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NSK

Ultrasonic Bone Surgery System

VarioSurg3



OPERATION MANUAL

CE 0197 MADE IN JAPAN

OM-E0636E

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English

Thank you for purchasing the VarioSurg 3.
Please read this Operation Manual carefully before use to become familiar with operation instructions and care & maintenance. Keep this Operation Manual for future reference.

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1 User and Intended Use

User: Qualified Professionals
Intended use: Dentistry and oral surgery (implant site preparation, bone cutting, maxillary sinus floor (mucus membrane) elevation, osteoplasty, bone resection in radectomy, periodontal operation, prosthesis maintenance, surgical endodontic procedure

2 Precautions for handling and operation

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

Class	Degree of Risk
⚠ WARNING	A hazard that could result in serious injury or damage to the device if the safety instructions are not followed.
⚠ CAUTION	A hazard that could result in light or moderate injury or damage to the device if the safety instructions are not followed.
NOTICE	General product specification information highlighted to avoid product malfunction and performance reduction.

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⚠WARNING

- Do not handle the power cord with wet hands. Wet hand contact with electricity may result in an electric shock.
- Keep away from explosive substances and flammable materials.
- If the product overheats or smells of burning, immediately turn off the power and disconnect the main power plug. Contact your Authorised NSK Dealer.
- TO PREVENT ELECTRIC SHOCK, use a main electrical outlet that is protective earthed.
- Do not use on the following patients.
  - -Those with medical complications or allergies
  - -Those who have pre existing conditions
    (Eg Cardiac, Pulmonary, Renal disturbance or High blood pressure)
  - -Those who are pregnant or lactating
  - -Patients with cardiac pacemakers and infants
- Be careful not to get water or liquid disinfectant on the control unit. This could cause short circuits and lead to fire and/or electric shock.
- Repeatedly turning the Main Power Switch ON and OFF may blow a fuse.
- When installing the product, provide space of approximately 10cm around the product for easy access to the inlet and the Power Cord.
- The Irrigation Tubes, included in the product package, are sterile. When using these products, follow the instructions below.
  - The irrigation tube is a single-use item. Do not reuse nor sterillize as product breakage or infection could occur.
  - Check before use that the sterile package is NOT open nor damaged. Do not use products with open or damaged packages as sterility will be negated and infection could occur.
  - Observe the use-by date written on the sterile package label. Do not use expired products as sterility may be negated.
- Do not point the handpiece LED light directly to the eyes of the patient, nor the operator, as it may be harmful to eyes.

⚠CAUTION

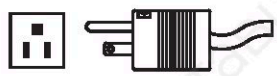
- To be confident in using this product, please read this Operation Manual before use. We suggest that to fully understand the product functions and file for future reference.
- When operating the product always consider the safety of the patient.
- The end user shall be responsible for any judgment that relates to the application of this product to a 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.
- Users are responsible for the operational control, maintenance and continual inspection of this product.
- This device is for indoor use only.
- Keep the Control Unit on a level surface.
- Do not attempt to disassemble the product or tamper with the mechanism except as recommend by NSK in this Operation Manual.
- Do not allow any impact on to the handpiece. Do not drop the handpiece.
- Operators and all others in the area must wear eye protection and a mask when operating this handpiece.
- Should the product function abnormally, cease operation immediately and contact your Authorized NSK Dealer.
- If the Irrigation Pump gets wet, wipe it dry. If it remains wet, the roller in the pump may slip and the pump may not operate properly.
- Do not bend or fold the Irrigation Tube while the Irrigation Pump is operating as the Tube may be damaged or may detach.
- If abnormality is detected in irrigation, it may be due to wear of the Irrigation Tube or leaking of saline from the Tube. In such cases, replace the Irrigation Tube.
- Do not use high acid water or sterilizing solutions to wipe, immerse or clean the product.
- The following products are delivered in a non-sterile condition and must be autoclaved prior to use. (Handpiece, Tip, Tip Wrench, Tip Holder, Tube Holder)
- Perform regular function and maintenance checks.
- If the product is not used for a long period check it is functioning correctly before using on a patient.
- To avoid clinical downtime it is recommended that a spare be kept on hand in case of a breakdown during surgery.
- This product may be affected by an electric scalpel. Turn OFF the Power Switch when an electric scalpel is used.

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- This product is rated Medical Electrical equipment. EMC (Electromagnetic compatibility) is described in the documentation included.
- Installation and use of this product requires special precautions regarding EMC according to the EMC information.
- Portable and mobile RF communications equipment can affect Medical Electrical equipment. Do not use RF equipment near the product.
- The use of ACCESSORIES such as handpieces and cables, other than those specified by the manufacturer, with the exception of handpieces 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.
- Do not place this product adjacent to, or on top of, another device. This product and NSK Surgic Pro can however be stacked for use with the NSK Link connection.
- The system may present a possibility of malfunction when used in the presence of an electromagnetic interference wave. Do not install the system in the vicinity of any device which emits magnetic waves. Turn OFF the Main Power Switch of the system an ultrasonic oscillation device or an electrode knife is located close to the vicinity of use.
- The handpiece may get hot when some types of tips are used at high power level or in an overloaded state. (The temperature of the handpiece surface might exceed 41˚C.) If such abnormality is found, stop using for about 5 minutes to allow the handpiece to cool.
- For added safety install the Control Unit in a place where the AC POWER Cord can be easily removed. (It is possible to disconnect the control unit from the power source by removing the AC POWER Cord.)
- Grounding reliability can only be achieved when the equipment is connected to an equipment receptacle marked "Hospital Only" or "Hospital Grade".
- U.S. Federal law restricts this device to sale by or on the order of a licensed physician.

Power plug below is used in North America area.



Plug Type NEMA 5-15P (Hospital Grade Type)

NOTICE

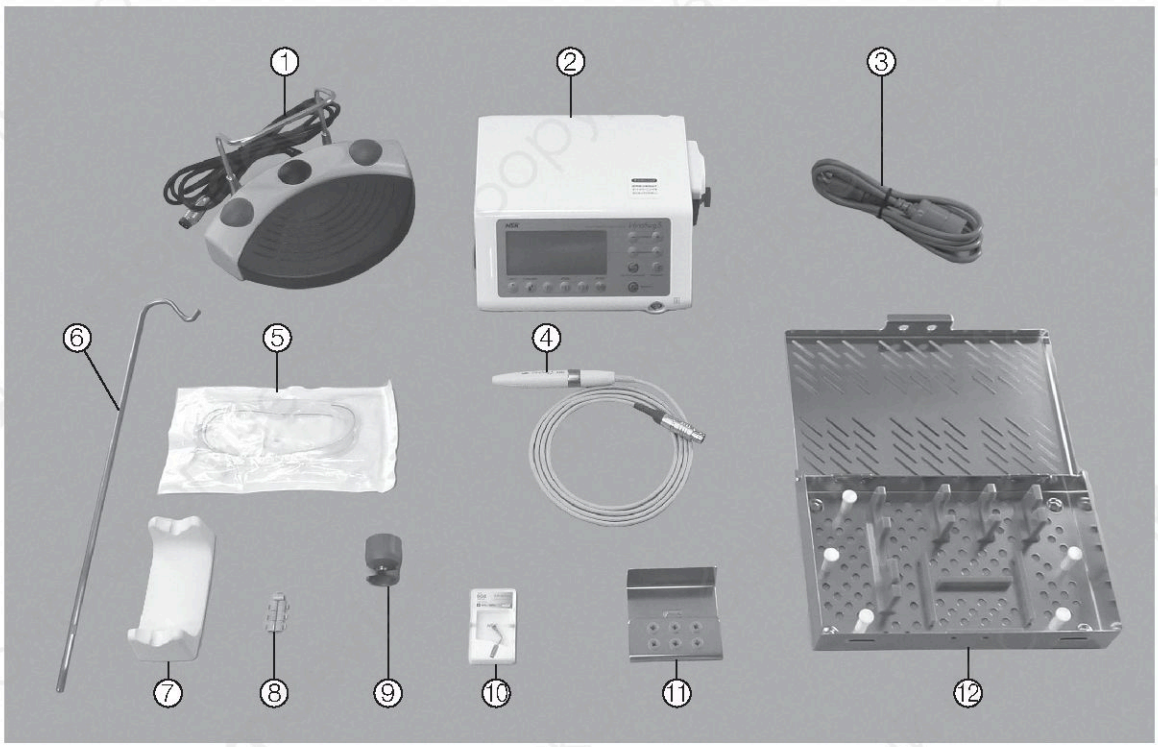
- No special training is required for this device.
- The handpiece or handpiece cord during operation could interfere with computers, LAN cables in close vicinity, or could cause noise in radio receivers nearby.

*Emission: Unnecessary energy generated by the device.
*Immunity: Tolerance to unnecessary energy received by the device.

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3 Package Contents



No.	Part Name	Quantity
1	Foot Control	1
2	Control Unit	1
3	AC Power Cord	1
4	LED handpiece with cord (Unshielded 2m)	1
5	Irrigation Tube	5
6	Irrigation Pole	1
7	Handpiece stand	1
8	Tube Holder	7
9	Tip Wrench	1
10	Tip	6
11	Tip Holder	1
12	Sterilization Cassette	1

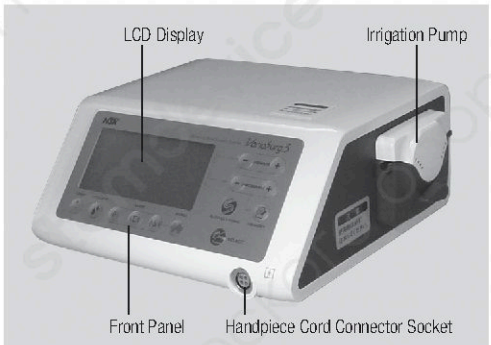
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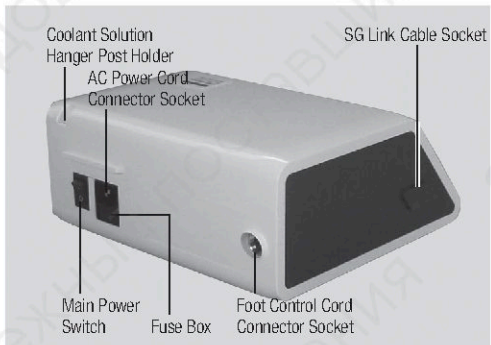
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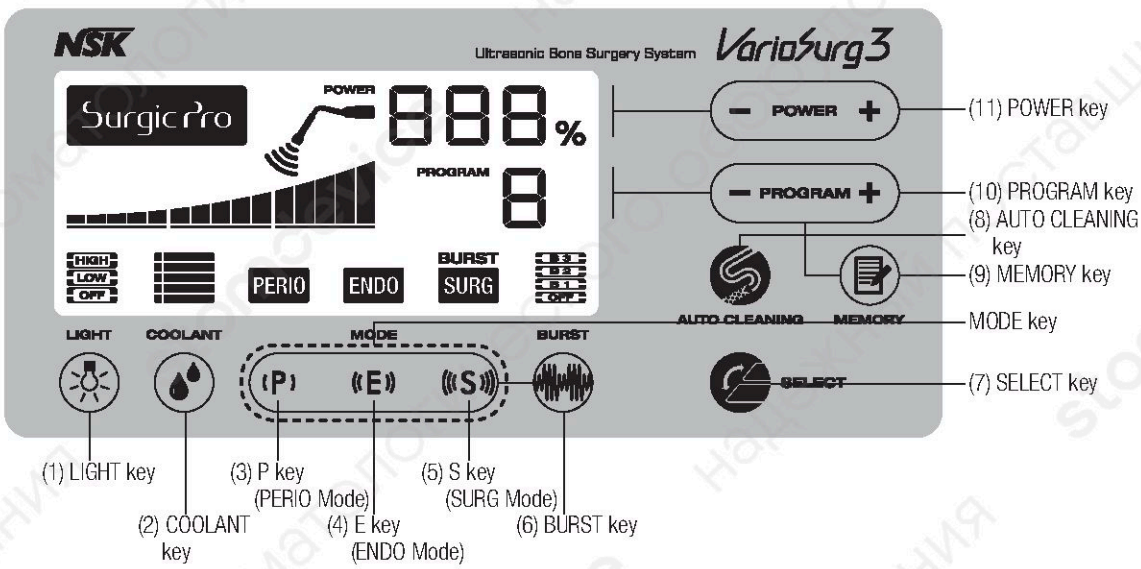
4 Component Names

4-1 Control Unit





Operation Panel



4-1-1 Keys on the Operation Panel

(1) LIGHT key
To select the Handpiece illumination intensity: OFF / LOW / HIGH
(Default setting : HIGH)

(2) COOLANT key
To select the Coolant Flow from 5 levels.

(3) P key
To set the PERIO Mode (the mode suitable for maintenance, etc.).

(4) E key
To set the ENDO Mode (the mode suitable for the root canal treatment).

(5) S key
To set the SURG Mode (the mode suitable for cutting bones).

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(6) BURST key

To set the Burst Output Level (only for the SURG Mode)

Each time the key is pressed, the setting changes as follows: OFF⇒B1⇒B2⇒B3⇒OFF.

*Burst function: Increases and decreases vibration at regular intervals. Select an appropriate setting according to the hardness of the patients' bones (bone density).

*Frequencies for Burst are B1: 10Hz, B2: 30Hz and B3: 60Hz.

(7) SELECT key

This key is used when two systems (NSK VarioSurg 3 and NSK Surgic Pro) are operated by a single Foot Control.

*Surgic Pro (sold separately) and the Link Set (sold separately) are required in order to use this key.

(8) AUTO CLEANING key

For cleaning the irrigation circuit in the Handpiece and tube.

(9) MEMORY key

To set the program memory for the values which are displayed in the Panel.

(10) PROGRAM key (- +)

For calling up the set values memorized in the program.

(11) POWER key (- +)

For setting the Power Level.

By pressing (+) and (-) keys, the set value increases and decreases respectively.

*When the key is held down, the value increases or decreases continuously. However, when (+) key is held down, the value stops at 100% for the sake of safety. If you want to further increase the value, press the key again.

NOTICE • Program numbers are allocated to each Mode as shown in the following table. Each program number can be set only for the allocated Mode.

Program No.	Mode	Burst function*1	Power range	Coolant flow (5 levels)	Lighting brightness
1	SURG	Available (Off, B1: 10Hz, B2: 30Hz, B3: 60Hz)	10 – 150% In multiples of 10%	17 - 95 ml/min*2	OFF/LOW/HIGH
2					
3					
4					
5					
6	ENDO	Not available	5 – 100% Below 50%, multiples of 5%. 50% and larger, multiples of 10%.	3 - 55 ml/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).

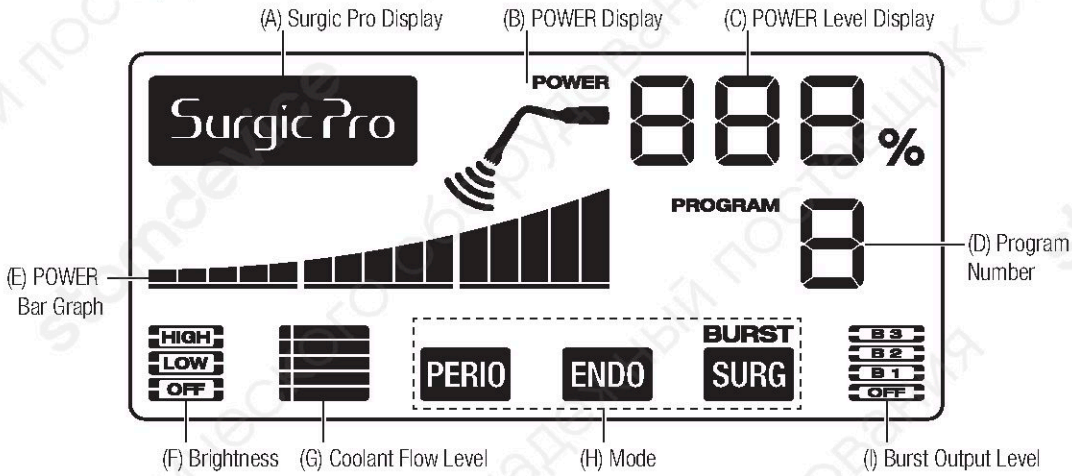
*2 The amount of water flow may vary slightly depending on the condition of the Irrigation Tube.

- While the Handpiece is vibrating, the following keys cannot be operated.
  - (3) P key
  - (4) E key
  - (5) S key
  - (7) SELECT key
  - (8) AUTO CLEANING key
  - (9) MEMORY key
  - (10) PROGRAM key (- +)

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4-1-2 LCD Display on the Operation Panel



(A) Surgic Pro Display
This is displayed only when the this VarioSurg 3 is connected to NSK Surgic Pro via the NSK Link Set and Surgic Pro has been selected by SELECT key.
*For the Link function, refer to "8-3 Link function with Surgic Pro".

(B) POWER Display
Displays when vibration is active from the Handpiece.

(C) POWER Level Display
Displays the set Power Level (5 – 150%).

(D) Program Number
Displays the selected program number.

(E) POWER Bar Graph
The relevant POWER level is indicated by the number of indicator bars illuminated.
Each lower horizontal bar represents 50 %.
Each upper vertical bar represents 10%. The maximum number of bars is 15.
In Auto Cleaning mode, the countdown of the remaining time is displayed.

(F) Brightness
Displays the selected illumination intensity.

(G) Coolant Flow Level
The selected Coolant Flow is displayed on a scale of 1 - 5 (1 is the least flow).

(H) Mode
Displays the selected Mode.

(I) Burst Output Level
Displays the Burst Output setting. Displays only in SURG Mode.

NOTICE • When the transparent protective sheet on the Operation Panel is peeled off or when an object charged with static electricity is placed near the LCD Display, fine lines may appear in the display area. This is normal and the lines will disappear after a short time.

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4-2 Foot Control



(a) Ultrasonic ON-OFF Button
To activate Tip Piezo vibration depress this control.

(b) Coolant Flow Level Selection Button
The Coolant Flow can be selected from 5 levels. Each time the button is depressed the flow will increase by 1 level. If the button is depressed when the Flow is in the level 5 it returns to level 1. (Level 0 cannot be selected for the Coolant Flow.)

(c) Program Selection Button
A specific Program Number can be selected.
Each time the button is depressed the Program Number increases by one. When the button is held down for approximately 1 second the program returns to the previous number.

(d) Burst Output Mode Selection Button
Burst Output Mode setting can be selected.

5 Installation

5-1 Connection of the LED handpiece & cord

1) Position the Handpiece Cord so that the ● mark is facing up and is aligned with the ● mark on the Control Unit. Firmly push the Cord Coupling into the Handpiece Cord Socket until it clicks.
2) Confirm that the Cord Coupling is properly locked in position by pulling it gently.

To disconnect the Coupling pull back the Lock Joint then pull back further to disconnect the cord.

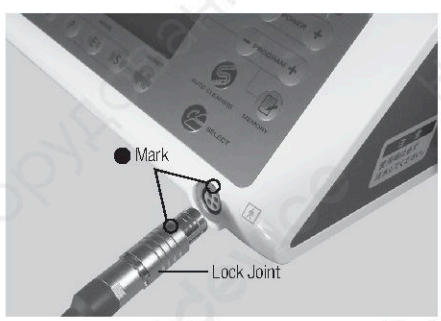


Fig. 1

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5-2 Connection of the Foot Control

1) Turn the Foot Control Cord Plug so that the screw faces down. Insert the Plug so that it correctly fits into the Foot Control Connector Socket of the Control Unit.
2) Secure the lock nut of the Foot Control Cord Plug.

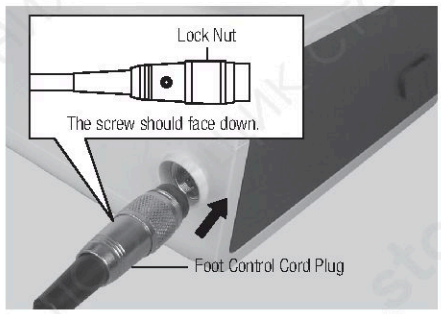


Fig. 2

5-3 Connection of the AC power cord

1) Turn the Power Switch OFF. (O side)
2) Insert the AC Power Cord so that it correctly fits into the AC Power Cord Connector Socket at the back of the Control Unit.
3) Plug the AC power cord into a wall outlet specified for medical use.

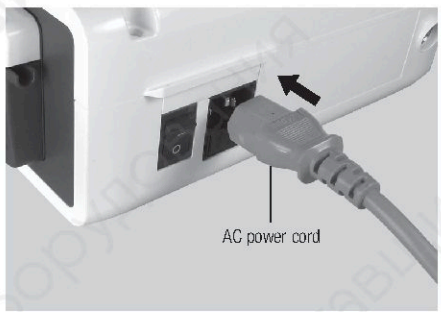


Fig. 3

⚠ CAUTION
- Do not tug the AC power cord by holding and pulling its cord.
- Make sure that the device has completely stopped before removing or inserting the AC power cord.

5-4 Connection of the Irrigation Tube

1) Turn the Pump Cover lever for the Irrigation Pump, located at the side of the Control Unit, clockwise by 180 degrees to open the Pump Cover.
2) After checking the irrigation direction, insert the tube into the Irrigation Pump.
3) Align the Tube Clamps of the Irrigation Tube with the tube guides and set the Tube.
4) Turn the Pump Cover Lever anticlockwise by 180 degrees to close the Pump Cover.

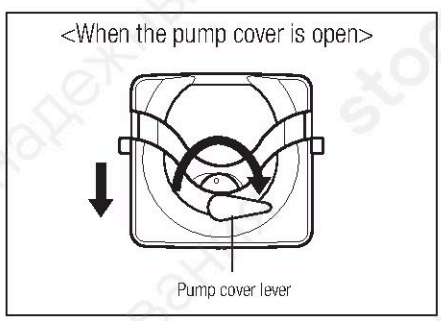


Fig. 4

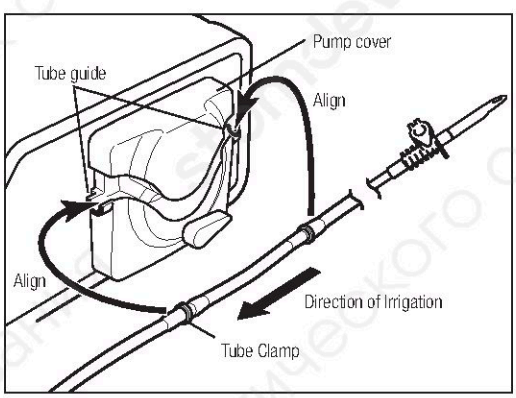


Fig. 5

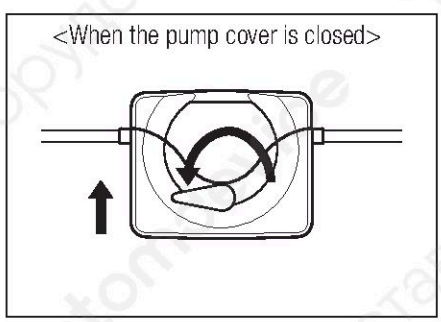


Fig. 6

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CAUTION

- Before closing the Pump Cover, make that the tube is correctly positioned on the rollers. If the tube is not correctly positioned, and the Cover is closed, the tube could be crimped or sheared.
- Before fitting the Irrigation Tube, make sure the Irrigation Pump is stopped.

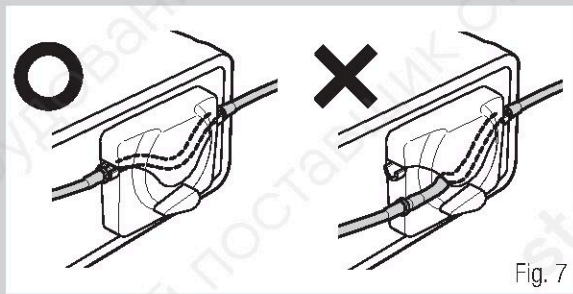


Fig. 7

5-5 Connection of the Coolant Solution Hanger Post

Align the Coolant Solution Hanger Post onto the Control Unit holder and firmly push it down.

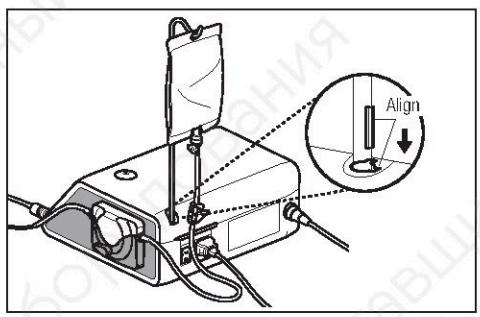


Fig. 8

CAUTION

- Insert the Coolant Solution Hanger Post all the way down firmly. If the Post guide and the groove guide are not aligned, the Post cannot be inserted all the way down.
- Use a 500ml pack of solution. Maximum pack size is 800g for the Coolant Solution Hanger Post.

5-6 Insertion of the Irrigation Tube

1) Close the Tube Clamp which is placed between the Irrigation Needle and the Irrigation Pump. (Fig. 9)
2) Hang the Solution Pack onto the Coolant Solution Hanger Post.
3) Insert the Irrigation Needle into the Pack entry point. (Fig. 10)
4) Insert the other Irrigation Tube tip into the handpiece Irrigation Nozzle. (Fig. 11)
5) Open the cap to let air into the Pack. (Fig. 12)
6) Open the Tube Clamp.

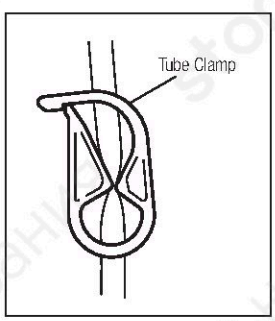


Fig. 9

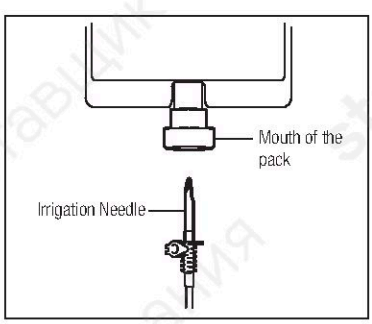


Fig. 10

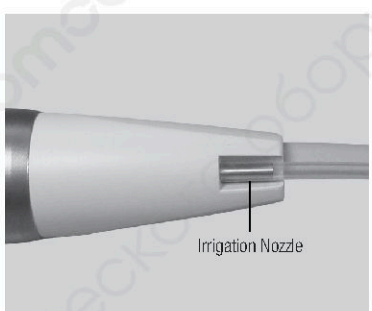


Fig. 11

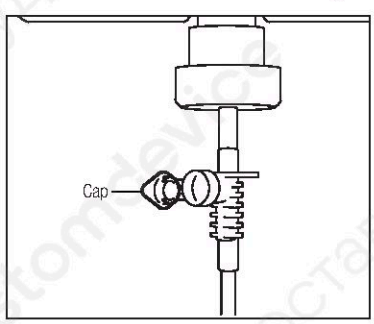


Fig. 12

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CAUTION

- Always use a Pack with a sufficient quantity of saline.
- Before opening the Tube Clamp, always close the Pump Cover. If the Tube Clamp is opened while the Pump Cover is open, saline will flow out of the Irrigation Tube Tip.
- When the coolant solution runs short, stop using the system and replace the Coolant Solution Pack.
- Be sure to check that the coolant solution is flowing properly before using the system again.

5-7 Connection of the Tube Holder

Push the Tube Holder on to the Handpiece Cord, then push the Irrigation Tube into the Tube Holder.

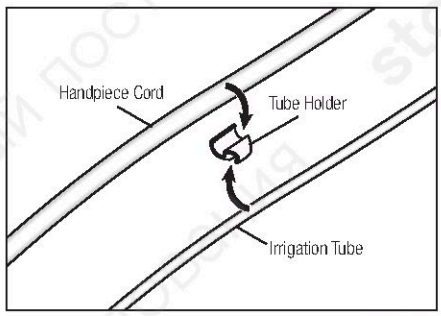


Fig. 13

CAUTION

- Bundle the Handpiece Cord and the Irrigation Tube at a total of 7 locations.

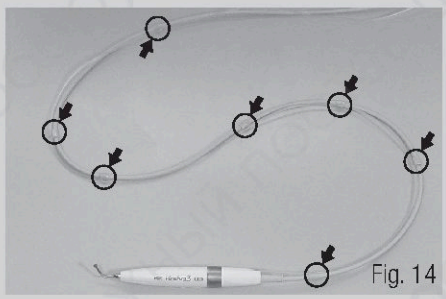


Fig. 14

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5-8 Mounting the Tip

1) First, lightly screw in the Tip with by hand. (Fig. 15)
2) Match the square shape of the Tip with the hole of the Tip Wrench, then insert the Tip into the hole. (Fig. 16)
3) Rotate the wrench in the (clockwise) direction, (Fig. 17 and 18) until it makes a click sound and cannot rotate any further.

* To remove the Tip, rotate the wrench in the (counter-clockwise) direction shown in Fig. 17 and Fig. 18.

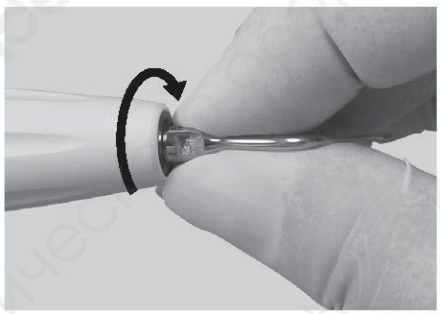


Fig. 15

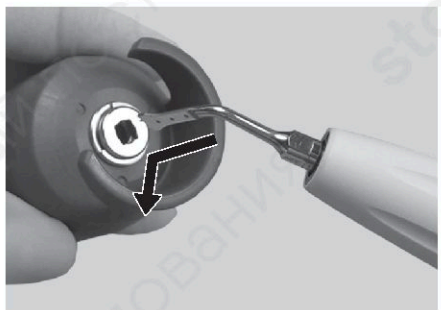


Fig. 16

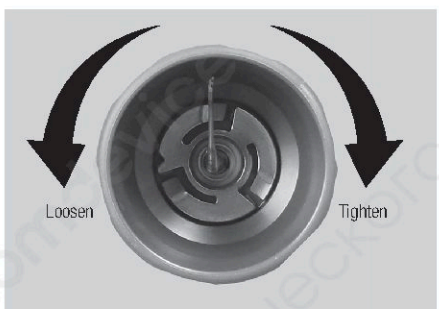


Fig. 17

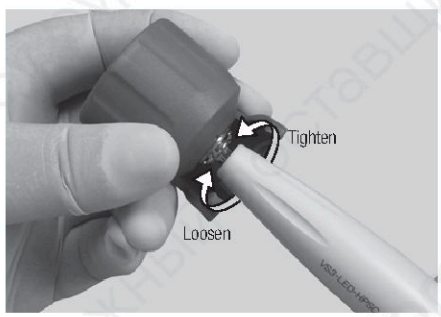


Fig. 18

CAUTION

- When attaching or removing a Tip, which is longer than the Tip Wrench, be careful that the protruding Tip does not cause an injury.
- Do not use a Tip which has been damaged, bent or corroded as it will be weakened and may break while in use.
- To avoid bending of the Tip thread or disengaging of the Tip, always make certain that the Tip is inserted at the correct angle and firmly tightened.
- If debris is found on the Tip thread clean the Tip immediately so as to avoid possible weak vibration
- Do not attempt to sharpen or bend the Tip as this may cause the Tip to break during operation, or the vibration may be weakened.
- When Tip become worn vibration may weaken or the Tip may suddenly break. If a weak Tip is detected replace with a new one.
- Tips need to correctly inserted and tightened using the Tip Wrench. If the Tip is not tightened sufficiently vibration may be weak.
- When inserting a Tip always wear surgical gloves and ensure the Tip, Handpiece and Tip Wrench are in an hygienic condition.
- Before connecting or disconnecting the Handpiece Cord or Irrigation Tube make sure to remove the Tip first to avoid injury by the Tip.
- Tip Wrench will wear with frequent use time and may need annual replacement.
- Use only genuine NSK Tips. Other brand Tips may cause malfunction, damage or injury:
  - Poor vibration when an incompatible thread has been forcibly fitted.
  - The patient may swallow pieces of broken non genuine Tips.
  - Damage or premature wear of the Handpiece thread.

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5-9 Handpiece Stand

When the Handpiece is not in use, place the Handpiece horizontally on the Handpiece stand.

⚠ CAUTION
- Make sure that the Tip does not rest on the Handpiece Stand.
- Make sure that the Handpiece rests horizontally on the Handpiece stand, and not at an angle.
- To maintain an hygienic condition, the Handpiece Stand should frequently be cleaned with alcohol.

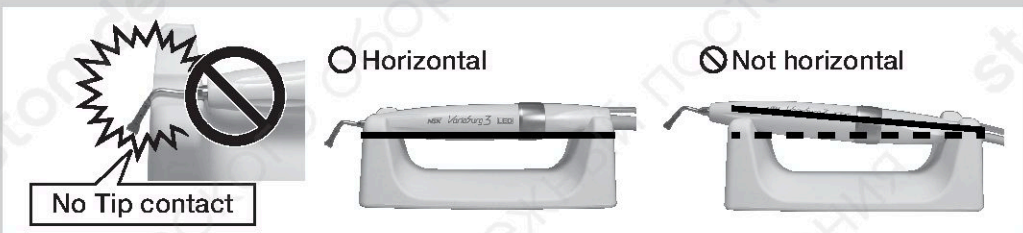


Fig. 19

6 Check before treatment

Before use, operate the product without patient contact and check the following points. If any abnormality, such as low vibration, noise, heat, is detected at anytime disconnect the product and contact your Authorized NSK Dealer.

-Is irrigation solution flowing correctly at the Tip?
-Is the Tip vibrating correctly?
-Are there any abnormalities at the Tip, Eg. vibration, noise and heat?
-Is the Handpiece illumination operating correctly?

7 Operating method

7-1 Check Irrigation

1) Confirm that the Irrigation Tube correctly connected to the Coolant Solution Pack, the Irrigation Pump and the Handpiece.
2) Turn ON (-side) the Power Switch.
3) Open the Tube Clamp which is placed between the Irrigation Needle and the Irrigation Pump. Then, depress the Ultrasonic ON/OFF Button on the Foot Control and confirm that the irrigation solution correctly flows from the Tip. When a new Irrigation Tube is used, it may take several seconds before irrigation solution flow commences.

7-2 Set the Power Level

1) Change the Mode – Use MODE key.
2) Select the Program No. – Use PROGRAM key.
3) Adjust the Power Level – Use POWER key.
4) Adjust the Coolant Flow Level – Use COOLANT key.
5) Adjust the Handpiece illumination intensity – Use LIGHT key.
6) Select the Burst Output Level – Use BURST key. (In SURG Mode only).

* Power outputs at various Modes are compared in Fig. 20.

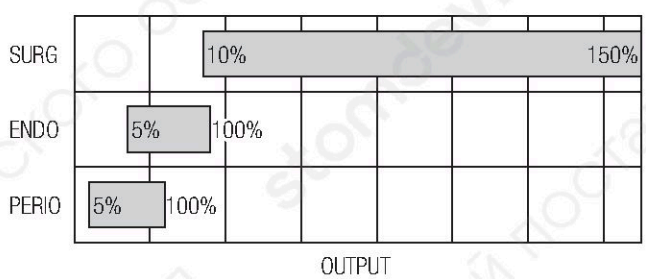


Fig. 20

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CAUTION

- Use the Tip ONLY in the Mode, and within the Power Range, as displayed on the Tip case label. If used outside the prescribed power range the Tip may break, and the tooth surface or soft tissue may be damaged. (Fig. 21)
- ONLY tips specified for maintaining prostheses can be applied to prostheses. Contact of other types of tips with prostheses may cause Tip breakage.

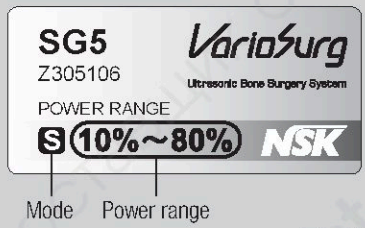


Fig. 21

7-3 Activation

The Tip will commence vibrating when the ON-OFF Foot Control button is depressed.

CAUTION

- Start with a low power setting within the power range, observing the patient's reaction and according to the treatment plan.
- Always use the irrigation. If the irrigation is not sufficient, the Handpiece may excessively heat, or oral injury may occur.
- Do not apply excessive pressure to the Tip.
- Do not place the active Tip anywhere other than the specific treatment area, as the ultrasonic vibration may cause oral injury.
- Even if the power level is correctly set for the Tip in use application of excessive pressure to the Tip may cause Tip damage. Should Tip breakage occur, immediately evacuate the oral cavity of any Tip pieces using strong suction.
- If Tip vibration reduces during operation, release the Foot Control activation button, and then again depress the Foot Control activation button. If the vibration level still does not return to normal check that the Tip is correctly and firmly positioned. Incorrectly inserted Tips may loosen during operation and power loss may be experienced.
- Do not connect or disconnect the AC power or the Handpiece Cord while Foot Control is depressed.

8 Various functions

8-1 Memory function

The set values displayed in the panel (Eg. Mode, Program No., Power Level, Irrigation Flow Level, illumination intensity) can be memorized in each program. Once memorized, the programs can be called up whenever required.

1) Press the PROGRAM key and select the Program No. for memory.
2) Check the values of the parameters to be stored.
3) Hold down the MEMORY key for approximately one second. When the notification tone beeps, memorizing the setting is complete.

8-2 Volume selection function for the notification tone

Sound volume of the notification tone can be selected between high & low.

1) Make sure the power is off. Then turn ON the power while holding down the BURST key.
2) The notification tone in the selected volume sounds.
3) To change the sound volume, repeat 1) and 2) above.

8-3 Link function with Surgic Pro

This product has a link function whereby two systems (NSK VarioSurg 3 and NSK Surgic Pro) can be operated via one Foot Control.

* To use this function, Surgic Pro (sold separately) and the SG Link Set (sold separately) are required. For the Link function, refer to the Operation Manual included with the SG Link Set.

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8-4 Factory Settings

When initialized, the device will revert to factory settings. Preferred settings and programs, etc. will be erased, so be sure to make memos of them.

1) Turn power on while pressing the PROGRAM (+ -) key.
2) "SEt" will come up on the LCD Display. (there will also be a short beep) By pressing BURST key, the device will revert to factory settings.
3) "FIn" will come up on the LCD Display. (there will also be a long beep) Initializing is complete when the screen goes back to its usual display.

9 Maintenance

After each patient maintain the product as follows.

9-1 Auto Cleaning

1) Remove the Irrigation Needle from the solution pack.
2) Place the Irrigation Needle in distilled or deionized water in an open container.
3) Place the Tip of the Handpiece into the water.
4) Start Auto-Cleaning by holding down the AUTO CLEANING key for approximately one second.
   While Auto-Cleaning is active "CLn" appears in the POWER Display on the LCD Display. The Bar Graph indicates the time remaining (Auto Cleaning lasts for approximately 30 seconds).
   *Auto Cleaning can be stopped anytime by pressing AUTO CLEANING key.
5) Once Auto Cleaning has completed, the LCD Display returns to normal display.

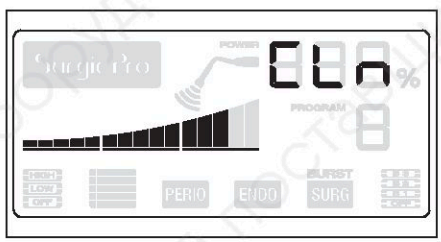


Fig. 22

⚠ CAUTION
- Perform Auto Cleaning after every use. If Auto Cleaning is omitted, the Handpiece may clog or malfunction.

9-2 Cleaning the LED handpiece with cord

1) Detach the Handpiece Cord from the Control Unit.
2) Remove the Irrigation Tube from the Handpiece and dispose.
3) Remove any debris from the product. Do not use a wire brush.
4) Wipe clean with alcohol.

This icon denotes that the product can be washed via Thermo Disinfector.
At the print date of this Operators Manual, the Miele (Model:G7882) is the only Thermo-Disinfector verified for use with the VarioSurg 3.
Refer to the Thermo-Disinfector manual.

⚠ CAUTION
- When using in a Thermo-Disinfector, ensure that the Handpiece and Handpiece Cord are stable by placing them in a basket or container.
- Never use solvents, such as benzene and thinner for cleaning.

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9-3 Cleaning the Glass Rod

Wipe clean the Glass Rod tip with an alcohol immersed cotton swab. Remove all debris. (Fig. 23)

CAUTION

- Do not use needles or blades when cleaning the Glass Rod as the glass surface may be scratched and illumination intensity will be reduced.

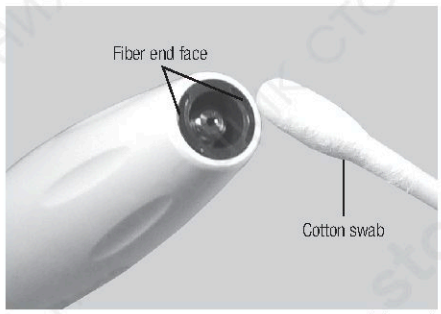


Fig. 23

9-4 Cleaning the Control Unit and the Foot Control

1) Turn OFF the power and disconnect the AC power cord from the wall power socket.
2) Wipe the surface, first with a moist cloth, then with an alcohol soaked cloth.

9-5 Cleaning other components

Remove surface debris with a bristle brush (NOT METAL BRISTLES) then wipe the surface with an alcohol soaked cloth.

9-6 Sterilization

Autoclave sterilization is recommended.
Autoclave sterilization is required for before the first use and then after each patient as noted below.
The following items can be autoclaved.
LED Handpiece with cord, Tip, Tip Wrench, Tip Holder, Handpiece Stand, Tube Holder, Sterilization Cassette.
1) Place the Handpiece and Tip Wrench in the Sterilization cassette. (Fig. 24)
2) Place the Tips onto the Tips Holder before putting the Tips Holder in the Sterilization Cassette.
3) Commence Autoclave sterilization. Autoclavable under the conditions below.
Autoclave for more than 20 min. at 121°C, or 15 min. at 132°C, or 3 min. at 134°C.
4) To maintain sterility, keep the product sealed in the autoclave pouch until required for use.

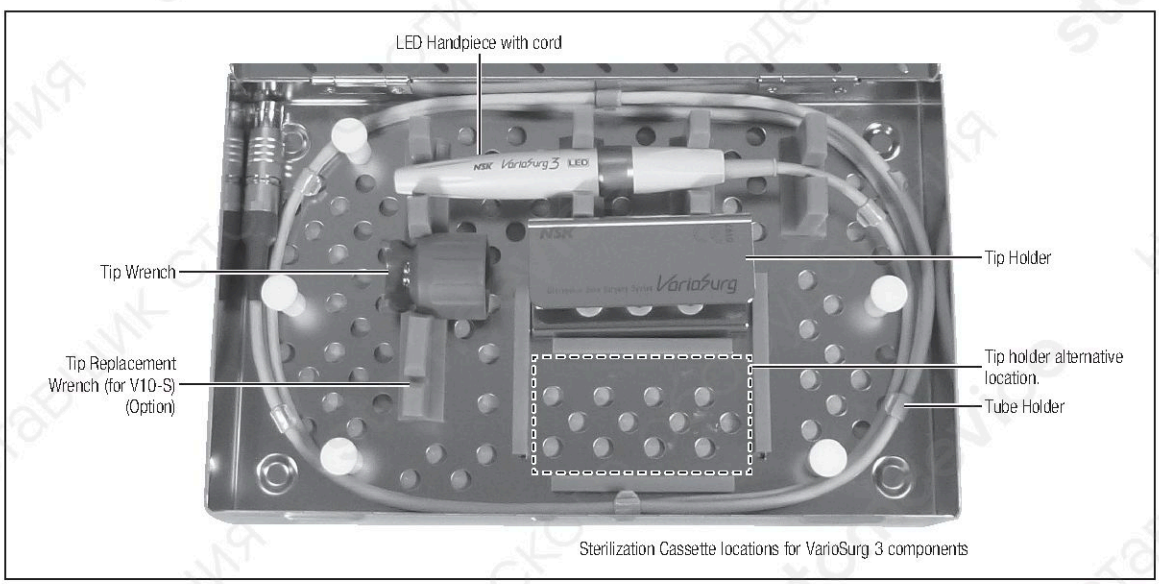


Fig. 24

CAUTION

- Do not place Maintenance Tips in the Tip Holder, as these Tips are too long. Use an autoclave pouch when sterilizing Maintenance Tips.
- Do not autoclave the product with other instruments even when it is in a cassette. This is to prevent possible discoloration and damage to the product from chemical residue from other instruments.
- Keep the product in suitable atmospheric pressure, temperature, humidity, ventilation, and sunlight. The

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CAUTION

air should be free from fine dust, salt and sulphur.

- Do not heat or cool the product too quickly. Rapid temperature change could cause damage to the product.
- If the sterilizer chamber temperature exceeds 135°C during the dry cycle then delete the dry cycle.
- Autoclave sterilization is recommended for the product. The validity of other sterilization methods is not confirmed.
- Do not touch the product immediately after autoclaving as it will be very hot and it must remain in a sterile condition until used.
- After autoclave sterilizarion if there are water drops on the LED Handpiece with Cord, wipe them away, as they may cause discolouration.

NOTICE

- NSK recommends Class B Sterilizers as stated in EN13060.

10 Periodical Maintenance Checks

Perform periodical maintenance checks every three months, referring to the check sheet below. If any abnormalities are found, contact your Authorized NSK Dealer.

Points to check	Details
Vibration	Operate the Handpiece and confirm that there are no vibration, noise, or heat abnormalities
Irrigation	Confirm that there are no abnormalities in the Coolant Flow Level or no leaks
Illumination	Confirm that the Handpiece LED illumination is correctly functioning
Display	Immediately after AC power is switched ON, all display lights should illuminate. Confirm that all display lights are working
Foot Control	Confirm that all the buttons operate normally

11 Error code

If the device stops operating due to excessive pressure, Tip or cord disconnection or incorrect usage, the LCD Display will show an error code. If this happens, release, then depress the Foot Control to repeat the error check. If the problem self corrects the error display will cancel and operation can be resumed. If the error display is repeated refer to the table below and take appropriate action.

Error code	Description of error	Cause of error	Check / Remedy
E2	Vibrator error	The end of the Tip is under too much pressure.	Avoid applying excessive pressure. If the Tip is caught during a cutting operation, press the Ultrasonic ON-OFF Button and gently extract the Tip while vibrating it. (Never use force)
		The Tip is not correctly inserted. The Tip is not tightened sufficiently.	Insert the Tip and tighten it using the Tip Wrench until it clicks into position.
		The Handpiece Cord is not properly connected. Breaking in the Handpiece Cord.	Check the connection of the Handpiece Cord. If the problem persists, contact your Authorized NSK Dealer.
E4	Overheating inside the Control Unit	Increase in temperature inside the Control Unit due to prolonged use under high pressure.	Turn OFF the power, allow time to cool, then operate the device again. If this error code is displayed frequently, contact your Authorized NSK Dealer.
E8	Pump error	The Irrigation Tube is caught in the Pump Roller. Failure of the Pump.	Check the Irrigation Tube is correctly connected If the problem persists, contact your Authorized NSK Dealer.

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12 Troubleshooting

If a problem is detected, check the following list before requesting service. If none of the listed remedies corrects the fault contact your Authorized NSK Dealer.

Trouble	Cause	Remedy
Control Unit cannot be turned ON (LCD display does not turn on)	AC Power Cord is not connected to Control Unit.	Check the connection.
	AC Power Cord is not plugged into wall outlet.	Check the connection.
	Fuse has blown.	Service only by Authorized NSK Dealer.*
Control Unit turns ON, Ultrasonic Output is displayed, and beep sound is heard. 	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. Activate the Foot Control again.
The Tip does not vibrate (no indication of Ultrasonic Output Display).	Foot Control is not connected.	Check the connection.
	Handpiece Cord is not connected to Control Unit.	Check the connection.
The Tip does not vibrate (Indication of Ultrasonic Output Display).	Faulty circuit.	Service only by Authorized NSK Dealer.*
Weak vibration	The Tip is worn or broken.	Replace with a new Tip.
	Wrong mode.	Change to the correct mode.
	The Tip is not correctly tightened.	Tighten the Tip until the Tip Wrench clicks.
	Incorrect power setting.	Change to the correct mode and power range for the Tip as indicated on the Tip case.
	Foot Control not connected properly.	Connect Foot Control properly.
	Failure inside the Handpiece.	Service only by Authorized NSK Dealer.*
	Failure inside the Foot Control.	Service only by Authorized NSK Dealer.*
The Tip breaks easily.	Power Level is not right for the Tip mounted.	Change to the correct mode and power level indicated on the selected Tip case.
The Tip comes off.	The Tip is not correctly tightened.	Tighten the Tip until the Tip Wrench clicks.
Handpiece makes a loud noise.	Power Level is not correct for the selected Tip.	Change to the mode and power level indicated on the selected Tip case.
	Tip is not correctly tightened.	Tighten the Tip until the Tip Wrench clicks.
	Failure inside the Handpiece or the Control Unit.	Service only by Authorized NSK Dealer.*
Handpiece becomes hot.	Power Level is not right for the selected Tip.	Change to the mode and power level indicated on the selected Tip case.
	Tip is not tightened sufficiently.	Tighten the Tip until the Tip Wrench clicks.
	Failure inside the Handpiece or the Control Unit.	Service only by Authorized NSK Dealer.*
	Debris is clogging the Handpiece and blocking irrigation flow.	Place air syringe against Water Pipe and blow air through it. If this does not clear it, Contact your Authorized NSK Dealer.
	Irrigation is not supplied.	Make sure the pack contains solution and the Irrigation Tube is not leaking nor blocked.
Irrigation does not exit as spray.	Spray 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.

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Water does not exit, or flow level is low.	Foot Control is not connected.	Check the connection.
	Irrigation Tube is not connected to Irrigation pack or Handpiece.	Check the connection.
	Irrigation Tube is not properly mounted to the pump.	Check the connection.
	The Pump Cover is open.	Close the cover.
	The Irrigation Tube is broken (leaking).	Replace the Irrigation Tube.
Irrigation leak.	Leak from the connection between Irrigation pack and Irrigation Tube.	Insert Irrigation Tube Needle all the way into the Irrigation pack.
	Leak from the connection between Handpiece and Irrigation Tube.	Insert the end of the Irrigation Tube completely into the Handpiece water pipe.
	Leak from Irrigation Tube.	Replace the Irrigation Tube.
Irrigation does not stop.	Mode is set to Auto Cleaning.	To stop irrigation, press the Flow key.
	Faulty circuit.	Service only by Authorized NSK Dealer.*
Handpiece LED does not illuminate.	LED is burned out.	Service only by Authorized NSK Dealer.*
	Failure inside the Control Unit or inside the Handpiece Cord.	Service only by Authorized NSK Dealer.*
	Failure or disconnection of the circuit.	Service only by Authorized NSK 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 ON. If part of initial display is still missing Contact your Authorized NSK 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 to the original setting.
	Foot control is being operated.	Settings cannot be saved while LED Handpiece with cord is operating.
	An Error Code is displayed.	Refer to the Error Code table.

* Repairs cannot be made by the customer.

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13 Specifications

<Control Unit>

Model	VarioSurg 3
Rated voltage	AC120V 50/60Hz
	AC230V 50/60Hz
Drive frequency	28 - 32kHz
Maximum output	25W
Power input	54VA
Dimension	W265 x D220 x H103mm
Weight	3kg

<Handpiece>

Model	VS3-LED-HPSC
Cord Length	2m
Type of oscillation	Piezo type
Optic	White LED
Consumption current(LED)	0.17A (3.5V)
Dimension	ø20×129mm (except cord)
Weight	70g (without cord)

<Foot Control>

Model	FC-78
Cord Length	2m
Dimension	W268 x D230 x H103mm
Weight	1.4kg

	Temperature	Humidity	Atmospheric pressure
Use environment	0 - 40°C	30 - 75%	-
Transportation and Storage environment	-10 - 50°C	10 - 85%	500 - 1060hPa

* No liquid freezing allowed
* When operated outside the above range, there is a risk of failure.

14 Classification of Equipment

- Type of protection against electric shock
  - Class I equipment
- Degree of protection against electric shock:
  - Type BF applied part (Applied part: Tip, Handpiece)
- Method of sterilization or disinfection recommended by the manufacturer:
  - See"9-6 Sterilization"
- Degree of protection against ingress of water as detailed in the current edition of IEC 60529:
  - Foot Control: IPX8 (Protected against the effects of continuous immersion in water)
- 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. (Without Foot Control)
- Foot Control: Category AP Equipment
- Mode of operation:
  - Continuous operation

15 Operation Principle

A sinusoidal electrical signal, at ultrasonic frequency (f>20kHz), 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 "TIP" insert, which is attached at the distal end of the transducer, vibrates at ultrasonic frequencies and makes it possible to achieve the aimed purpose.

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16 Symbol


This product is Autoclavable up to Max.135°C


This product can be washed via Thermo Disinfector


Conforms to CE European Directive of "Medical device directive 93/42/EEC"


Manufacturer


Authorized representative in the European community


Follow the waste of electric and electronic equipment (WEEE) Directive (2002/96/EC) for product and accessory disposal


Consult operation instructions


Caution, Refer to attached instructions


Type BF applied part


This product is designed not to become an ignition source in flammable air and anesthetic gas environment


Protected against the effects of continuous immersion in dust and water


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


Do not reuse


Use by


EOG sterilization


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


Batch Code


Caution: U.S. Federal law restricts this device to sale by or on the order of a licensed physician

17 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.

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18 Option Parts List

Model	Order Code	Remarks
SG Link Set	Y1002729	

19 Spare Parts List

Model	Order Code	Remarks
LED handpiece with Cord	E1133001	
Irrigation Tube	Y900113	5 pcs
Tube Holder	Y900767	7 pcs
Tips Holder	20001327	
Tip Wrench	10000977	
E Tip Wrench	Z217399	For V10-S

20 Disposal of the product

In order to avoid the health risks of operators handling the disposal of medical equipment, as well as the risks of environmental contamination caused thereof, a surgeon or a dentist is required to confirm the equipment is sterile. Ask specialist firms who are licensed to dispose of specially controlled industrial wastes, to dispose the product for you.

21 EMC Information (Electromagnetic Compatibility Information)

Guidance and manufacturer's declaration - Electromagnetic Emissions

The product is intended for use in the electromagnetic environment specified below. The customer or the user of the product should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11/EN55011	Group 1	The product 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/EN55011	Class B	The product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions EN/IEC61000-3-2	Not Applicable	
Voltage fluctuations/flicker emissions EN/IEC61000-3-3	Not Applicable	

Guidance and manufacturer's declaration - Electromagnetic Immunity

The product is intended for use in the electromagnetic environment specified below. The customer or the user of the product 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	±(2, 4) 6kV contact ±(2, 4) 8kV air	±(2, 4) 6kV contact ±(2, 4) 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 lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN/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 EN/IEC61000-4-11	<5% Ut (>95% dip in Ut) for 0.5 cycles 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 0.5 cycles <5% Ut (<95% dip in Ut) for 5 sec	<5% Ut (>95% dip in Ut) for 0.5 cycles 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 0.5 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 product requires continued operation during power mains interruptions, it is recommended that the product 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 AC mains voltage prior to application of the test level.

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Guidance and manufacturer's declaration - Electromagnetic Immunity			
The product is intended for use in the electromagnetic environment specified below. The customer or the user of the product 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 Radiated RF EN/IEC61000-4-3	3Vrms 150kHz to 80MHz 3V/m 80MHz to 2.5GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the product, 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[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE1: At 80MHz and 800MHz, the higher frequency range applies. **NOTE2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the product is used exceeds the applicable RF compliance level stated above, the product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the product. **b:** Over the frequency range 150kHz to 80MHz, the field strength should be less than 3V/m.			

Cables and accessories	Maximum length	Complies with	
Handpiece Cord	2.0m(Unshielded)	RF emissions, CISPR11	Class B/ Group 1
Foot Control Cord	2.0m(Unshielded)	Electrostatic discharge (ESD):	EN/IEC61000-4-2
AC Power Cord	2.0m(Unshielded)	Electrical 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/IEC 61000-4-6
		Radiated RF:	EN/IEC61000-4-3

Recommended separation distances between portable and mobile RF communications equipment and the product			
The product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the product 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.			
NOTE1: At 80MHz and 800MHz, the higher frequency range applies. **NOTE2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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Specifications are subject to change without notice.

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