used only in dental clinics, hospitals or other medical institutions. Assistants should use it under the supervision of a specializing physician.
- It is recommended that a spare system be kept on hand in case of a breakdown during surgery.
- When operating the product always consider the safety of the patient.
- This product does not consider patient's age (except infants), gender, weight or nationality.
- This product does not consider operator's age (mature person), height, weight, gender, or nationality.
- Do not use this product if the patient has the any of the following conditions:
    - Patient complications
    - Patient allergic reactions
    - Patient has preexisting condition e.g. (heart, lung, renal, high-blood pressure)
    - Patient is Pregnant, patient of child-bearing potential or lactating patient
    - Patient is an infant (Age)
    - Patient has a heart pace maker fitted
- The end user shall be responsible for any judgment that applies this product to a patient.
- Keep the Control Unit on a level surface and make sure it is not subject to strong impact (such as being dropped, etc.).
- Before using the product, make sure to operate it outside the oral cavity for checking. Then, if you find any abnormality, immediately stop using it and contact the dealer.
- Disconnect from AC Power Cord and remove the Handpiece Cord after turning off the Control Unit. Pull the plug out holding the plug itself. Pulling by the Cord will result in damage to the Cord.
- Use only the fuses indicated.
- Do not insert or remove the AC Power Cord or Handpiece Cord with foot on the foot control.
- When the pump gets wet, wipe well and dry it. If the pump remains wet, it may not work normally as the roller inside the pump may slip.
- If the Irrigation Tube is bent or folded while the Irrigation Pump is in operation, the tube may be damaged or disconnected.
- If the irrigation seems abnormal, it may be because of wear of the Irrigation Tube or that saline, etc. is leaking from the tube. Replace the Irrigation Tube.
- The Irrigation Tube cannot be reused. After using, dispose of it as medical waste.
- Do not remove both the Handpiece and cord.
- Do not turn ON the Main Power with the Handpiece disconnected or while foot is on the Foot Control.
- Remove the Tip when inserting or removing the Handpiece Cord or Irrigation Tube. It could cause injuries.
- When in use, always pump cool saline, etc. Insufficient liquid will destroy bone tissue or damage tooth surface.
- In use, never allow the vibrating Tip to touch any prosthesis such as ceramics. Touching might cause break or chipping.
- In use, never allow the vibrating Tip to touch a metal crown, porcelain crown, etc., which may cause loosening or breakage, etc.
- Use the Tip within the power range indicated on the tip case. If you use it out of the power range, the Tip might break or damage an operative site.
- Do not use the Tip that is damaged, bent or rusted. The Tip could break while in use.
- Do not sharpen the Tip or bend it to change the angle. The Tip could break during use or fail to vibrate.
- Even if used within the recommended power range, a Tip could become chipped or break due to an overload. Be sure to use suction to make sure no pieces of a broken Tip are left in the patient's mouth.
- Make sure that the saline, etc. that emits from the Tip does not come into contact with the control unit. It could cause color to fade or rusting.

⚠ CAUTION

- Only Use Tips that NSK has approved for VarioSurg use. Damage, failure or an accident may occur; the following are possible failure modes (NSK Warranty Exclusions).
    - Vibration failure caused by using non conforming screws (Incorrect Tip).
    - Patients' accidental ingestion of Broken or damaged Tip.
    - Damage to thread of Handpiece output shaft.
- Handpiece, Handpiece Cord, Tips, Tip Wrench, and Tips Holder are all non-sterile items. Be sure to sterilize them before use.
- Never sterilize the Handpiece etc., using ultraviolet sterilization. It may cause discoloring.
- After autoclave sterilization, wipe away any remaining water drops. They may cause discoloring.
- Do not press the Tip against anything unless it is part of treatment. Ultrasonic vibrations may damage tooth surface.
- The Tip wears down after every use. After wearing down, vibrations become weak and coating may come off. If these problems occur, be sure to replace the Tip with a new one. It is recommended that the Tip be changed after 5 uses.
- When replacing the Tip, use the Tip Wrench to ensure that the new Tip is securely mounted to the Handpiece. If mounting is loose, vibrations may be weak and output inadequate.
- If a new Tip is mounted with stray objects on the screw, vibrations may be weak and output inadequate. If there is anything on the Tip, clean it off before mounting to Handpiece.
- If it feels as though the Tip is not vibrating during use, remove the Handpiece from the mouth of the patient, and step on the foot control again. If the situation is no better, the Tip may have become loose during use, so check to make sure it is securely mounted.
- Do not shine the LED into the eyes of the patient or the operator. It may damage eyesight.
- This product is Medical Electrical equipment. EMC (Electromagnetic compatibility) is described in the accompanying documentation.
- 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 Medical Electrical equipment. Do not use RF equipment outskirts for the product.
- The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of this product as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of this product.
- This system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this product should be observed to verify normal operation in the configuration in which it will be used.

⚠ 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.
- Turn the Main Power Switch OFF when not in use. If left unused for a long period of time, remove the plug from the power outlet.
- Clean and sterilize immediately after use and before storing. Lack of cleaning or sterilization could result in breakdowns.
- When you have not used the product for long time and use it again, check the operation before use.
- Users are responsible for operational control, maintenance and inspection.
- No special training is required for this device.
- Applied parts for patient and/or operator are/is Tip and Handpiece.

Principle of Operation

A sinusoidal electrical signal, at ultrasonic frequency, is delivered by the generator. This signal is applied to the piezoelectric ceramic located inside the transducer. Piezoelectric ceramic converts this signal into mechanical vibrations. These vibrations are at the same ultrasonic frequency as the electrical signal. The mechanical vibrations are propagated towards the distal end of the transducer. The insert, which is attached at the distal end of the transducer, vibrates at ultrasonic frequency and makes it possible to achieve the aimed purpose.

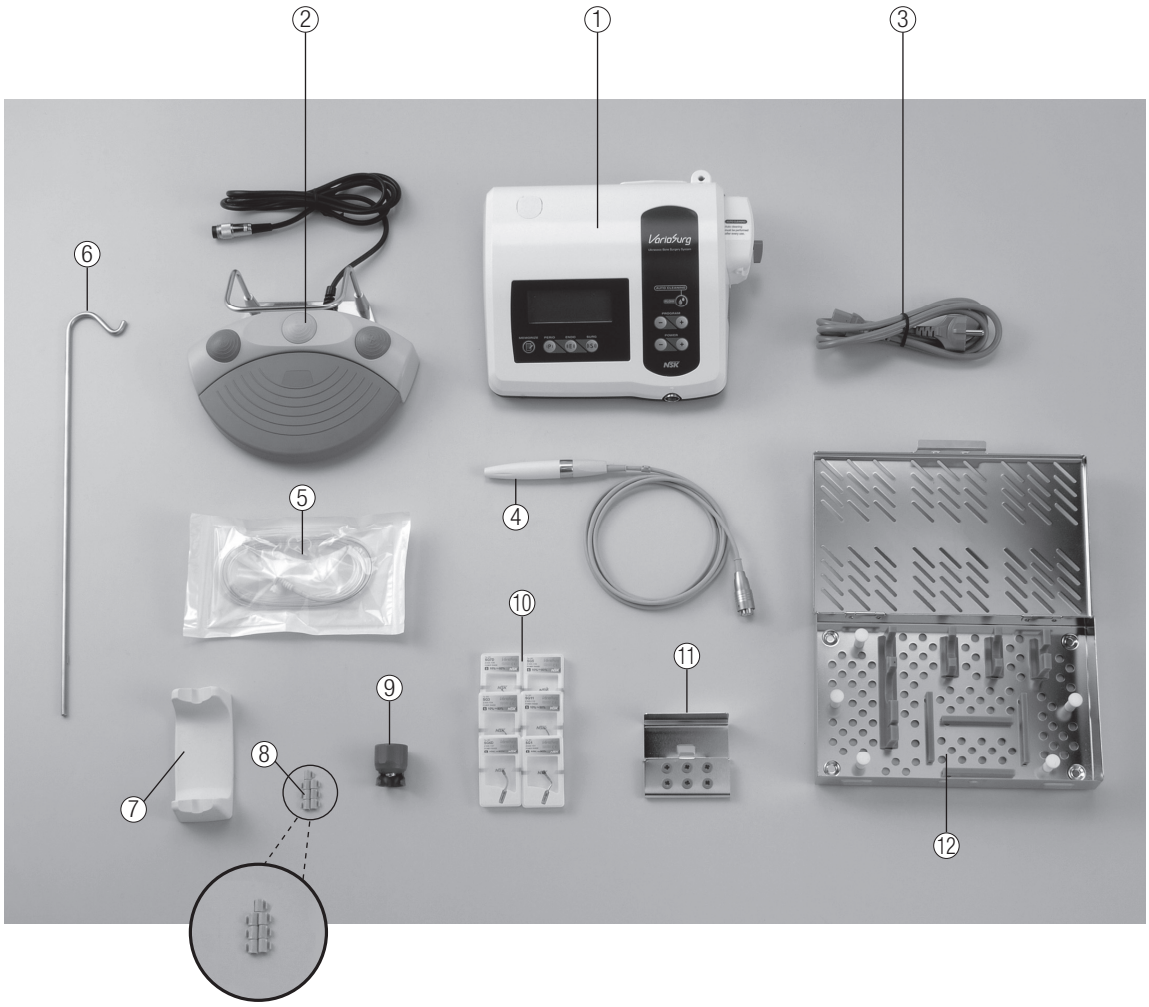
2. Specifications

Type	NE214	
Rated power supply	AC100V 50/60Hz, AC120V 50/60Hz, AC230V 50/60Hz	
Resonance frequency	28~32kHz	
Maximum output	17W	
Power supply input	50VA	
Lighting	White LED (Optic Handpiece (VS-LED-HPSC) only)	
Activate Voltage	3.5V	
Consumption current	0.1A (Typ. 3.5V)	
Dimensions	W268 x D230 x H103(mm)	
Weight	3.1kg	
Fuse	100/120V Specification...T2AL 250V 230V Specification...T1AL 250V	
Use environment	Temperature	0 - 40 ˚C*
	Humidity	30 - 75 %**
	Atmospheric pressure	70 - 106 kPa
Transportation and Storage environment	Temperature	-10 - 60 ˚C
	Humidity	10 - 85 %**
	Atmospheric pressure	50 - 106 kPa

* No liquid freezing allowed

** No condensing allowed

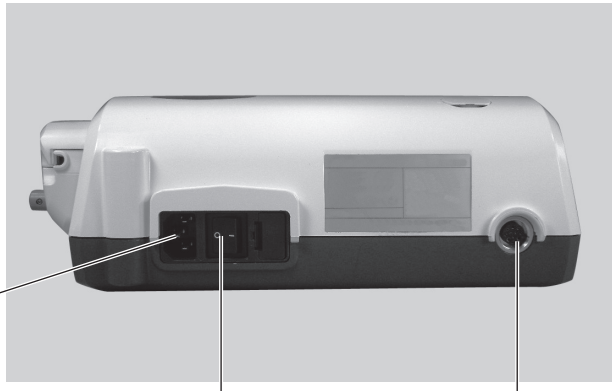
3. Package Contents



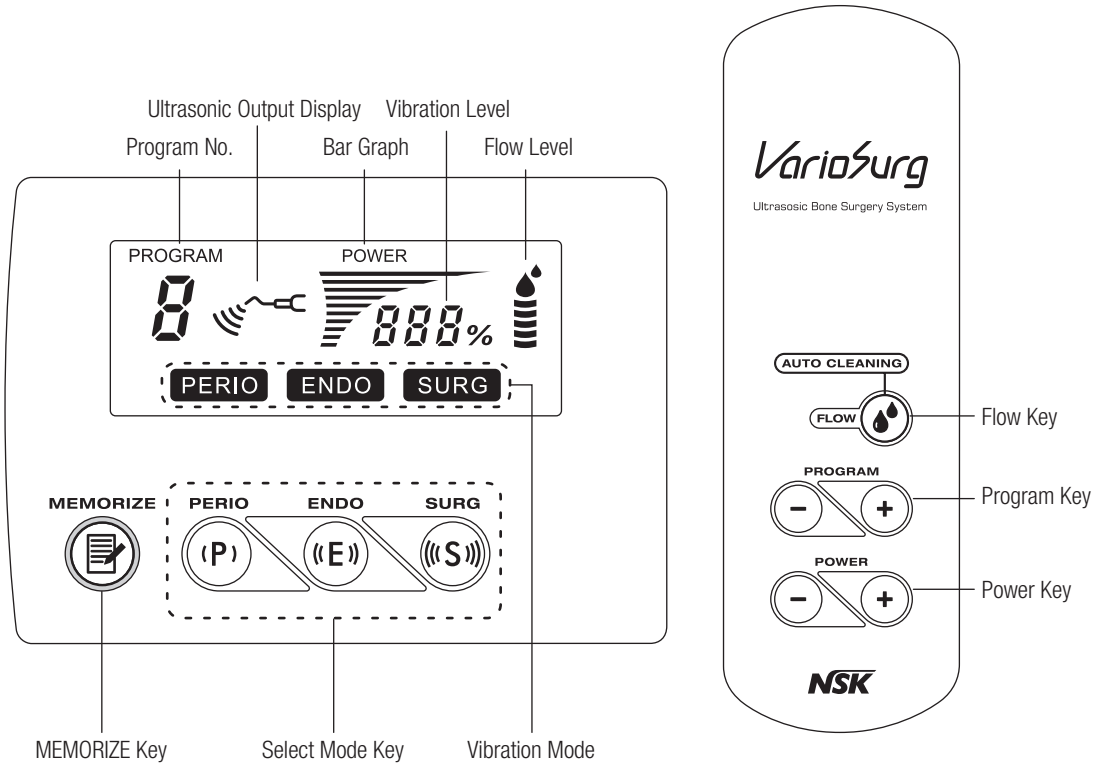
No.	Part Name	Quantity
1	Control Unit with Irrigation Pump	1
2	Foot Control	1
3	AC Power Cord	1
4	Handpiece with Cord (unshielded 2m) (Optic / Non-Optic)	1*
5	Irrigation Tube	5
6	Saline Solution Hanger Post	1
7	Handpiece Stand	1
8	Tube Holder	7
9	Tip Wrench	1
10	Tips	6 (Basic kit)
11	Tips Holder	1
12	Sterilization Cassette	1

* One of these Handpiece with Cord should be packed.

4. Control Unit with an Irrigation Pump



◆ Front Panel and Operation Panel



LCD display

PROGRAM
8

Program No.
Indicates the Program No. selected.

Ultrasonic Output Display
Indicates via animation that ultrasonic waves are being transmitted.

POWER

Bar Graph
Indicates the power level selected on a scale of 10.

888%

Vibration Level
Indicates the power level selected.

Flow Level
Indicates the flow level selected on a scale of 5.

PERIO
ENDO
SURG

Vibration Mode
Indicates the vibration mode selected.

⚠ NOTICE

A program number is given to each of the different modes as shown in the table below. **Only the preprogrammed modes can be selected.**

Program No	Vibration mode		Power range	Flow level (5 levels)
1	SURG	With Burst function *1 10Hz	10-100%, in 10% increments	15~90ml/min*2
2		With Burst function *1 30Hz		
3		With Burst function *1 60Hz		
4		No Burst function *1		
5		No Burst function *1		
6	ENDO		5-50%, in 5% increments 60% and up, in 10% increments	9~38ml/min*2
7				
8	PERIO			
9				

*1 Burst function: Vibration levels can be changed at certain intervals. Levels can be selected depending on patient's bone hardness (density).

*2 Amount of water may vary slightly depending on the condition of the Irrigation Tube.

Select Mode Key

For switching to SURG, ENDO, and PERIO modes. Switching modes will automatically change the program number and power range.

Program Key

For selecting a program number. Press the "+" key to increase the number by one, or the "-" key to decrease by one. The program numbers that can be selected are different depending on the mode selected. Program numbers can't be changed while the Handpiece is in operation.

Power Key

For adjusting power level. Press the "+" key to increase the number by one, or the "-" key to decrease by one. The power range is different depending on the mode selected. This key can be used while the Handpiece is in operation.

Flow Key

For adjusting the flow level. There are 5 flow levels to choose from (see the table above).

■ Auto Cleaning mode

Pressing the Flow Key for 3 seconds will activate the Auto Cleaning mode in which the pump rotates at maximum flow rate for 30 seconds to clean the inside of handpiece. Refer to 8-1 Auto Cleaning for more details.

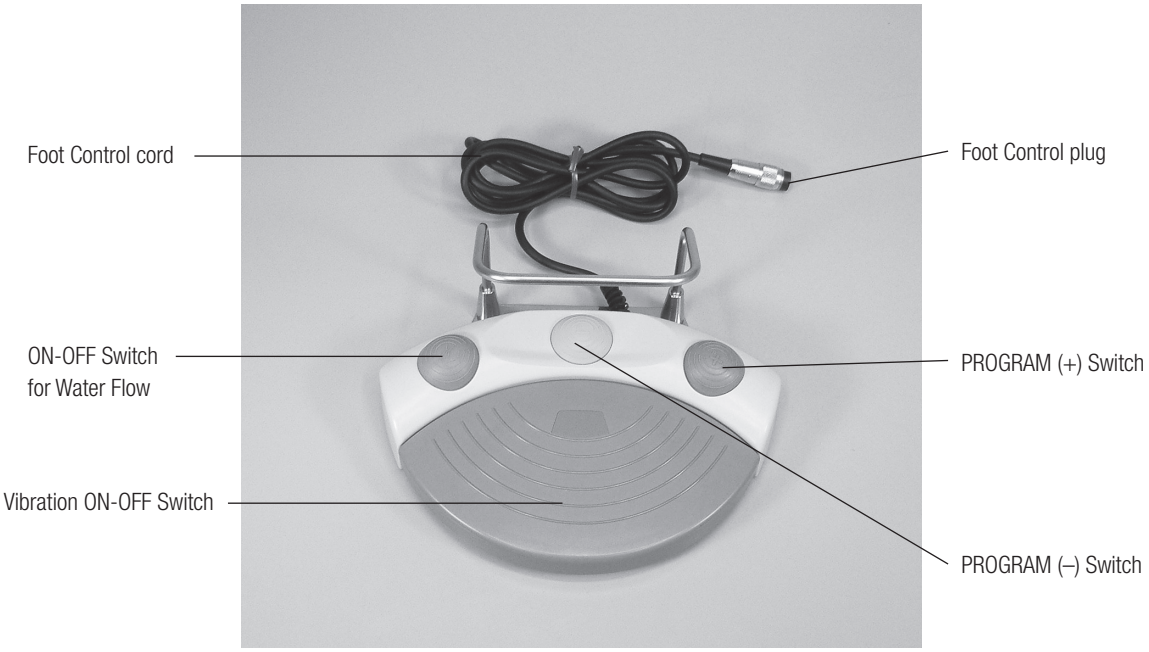
MEMORIZE Key

For saving settings. Press the key for about 1 second, and the current settings will be saved under the program number selected and a beep will let you know memorizing is complete.

⚠ CAUTION

Be careful not to place heavy things on the LCD display of the Operation Panel and avoid any strong impact (e.g. dropping something onto it). This may lead to damage or malfunction.

5. Foot Control



ON-OFF Switch for Water Flow

While you are pressing on that switch, irrigation is delivered at the setting of 5.
LED of handpiece will LIGHT ON without vibrating the Tip (Optic Handpiece).

PROGRAM (+) Switch

Every time you step on the switch, the program number increases by 1.

PROGRAM (–) Switch

Every time you step on the switch, the program number decreases by 1.

Vibration ON-OFF Switch

While you are pressing on the switch, vibration are generated at the setting level displayed on the panel.

⚠ CAUTION

Turning the Main Power Switch ON while stepping on the Vibration ON-OFF Switch will not, for safety's sake, activate the Handpiece, but there will be a warning sound.

6. Installation

6-1 Connecting the Handpiece Cord

Align the ▲ mark on the Handpiece Cord with ▼ mark on the Control Unit; push the Base of Handpiece Cord Plug into the jack until the locking joint 'clicks' into place (Fig. 1).
To disconnect the plug; pull back the Lock Joint, pull further to disconnect the cord.

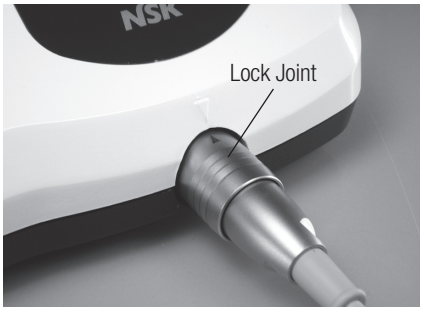


Fig.1

6-2 Connecting the Foot Control

Matching the shapes of the Foot Control Plug and the Foot Control Cord Jack of the control unit, insert the plug into the jack and then tighten the Lock Ring (Fig. 2).

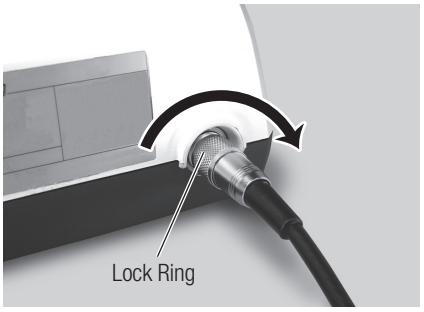


Fig.2

6-3 Connecting the AC Power Cord

Before connecting the AC Power Cord, make sure the Main Power Switch is OFF (on the ○ side).
Matching the shapes of the AC Power Cord and the AC Power Cord Connection Jack on the back of the control unit, insert the cord tightly into the AC Power Cord Connection Jack (Fig. 3).
Then plug the AC Power Cord into the outlet.

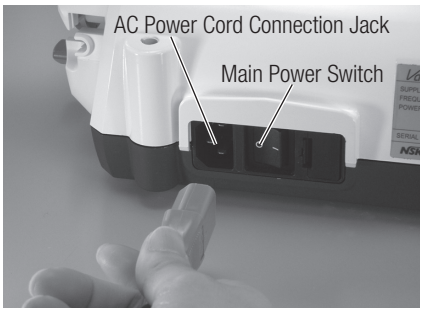


Fig.3

6-4 Mounting the Saline Solution Hanger Post

Insert the Saline Solution Hanger Post into the holder, making sure to fit the guiding pin of the hanger into the slit of the holder (Fig. 4 and 5). The bottle should be hung facing the side of the Control Unit.

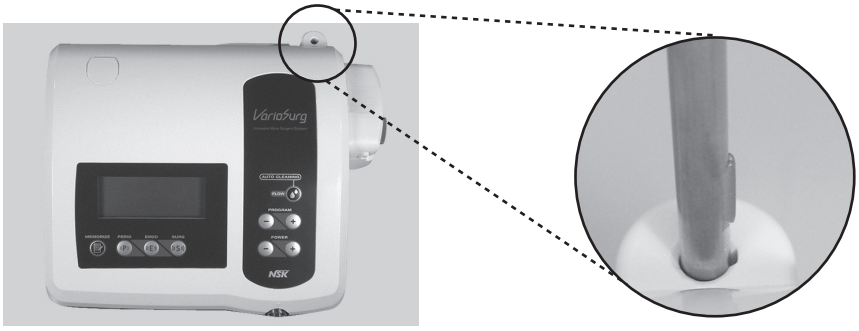


Fig.4 Fig.5

6-5 Mounting the Irrigation Tube

Mount the Irrigation Tube as shown in Fig. 6.

Fig.6

6-5-1 Mounting to the Irrigation Pump

1) Turn the Pump Knob on the side of the Control Unit 180 degrees to the right to open the Pump Cover.
2) Insert the Irrigation Tube (on the bottle side) into the Irrigation Pump, hitching it onto A in Fig. 7.
3) Insert the Irrigation Tube along the guide and fit it into B in Fig. 8.

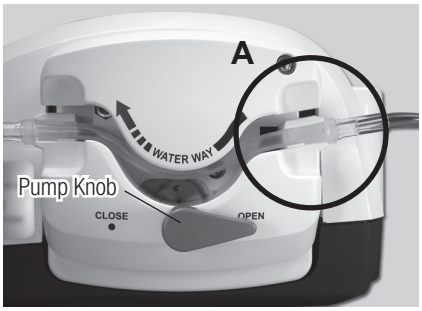


Fig.7

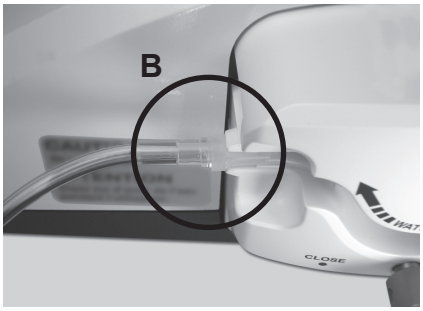


Fig.8

4) Make sure that the tube is inserted well behind the roller as shown in Fig. 9. If not, the tube may be damaged or cut when the Pump Cover is closed.
5) Close the Pump Cover.

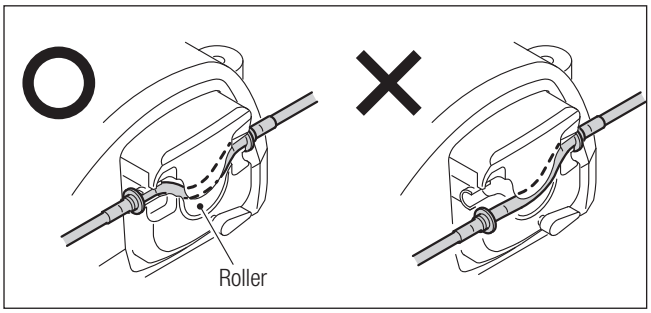
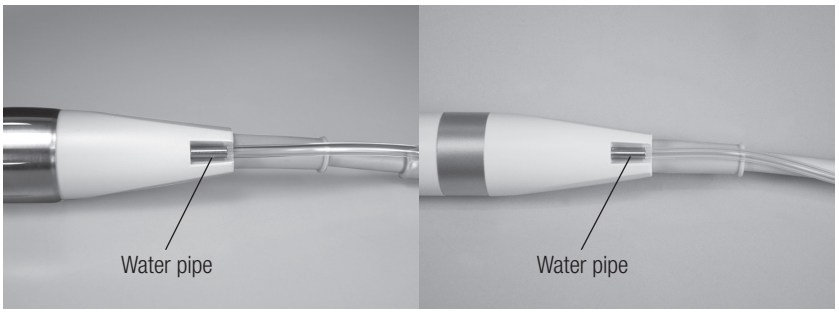


Fig.9

Fig.10

6-5-2 Mounting to the Handpiece

Insert the end of the Irrigation Tube all the way into the Water pipe of the Handpiece (Fig. 11).



Optic handpiece Non-Optic handpiece Fig.11

⚠ CAUTION

Improper connection of the Irrigation Tube can lead to water leakage. Make sure that the Irrigation Tube and Water pipe are connected tightly.

6-5-3 Mounting to the Bottle

1) Close the Tube Clamp located between the Irrigation Tube Needle and the irrigation pump, as illustrated in Fig.12.
2) Hook the bottle to the hanger post and insert the Irrigation Tube Needle into the Bottle Cap.

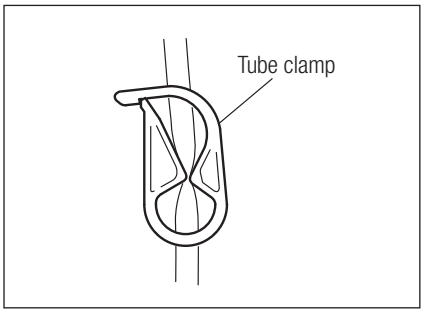


Fig.12

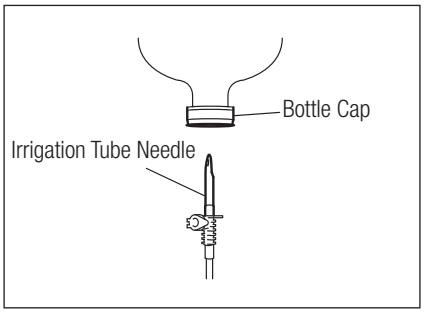


Fig.13

⚠ CAUTION

- Use only 500ml saline solution bottles. Never hang more than 800 grams to the hanger post.
- At any time, insure that there is enough saline solution inside the bottle.

3) Open the Tube Cap to supply air into the bottle.

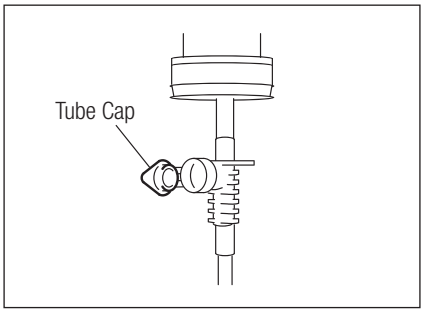


Fig.14

6-6 Attaching the Tube Holder

Use the Tube Holder to bundle together the Handpiece Cord and the Irrigation Tube. It is easier to fasten them onto the Handpiece Cord first and, next, onto the Irrigation Tube.

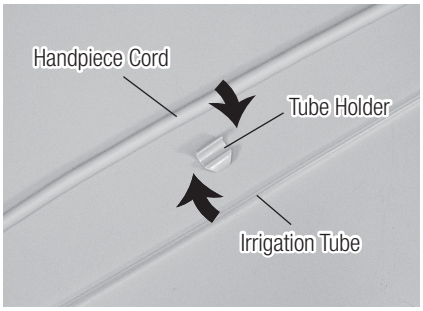


Fig.15

⚠ CAUTION

- Bundle the Handpiece Cord and the Irrigation Tube at a total of 7 locations as shown in Fig. 16.
- The tube may burst or come off the bottle if the Irrigation Pump is activated with the tube bent, the Tube Clamp closed, or the bottle empty.

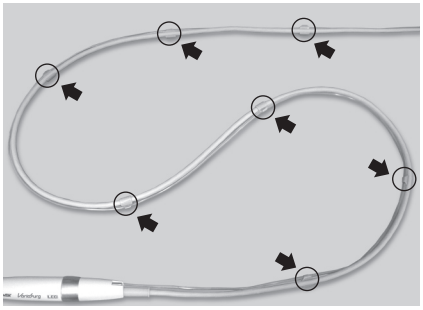


Fig.16

6-7 Handpiece stand

Place the Handpiece horizontally on the Handpiece stand (Fig. 17).

Fig.17

⚠ CAUTION

- Make sure that the Tip does not contact the Handpiece stand (Fig. 18).
- Make sure that the Handpiece is placed on the Handpiece stand horizontally, and not at an angle.
- To clean the Handpiece stand, wipe with a cloth dampened with alcohol.

Fig.18

7. Operation

7-1 Mounting and Removing the Tip

1) First, lightly screw in the Tip with your hands (Fig. 19).
2) Matching the square shapes of the Tip and the hole of the Tip Wrench, insert the Tip into the hole (Fig. 20).
3) Rotate the wrench in the tightening direction, as shown in Fig. 21 and 22, until it makes a clicking sound as it spins without tightening any further.

To remove the Tip, rotate the wrench in the loosening direction shown in Fig. 21 and 22.

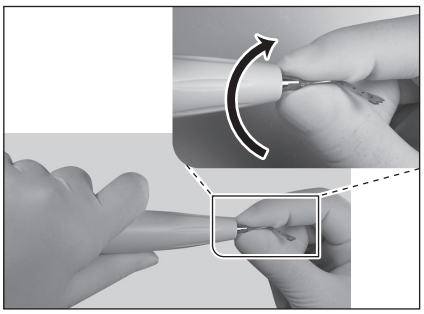


Fig.19

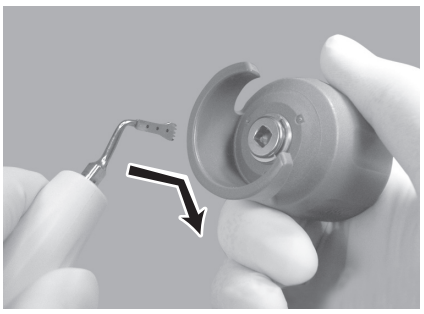


Fig.20

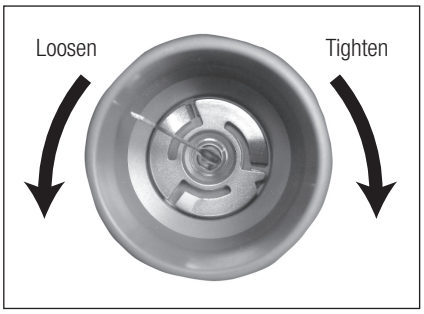


Fig.21

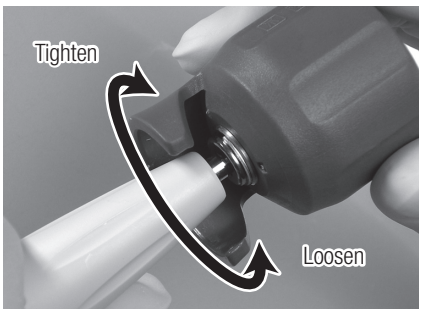


Fig.22

⚠ CAUTION

- Be careful when mounting or removing a Tip that is longer than the Tip Wrench, as the end of the Tip that sticks out of the wrench might cause injury.
- Rotating the wrench at an angle may damage the thread or the Tip so that it cannot be tightened enough to produce vibrations.
- Always mount a sterilized Tip.
- Do not use damaged, bent, or rusty Tips as they might break during use.
- Tips wear down and decrease in cutting power. Change the Tip when its cutting power has decreased.
- Tip Wrench is consumable. For reliable operation replace annually.

7-2 Checking and Setting Up

(1) Checking the Irrigation Tube
Make sure the Irrigation Tube is mounted properly to the bottle, Irrigation Pump, and Handpiece.

(2) Main Power
Turn on the Main Power Switch.

○	I
Power OFF	Power ON

(3) Checking water flow
Open the Tube Clamp that is located between the Irrigation Tube Needle and the Irrigation Pump, press the ON-OFF Switch for Water Flow on the Foot Control, and make sure that saline comes out of the Tip. With a new tube, it usually takes several seconds before saline comes out.

(4) Setting the output

⚠ CAUTION

Set to the Power indicated on the Tip Case. Use Tips within the appropriate Power Range (Fig. 23). The abbreviations for the selection modes mean the following : S: SURG mode, E: ENDO mode, P: PERIO mode

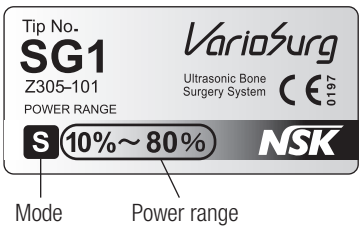


Fig.23

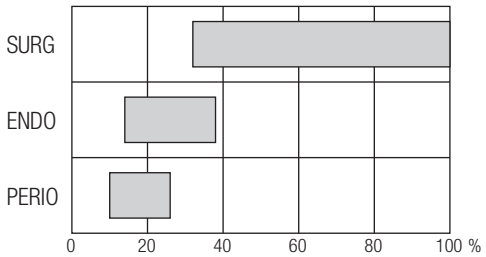


Fig.24

1) Switch modes using the Select Mode key.
2) Select a program number using the Program Key.
3) Adjust power level using the Power Key.
4) Adjust flow level using the Flow Key.

* See Fig. 24 for a comparison of outputs of different modes.

⚠ CAUTION

Always use a Tip within the mode and power range indicated on the label on the Tip Case. Using a Tip outside its power range may lead to Tip breakage or damage to tooth surface, gums, or soft tissue.

7-3 Operation

Operating the Foot Control activates the Tip. Before actually using the Tip inside a patient's mouth, test to make sure it works properly, specifically in terms of the points listed below. If there is any abnormalities, immediately stop using and contact the dealer.

- Make sure the Tip supplies saline properly.
- Make sure the Tip vibrates properly.
- Make sure there is no Tip looseness, abnormal vibrations, noise, or overheating.
- Make sure the Optic Handpiece lamp turns on.

⚠ CAUTION

- After a new saline bottle is installed, always test the Tip before putting it inside patient's mouth to make sure saline comes out of the end of the Tip.
- Taking the patient's condition into consideration, start with a lower power level within the power range.
- Always irrigate with saline when using. Insufficient irrigation might cause the Handpiece to overheat or damage the treatment area and tooth surface.
- Do not apply more pressure than necessary to the end of the Tip.
- If the Irrigation Pump does not work due to some type of malfunction, the Vibration Level displays shows an error code, "E-P" (refer to the Error Code table).

⚠ NOTICE

When the Main Power Switch is turned ON, the settings selected at the time the Main Power was last turned OFF (mode, program No., power level, and flow level) will be retrieved (from the memory function).

8. Maintenance

8-1 Auto Cleaning

After using saline, clean the inside of the Handpiece with distilled water or equivalent.
Remove the Irrigation Tube Needle from the bottle and put it in a container (such as a cup, etc.) of distilled or pure water. Then press the Flow Key for about 3 seconds to start Auto Cleaning.
During Auto Cleaning, a Water Mark ( ) blinks above the Flow Level and the Vibration Level display indicates "CLN." Meanwhile, the Bar Graph indicates remaining time for Auto Cleaning, turning off one bar about every 3 seconds. Auto Cleaning takes about 30 seconds. When it is complete, the LCD display returns to its normal indication.

⚠ CAUTION

- During Auto Cleaning, the Irrigation Pump feeds at full flow rate and the Tip of the Handpiece discharges water that was used for cleaning. Have a glass or other container ready to receive the water.
- Always conduct Auto Cleaning after using saline, otherwise the Handpiece will clog or break.

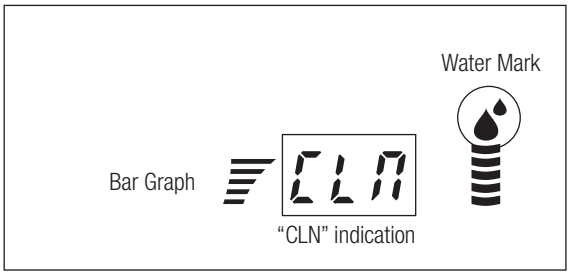


Fig.25

8-2 Sterilization

Autoclave sterilization is recommended.
Autoclave sterilization is required for the first time use and after each patient as noted below.
The following items can be autoclaved.
Handpiece with Handpiece Cord (Optic/Non-Optic), Tip, Tip Wrench, Tips Holder, Handpiece stand, Tube Holder, and Sterilization Cassette.

8-2-1 Handpiece

■ Optic Handpiece

1) Disconnect the Handpiece cord from the Control Unit.
2) Remove the Irrigation Tube from the Handpiece and dispose of it.
3) Brush (do not use a metal brush) dirt off the surface, and then wipe with alcohol soaked cloth.
4) Set the Handpiece with Handpiece Cord in the Sterilization Cassette.

■ Non-Optic Handpiece

1) Turn the Nose Cover counter-clockwise to remove.
2) Brush any contaminants from inside the Nose Area with a soft brush. (Do not use metal brush) Wipe with alcohol soaked cloth (Fig. 26).
3) Replace the Nose Cover onto the Handpiece turn clockwise.
4) Set the Handpiece with Handpiece Cord in the Sterilization Cassette.

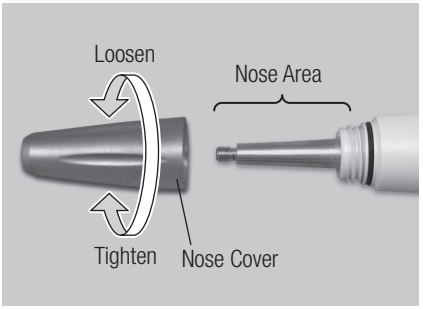


Fig.26

⚠ CAUTION

Only handpiece with cord can be washed via Thermo Disinfector.

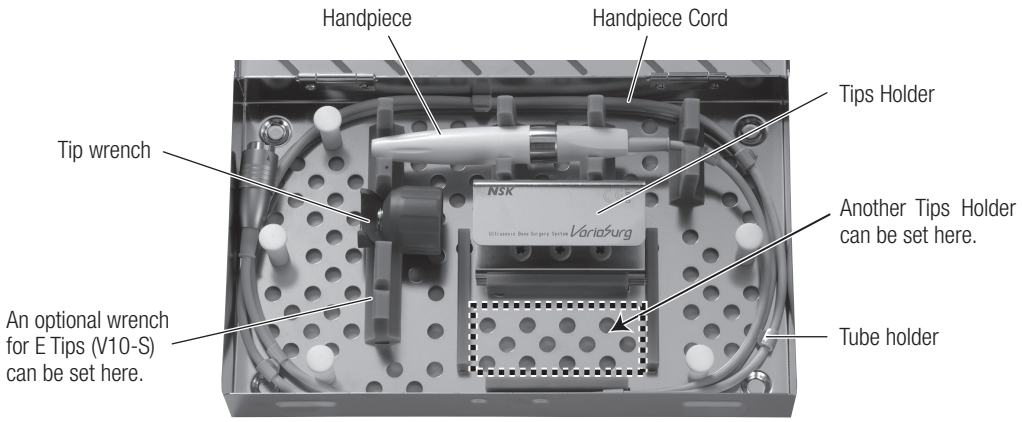
* Confirmed Thermo Disinfector is "Type: G7882" (Miele & Cie)

8-2-2 Tip, Tip Wrench, and Tips Holder

1) Brush (do not use a metal brush) dirt off the surfaces of the Tip, Tip Wrench, and Tips Holder, and then wipe with alcohol soaked cloth.
2) Mount the Tip to the Tips Holder before setting it in the Sterilization Cassette. The case accommodates up to 2 Tips Holders.
3) Set the Tip Wrench in the Sterilization Cassette.

⚠ CAUTION

Use rubbing alcohol only.



* A Sterilization Cassette with a Handpiece and other items set in it.

⚠ CAUTION

Do not mount a maintenance Tip (V10-S or V-P10) to the Tips Holder as the holder lid cannot be fully closed. Use a autoclaving pouch for autoclave sterilizing of maintenance Tips.

8-2-3 Autoclave

Autoclave up to max. 135˚C.
Autoclave for 20 min. at 121˚C, or 15 min. at 132˚C.
Keep the sterilization cassette to keep it clean until you use it.
* Sterilization at 121 ºC for more than 15 minutes is recommended by EN13060 or EN ISO17665-1.

⚠ CAUTION

- Do not autoclave the Control Unit and the Foot Control.
- Never sterilize the Handpiece, etc., with ultraviolet radiation, which might cause discoloration.
- If you autoclave the Handpiece together with any instrument to which antiseptic solution adheres, discoloration might occur.
- If any saline solution or stain adheres to the Control Unit, well wipe it off with a cloth impregnated with clean water and squeezed out. Then, wipe the Control Unit well with a dry cloth.
- Do not clean the Control Unit with any solvent such as thinner, benzene, etc.
- We do not recommend you to sterilize on plasma sterilization or EOG sterilization.

8-2-4 Cleaning of Optic Fiber (Optic Handpiece)

Wipe the debris off the end of the Optic Fibers at the Handpiece with alcohol soaked cotton swab (Fig. 27).

⚠ CAUTION

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

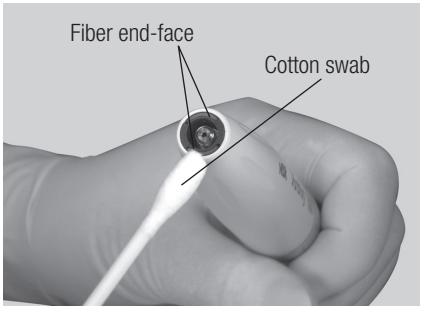


Fig.27

10. Troubleshooting

When you suspect a failure, refer to the following before requesting a repair. If your problem does not fall into any of the following, or troubleshooting as suggested does not improve the problem, contact dealer as it is likely that the product is faulty.

Case	Possible Cause	Remedy
Control Unit cannot be turned ON (LCD display does not turn on).	AC Power Cord is not connected to Control Unit.	Make sure it is connected.
	AC Power Cord is not plugged into wall outlet.	Make sure it is plugged in.
	Fuse has blown.	Contact dealer. *

Case	Possible Cause	Remedy
Control Unit turns ON but displays Ultrasonic Output Display and beeps. 	Foot Control is being operated.	To prevent accidents, the Handpiece will not work if the Main Power is turned ON while the Foot Control is being operated. Try stepping on the Foot Control again.
The Tip does not vibrate (no indication of Ultrasonic Output Display).	Foot Control is not connected.	Make sure it is connected.
	Handpiece with Handpiece Cord are not connected, or Handpiece Cord is not connected to Control Unit.	Make sure they are connected.
The Tip does not vibrate (indication of Ultrasonic Output Display).	Faulty circuit.	Contact dealer. *
Weak vibrations.	Worn or broken the Tip.	Replace with a new Tip.
	Wrong mode.	Change to the correct mode.
	The Tip not tightened sufficiently.	Tighten the Tip until the Tip Wrench clicks.
	Improper power setting.	Change to the correct mode and power range as indicated on the Tip case.
	Foot Control not connected properly.	Connect Foot Control properly.
	Failure inside the Handpiece.	Contact dealer. *
	Failure inside the Foot Control.	Contact dealer. *
The Tip breaks easily.	Power Level is not right for the Tip mounted.	Change to the correct mode and power level as indicated on the Tip case.
The Tip comes off.	The Tip is not tightened sufficiently	Tighten the Tip until the Tip Wrench clicks.
Handpiece makes a loud noise.	Power Level is not right for the Tip mounted.	Change to the mode and power level indicated on the Tip case.
	Tip is not tightened sufficiently.	Tighten the Tip until the Tip Wrench clicks.
	Failure inside the Handpiece or the Control Unit.	Contact dealer. *
Handpiece gets hot.	Power Level is not right for the Tip mounted.	Change to the mode and power level indicated on the Tip case.
	Tip is not tightened sufficiently.	Tighten the Tip until the Tip Wrench clicks.
	Failure inside the Handpiece or the Control Unit.	Contact dealer.*
	Foreign substance is clogging Handpiece and blocking saline.	Place air syringe against Water Pipe and blow air through it. If this does not clear it, contact dealer.
	Saline is not supplied.	Make sure bottle still has saline in it and Irrigation Tube has no cracks.
Saline does not come out as spray.	It depends on the combination of flow level, power level, and Tip shape.	With some flow levels and Tip shapes, it is more difficult to form a spray. This is not a malfunction.

Case	Possible Cause	Remedy
Water does not come out, or flow level is low.	Foot Control is not connected.	Make sure it is connected.
	Irrigation Tube is not connected to bottle or Handpiece.	Make sure they are connected.
	Irrigation Tube is not properly mounted to the pump.	Make sure it is mounted properly (Refer to 6-5-1 Mounting to the Irrigation Pump).
	The Pump Cover is open.	Close the cover.
	The Irrigation Tube is broken (leaking).	Replace the Irrigation Tube (Refer to 6-5 Mounting the Irrigation Tube).
Water leak.	Leak from the connection between bottle and Irrigation Tube.	Insert Irrigation Tube Needle all the way into the bottle (Refer to 6-5-3 Mounting to the Bottle).
	Leak from the connection between Handpiece and Irrigation Tube.	Insert end of Irrigation Tube all the way into the Handpiece water pipe (Refer to 6-5-2 Mounting to the Handpiece).
	Leak from Irrigation Tube.	Replace the Irrigation Tube (Refer to 6-5 Mounting the Irrigation Tube).
Irrigation doesn't stop.	Mode is set to Auto Cleaning.	To stop irrigation, press the Flow Key.
	ON-OFF Switch for Water Flow on Foot Control is being operated.	Remove foot from the Foot Control.
	Faulty circuit.	Contact dealer.*
Handpiece LED does not illuminate. (optic Handpiece)	LED is burned out.	Contact dealer.*
	Failure inside the Control Unit or inside the Handpiece Cord.	Contact dealer.*
	Failure or disconnection of the circuit.	Contact dealer.*
LCD display does not properly display. Part of display is missing.	Overheating.	Heat can cause LCD display malfunction. Turn the Main Power OFF to cool down.
	Error Code is displayed.	Refer to the Error Code table.
	Failure of the LCD display or driving circuit.	Turn the Main Power OFF and then back ON. If part of initial display is still missing, contact dealer.
Settings are not memorized. Wrong settings are memorized.	Figures have been temporarily changed.	Increase or decrease the Program No. by one, and then return.
	Foot control is being operated.	Settings cannot be saved while Handpiece is operating.
	An Error Code is displayed.	Refer to the Error Code table.

* Repairs cannot be made by the customer.

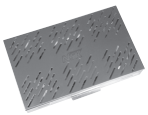
◆ Error Codes

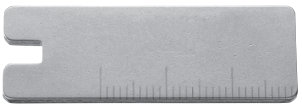
The LCD display shows an Error Code when vibration stops due to malfunction, overload, disconnection, human error, etc. These codes should be used to understand the condition of the control unit and the cause of abnormality.

Error code	Cause of error	Check / Remedy
E-0	Faulty circuit.	Contact dealer.*
E-2	The end of the Tip is under too much pressure, or stuck .	Step on the Vibration ON-OFF Switch on the Foot Control and slowly pull the Tip out as it vibrates. Be careful not to apply too much pressure to the end of the Tip.
	Tip is not tightened sufficiently.	Tighten the Tip until the Tip Wrench clicks.
	No Tip is mounted.	Mount the Tip.
	Cord disconnection, or a disconnection inside Handpiece.	Use a backup Handpiece, or contact dealer.
E-4	Control Unit overheats due to long use under large load.	Turn the Main Power OFF to cool down before using again. If this happens often under normal use, contact dealer.
E-F	Foot Control disconnection.	Replace the Foot Control or contact dealer.
E-P	Irrigation Tube is caught in pump roller. Faulty pump.	Check the Irrigation Tube. If Irrigation Tube is in normal condition and Error Code is still displayed, contact dealer.

* Repairs cannot be made by the customer.

11. Optional Accessories

Product Name	Items pictures	Order Code
Handpiece with cord (Optic)		E1084
Handpiece with cord (Non-Optic)		E377
Set of 5 Irrigation Tubings		Y900113
Set of 7 Tubing holders		Y900767
Sterilization Cassette		20001326

Product Name	Items pictures	Order Code
Tips Holder		20001327
Tip Wrench		10000977
E Tip Replacement Wrench For V10-S		Z217399

12. Disposing Product

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

13. Warranty

- The manufacturer will warrant the quality of the product for one year after you purchased it, provided that you use it in accordance with the method and procedures described in this operation manual.
- Note, however, that if you did not observe what is written in this operation manual or for any single use goods, the warranty will not apply.

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.

The product is designed not to become the ignition source in air and flammable anesthetic gas.
*Only Foot Control is AP equipment.

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

Protected against the effects of continuous immersion in dust and water.

Dispose of this device and its accessories via methods approved for electronic device and in compliance with the Directive 2002/96/CE.

Type BF applied part.

Follow Operation Manual for use.

Manufacturer

Authorised representative in the European community.

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

This product can be cleaned and disinfected with a Thermo-Disinfector.

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 VarioSurg is intended for use in the electromagnetic environment specified below. The customer or the user of the VarioSurg should assure that is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions ClSPR11/EN55011	Group 1	The VarioSurg 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 ClSPR11/EN55011	class B	The VarioSurg is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: VarioSurg is intended for use by healthcare professionals only. VarioSurg may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as re-orienting or relocating the VarioSurg or shielding the location.
Harmonic emissions EN/IEC61000-3-2	class A	
Voltage fluctuations/ flicker emissions EN/IEC61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The VarioSurg is intended for use in the electromagnetic environment specified below. The customer or the user of the VarioSurg should assure that it is used in such an environment.			
Immunity test	**EN/IEC60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) EN/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 EN/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 EN/IEC61000-4-5	±1kV line to line ±2kV lines to earth	±1kV line to line ±2kV lines 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 EN/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 sec	<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 VarioSurg requires continued operation during power mains interruptions, it is recommended that the VarioSurg be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field EN/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 VarioSurg is intended for use in the electromagnetic environment specified below. The customer or the user of the VarioSurg should assure that it is used in such an environment.			
Immunity test	**EN/IEC60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF EN/IEC61000-4-6	3Vrms150 kHz to 80MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the VarioSurg, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF EN/IEC61000-4-3	3V/m80MHz to 2.5 GHz	3 V/m	**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: 
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 VarioSurg is used exceeds the applicable RF compliance level above, the VarioSurg should be observed to verity normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the VarioSurg. b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the VarioSurg

The VarioSurg is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the VarioSurg can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the VarioSurg 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.

Cables and accessories	Maximum length	Complies with	
Handpiece cord	2m	RF emissions, CISPR11, EN55011	Class B/ Group 1
Foot Controller	2m	Harmonic emissions,	EN/IEC61000-3-2
		Voltage fluctuations/ flicker emission,	EN/IEC61000-3-3
		Electrostatic discharge(ESD),	EN/IEC61000-4-2
		Electric fast transient / burst	EN/IEC61000-4-4
		Surge	EN/IEC61000-4-5
		Voltage dips, short interruptions and voltage variations on power supply input lines	EN/IEC61000-4-11
		Power frequency(50/60Hz) magnetic field	EN/IEC61000-4-8
		Conducted RF	EN/IEC61000-4-6
		Radiated RF	EN/IEC61000-4-3