

KRUUSE-SP1 *Scaler /Polisher Combo Unit*

Instruction Manual



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Operator Safety

Please read this manual before operating unit.

The KRUISE-SP1 Scaler/Polisher Combo Unit should be operated, maintained and repaired by qualified and properly trained personnel.

- ***NOTE, CAUTION, AND WARNING STATEMENTS***

NOTE : Provides tips and advice

CAUTION : Provides correct operating or maintenance procedures

WARNING : Alerts users of danger that may cause severe injury when proper procedures are not followed

- ***SYMBOLS***



Complies with MDD 93/42/EEC



BF equipment



Grounding terminal



Attention! Please read instructions

Warnings

Important!

- **Only trained and qualified doctors, dentist, and hygienists should operate the KRUUSE-SP1.**
- **Patients with pacemakers cannot be treated with the KRUUSE-SP1**
- **Do not immerse the KRUUSE-SP1 in water!**
- **If the patient or operator is pregnant, consult a physician prior to performing dental scaling for safety purposes.**
- **The KRUUSE-SP1 requires a shielded AC power cord.**
- **Plug the power cord into a well-grounded outlet.**



Attention to users with cardiac pacemakers!

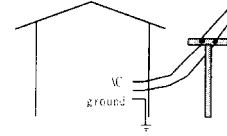
Patients with pacemakers should avoid treatment with the KRUUSE-SP1. Electronic appliances including razors, hair dryers, microwave ovens, TV receptors, and other medical equipment, such as the KRUUSE-SP1, may interfere with the performance of pacemakers.

For more information on this subject, please refer to the following articles:

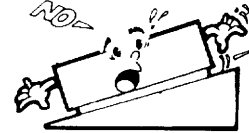
- "Advances in Cardiac Pacemaker", The New York Academy of Sciences, Vol. 167, Article 2, pp. 515-1075
- "Electromagnetic Radiation Interference with Cardiac Pacemaker", U. S. Department of Health, Education and Welfare
- "The Individual with a Pacemaker in the Dental Environment", Journal of the American Dental Association, Vol. 91, No. 6, pp. 1224-1229

Please Read Before Operating:

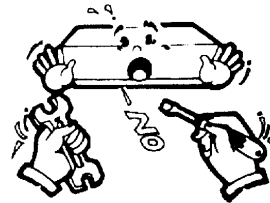
- Make sure the device is connected to a grounded outlet. Failure to meet this requirement may severely damage and harm the device or user.



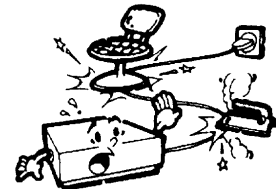
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- Place the device on a flat and stable surface. Placing the device on a tilted or unstable surface may degrade performance or damage the device.



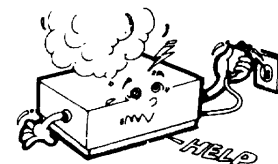
-
- Do not modify the device. Modifications to the device will violate safety codes and invalidate the warranty while endangering the patient and operator.



-
- Do not place heavy objects on top of the power cord and keep the power cord away from intense heat.



-
- Unplug the device and call Bonart for service and instructions if you observe any abnormalities while operating the device.



Preface

About the KRUUSE-SP1 Scaler/Polisher Comb Unit

The KRUUSE-SP1 is CE 0434 certified in compliance with the applicable requirements of the Council Directive 93/42/EEC. The reviewing council also classifies the KRUUSE-SP1 in accordance with EN60601-1 and EN60601-1-2 safety requirements.

How it works

The KRUUSE-SP1 consists of two parts: The main electronic system and the scaling hand piece. The main electronic system utilizes two closed loops. One loop provides automatic tuning to match the resonance of the insert. The other loop will control the tip stroke based on various working conditions.

The scaling hand piece utilizes a pulsing magnetic field. This magnetic field is applied to a metal “stack” which flexes and moves an installed scaling tip (insert) approximately 25,000 cycles per second in an elliptical pattern based on the amount of power used. Thus, more power results in greater tip displacement, which allows for more robust scaling. However, the vibrating metal stack generates heat and requires adequate amounts of fluid to cool the hand piece and tissues during treatment.

When the two parts of the KRUUSE-SP1 are placed together, the properties of the main unit and scaling hand piece enable the KRUUSE-SP1 to “power away” the heaviest calculus deposits. In addition, tips may be rotated 360 degrees within the hand piece to relieve cord tension and alignment. As a result, the KRUUSE-SP1 provides maximum comfort to the patient and ease of use to the operator.

Features:

- Scaler and polisher in one system
- Automatic phase lock and power control
- Automatic feedback control
- Micro-motor speed control of 2,000 to 30,000 RPMS

CAUTION : Since the scaling tip (insert) is made of stainless steel, avoid direct contact with teeth. Direct contact will cause damage to teeth enamel. For optimum performance, we suggest practicing on a model or aluminum plates to become more familiar with the scaling tips before performing on patients.

Table of Contents

Copyrights	1
Operator Safety	2
Warnings	3
Preface	5
Contents	7
Section I. Indications for Use	8
Section II. Contraindications and Warnings	8
Section III. Precautions	8
Section IV. Infection Control	9
Section V. Installation	11
Section VI. General Description and Information of Parts	15
Section VII. Techniques	18
Section VIII. System Maintenance	19
Section IX. Troubleshooting	20
Section X. Specifications	21
Section XI. Disposal	22

Section I: Indications for Use

Ultrasonic procedures:

- Removal of calculus and plaque during dental prophylaxis.
- General supra and sub-gingival scaling applications.
- Periodontal debridement for all types of periodontal diseases.
- Endodontic procedures.
- Polishing procedures.

Section II: Contraindications and Warnings

- Do not use the KRUUSE-SP1 for amalgam restorative dental procedures.
- Do not use the KRUUSE-SP1 if the patient or operator is wearing a pacemaker.
- Do not immerse the KRUUSE-SP1 in water or liquid. If the KRUUSE-SP1 has water damage, return the machine to Bonart for servicing.
- Do not modify the KRUUSE-SP1. Modifications will invalidate the warranty on the machine as well as invalidate safety codes and endanger the patient and operator.

Section III: Precautions

3-A: Precautions for all Ultrasonic Scaler Units and Systems

- Ensure sufficient water flow to the scaler tip during use to cool the hand piece and insert.
- Take precaution as all ultrasonic scalers produce aerosols that may transmit contagious diseases.
- Keep the unit away from intense heat. Excessive heat may damage the electronic components.
- Switch the water valve off when the KRUUSE-SP1 is not in use.
- Avoid treating patients with pacemakers due to the magnetic field produced by the KRUUSE-SP1.
- The magnetic field may cause monitoring devices to malfunction and provide inaccurate readings.

3-B: Precautions for Ultrasonic Prophylaxis Procedures

- Scaling tips (inserts) will wear with use. Inserts with 2mm of wear will lose approximately 50% of their scaling efficiency. In general, it is recommended that inserts be discarded and replaced after 2mm of wear to maintain optimal efficiency and avoid breakage.
- Avoid direct contact of inserts with the patient's lips, cheeks and tongue.
- Do not reuse scaling tips (inserts) that are damaged, bent, or reshaped. Discard immediately.

- Use the long axis of the scaling tip (insert) to wipe accretions from the tooth. Do not gouge the tooth with the tip.

3-C: Precautions for hand-piece

In order for the system's hand-piece to function consistently and effectively, Accumulated air pressure from the handle (or hand-piece) must be released every 10 to 15 minutes on every procedure by doing the following steps:

1. Put the insert into the hand-piece and make sure it is fully seated.
2. Hold the hand-piece vertically with the insert tip on top; depress the foot Switch (control).
3. Let the water spray out for a minute or so, then start scaling procedure.

Section IV: Infection Control

4-A: General Infection Control Recommendations:

As with all dental procedures, use standard protective equipment such as face masks, eyewear, face shields, gloves and protective gowns.

To ensure safety to the operator and patient, carefully follow the Infection Control Procedures detailed in this section.

4-B: Water Supply Recommendations

All dental water supply systems should conform to applicable Centers for Disease Control and Prevention (CDC) and the American Dental Association (ADA) standards. These standards should apply to flushing, chemical flushing, and general infection control procedures.

4-C: Cleaning and Sterilization:

Hand piece

Prior to cleaning, remove the insert from the hand piece. Next, drain any water left in the hand piece to clear the hand piece of any residue accumulated during treatment. Then, clean the surface of the hand piece with antiseptic soap or solution and rinse thoroughly with water. Afterwards, wipe or spray a chemical disinfectant on the hand piece. Please try to use a nonabrasive disinfectant to avoid damaging the hand piece.

After disinfecting the hand piece, a sterile insert may be re-inserted into the hand piece in preparation for the next patient.

At the end of the day, remove the insert from the hand piece and scrub both, the hand piece and cable, with antiseptic soap. Rinse thoroughly with water.

NOTE : Cleaning the hand piece after every patient is advised.

WARNING : Do not dip the hand piece and extension cable directly into sterilization fluid. Doing so will cause the KRUUSE-SP1 to malfunction.

WARNING : Do not leave the disinfectant on the surface of the hand piece and extension cable any longer than instructed by the manufacturer of the disinfectant.

Insert

Saliva, blood, and other debris will leave a residue on the insert after each use. Therefore, it is necessary to clean inserts after each use. Cleaning can be done manually by scrubbing the insert with a brush, water, and detergent. Be sure to rinse thoroughly after scrubbing. Let the insert dry. Then, place the insert in a bag and autoclave at 275 °F (135°C) for 15 minutes (or as recommended by the manufacturer of your sterilization unit) to sterilize the insert. Bio-indicators or chemical indicators for ensuring the efficiency of the sterilization cycle are recommended.

NOTE : Routine spore testing will determine the sterile conditions of your office.

NOTE : The Sterilization Assurance Level (SAL) of steam autoclave should be 10^{-6} (According to ISO 13683: Sterilization of health Care products)

WARNING : High room temperature conditions, improper dilutions, or extended immersion time in chemical sterilizers can result in damage to the plastic and other materials of the insert/tips.

CAUTION : The use of a dry heat oven, incompatible chemical vapor type sterilizers or quaternary ammonium compounds must be avoided as damage can result to the plastic and elastomeric materials.

Main Unit

To clean the main unit, wipe with a nonabrasive disinfectant.

Micro-motor

Remove all attachments to the micro-motor prior to cleaning. The outer surface of the micro-motor should be cleaned with an antiseptic solution. **Never oil the micro-motor. Make sure no moisture gets inside the micro-motor.**

Warning: Do not dip the micro-motor and extension wire directly into the sterilization chemical. The sterilization chemical will interfere with normal operations if it reaches the inside of the system.

Warning: Do not leave the disinfectant on parts longer than recommended by the disinfectant manufacturer to avoid damaging materials.

Note: The hand piece should be cleaned after each use between patients.

Straight Hand Piece Attachment (optional accessory)

The straight hand piece should be lubricated at the end of each day of use. Drop 2-3 drops of mineral oil into the top and allow it to flow down through the hand piece.

Prophy Head (optional accessory)

The prophy angle should be cleaned to remove hair and debris after each patient. At the end of the day it should be cleaned and lubricated. To clean the Prophy Head, follow the steps below.

1. Remove the rubber cup
2. Remove the cup holder with pliers by turning the knurled knob right (the knurled knob has a reversed thread). Wash away debris from the inside. Then put 1 drop of oil onto the gears (3-in-1 multipurpose oil works well).
3. Make sure all hair and fur, if any, is removed from the end of the prophy angle.
4. Replace the knurled knob.

Section V: Installation

5-A: General Information

If the installation of your KRUUSE-SP1 system is performed by non-Bonart distributor personnel, check to see that the requirements below are followed.

5-B: Water Line Requirements

- Incoming water supply line pressure to the Scaler must be 25 psi (172 kPa minimum) to 60 psi (414Kpa maximum). If your dental water supply line pressure is above 60 psi, install a water regulator on the water supply line to your KRUUSE-SP1 unit.
- After the above installation requirement is fulfilled, thoroughly flush the water prior to connecting to the scaler.

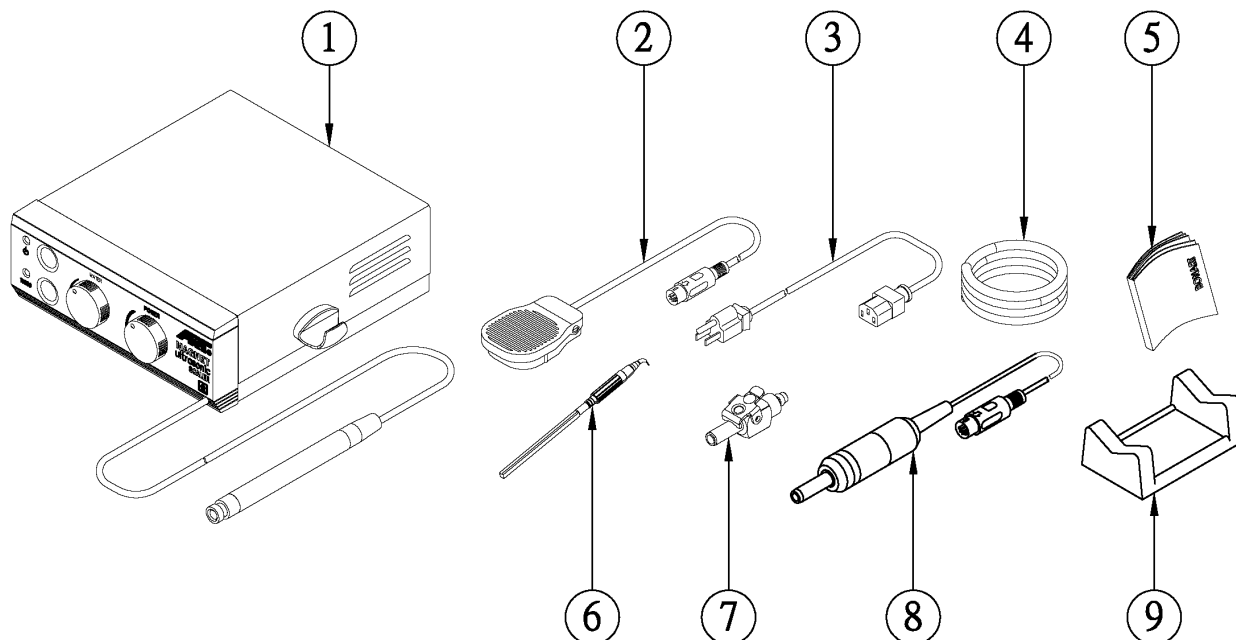
- Please use the manual shut-off valve on the dental water system supply line to shut-off water when the office is unoccupied.

5-C: Electrical Requirements

Refer to Section X: Specifications

5-D: Unpacking the Unit

Carefully unpack your KRUUSE-SP1 unit and verify that all components and accessories are included:



(Figure 1) All components and accessories

Item	Quantity	Item	Quantity
(1) Main Unit	1	(2) Foot Control / Foot Switch	1
(3) AC Power Cord Set.	1	(4) PU Water Tubing	1
(5) User Manual & Literature Packet			1
(6)			
ART IF-50 Streamline Universal Plastic Handle Internal Flow Insert.			Optional
ART P-10 Straight Angle Universal Metal Handle External Flow Insert.			Optional
(7) Water Hose/ Quick Disconnect Assembly.			Optional
(8) Micro-motor			1
(9) Micro-motor seat			1
(10) Straight Hand piece.			Optional
(11) Propfy Angle			Optional

NOTE :

While unpacking, check your KRUUSE-SP1 unit for any damages. If any damages are found, please contact your dealer immediately. Enter the unit serial number on your warranty card and mail it within 14 days from the date of purchase.

5-E: Power Cord / Power Connection

- Always make sure that the power switch is set to the OFF position before performing the following tasks:
 - Plug the detachable AC cord into the back of the unit.
 - Plug the 3-prong plug into a grounded outlet.



Safety Instructions

A. Grounding:

Prior to connecting accessories to the unit, check that the main unit is plugged into a grounded wall outlet.

B. Main voltage range and fuse:

Prior to plugging the AC adapter into the power outlet, check that the voltage is supported.

5-F: Foot Control Cable Assembly Connection

Align the pins of the foot control plug with the receptacle on the back of the device and push in until the plug is firmly seated.

5-G: Water Supply Line Connection

Push the blue water tube (hose) into the stainless steel receptacle until the hose cannot be pushed any further. Then tighten the screw.

Connect the quick connect to the water supply line. The KRUUSE-SP1 should be prepackaged with a male quick connect. If a female quick connect is necessary, please contact a Bonart distributor to purchase it.

Inspect all connections for leaks.

To remove the water line from the KRUUSE-SP1 scaler, first, turn off the water supply or disconnect the water supply line. Then loosen the screw on the water tube from the receptacle of the unit and gently pull the water hose out.

5-H: Hand piece Cable Assembly Connection

The KRUUSE-SP1 scaling hand piece is designed only for inserts with a frequency of 25khz. The KRUUSE-SP1 is no longer available in 30khz so please do not try using a 30khz insert with the KRUUSE-SP1.

5-1: Polishing Hand Piece Assembly and Start Up.



Propy Angle

Straight Hand Piece

Micro-motor



Knurled Knob



Locking Ring

To assemble the polishing hand piece, connect the Propy Head, Straight Hand Piece, and Micro-motor by following the steps below:

1. Connect the straight hand piece and the micro-motor by pushing the straight hand piece over the rod of the micro-motor. It should snap into place.
2. Attach the propy angle to the straight hand piece by following the steps below:
 - A) Unlock the propy head from the straight hand piece by turning the locking ring clockwise. This should open the lock. Note: When you first unpack the straight hand piece, there may be a metal rod at the top that serves as a placeholder. Remove the rod after you open the lock.
 - B) Match the groove at the base of the propy head with the top of the straight hand piece and connect them together.
 - C) Close the lock by turning the locking ring counter-clockwise. The propy head should now be locked onto the straight hand piece and should not fall off during operation.
 - D) If you wish to remove the propy head, follow step A to release the lock on the propy head.

WARNING : The propy head needs lubrication and cleaning on a regular basis.

When you are ready to begin polishing, follow the steps below:

1. Place a rubber cup on the propy head and put paste in the cup to begin polishing.
2. Press the Micro-motor (mode) button to switch from scaling to polishing mode
3. Adjust the Oscillating dial to a low speed, 2,000 rpm.
4. Press on the foot switch to engage the polishing hand piece and begin polishing.
5. Add paste as needed.

5-J: Assembling the Scaler Unit

1. Switch the power of the KRUUSE-SP1 off. The power indicator should not be lit if the machine is off.
2. Plug the power cord of the main unit into a grounded AC power outlet.
3. Install an insert into the hand piece pushing it into the hand piece until it is firmly seated.
4. Check the water tube connection to the water supply source and main unit.

Section VI: General Description and Information of Parts

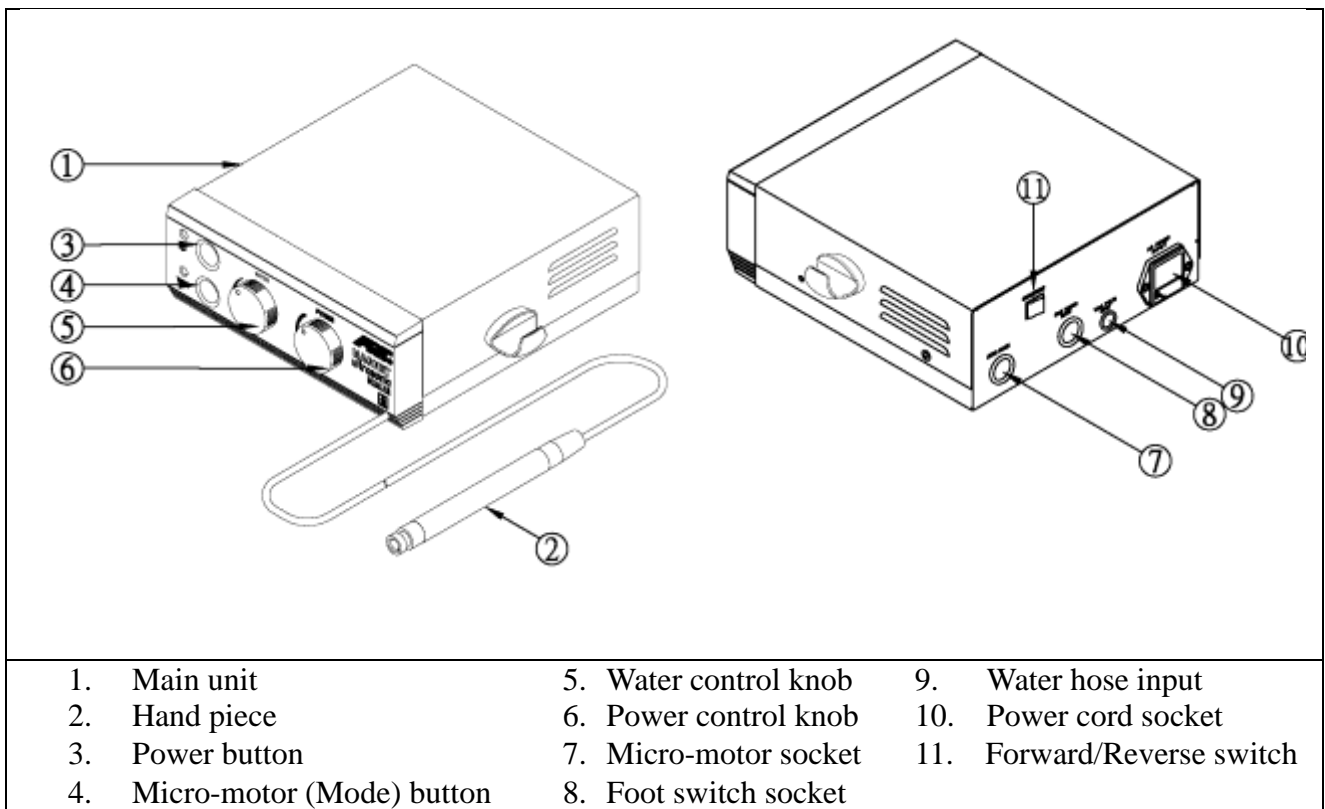


Figure 2. KRUUSE-SP1 diagram

1. Main Unit

The main unit generates power and produces a signal that is passed to the hand piece. The hand piece is then powered up and vibrates the installed insert.

2. Hand piece

The hand piece is the housing for scaling inserts. Inserts are interchangeable and can be installed with a firm push. To remove the insert, hold the insert at the grip and pull from the hand piece. Be careful not to cut yourself in the process. Inserts that are compatible with the KRUUSE-SP1 are made by: Bonart, Dentsply and Hu-Friedy.

The hand piece will heat up when used due to the power generated by the main unit. Therefore it is necessary to cool the hand piece by ensuring that an adequate amount of water flows through the hand piece.

CAUTION : Make sure that new insert is firmly seated.

CAUTION: Do not depress the footswitch when there is no insert installed. Doing so will cause the hand piece to melt!

NOTE : The KRUUSE-SP1 is a stand-alone unit and is now only available in 25Khz. Please do not use 30Khz inserts with the hand piece.

3. Power button (ON/OFF)

The power button is used to turn the KRUUSE-SP1 main unit on and off. When the power is on, the LED indicator should be lit. When turned off, the LED power indicator should not be lit.



Do not depress the foot switch while turning on the KRUUSE-SP1.

4. Micro-motor (Mode) button

The micro-motor (Mode) button is used to switch between polishing and scaling mode. When pushed, the LED indicator should be lit, indicating that the system is operating in **polishing** mode. Under polishing mode, the micro-motor is engaged. To return to **scaling** mode, push the button again.

5. Water control knob

The water control knob allows you to control the amount of water that flows through the hand piece. If turned clockwise, the amount of water will decrease. If turned counter-clockwise, the amount of water will increase. Please note that water is necessary to cool the tip and prevent overheating so it is necessary to ensure that an adequate amount of water flows through the hand piece while operating the device. The larger the water stream, the lower the temperature, and vice versa.

WARNING : Do not turn the water knob counter-clockwise more than three full turns. Doing so will damage the internal water line needle.

WARNING : If needed, gently adjust the water control knob to prevent any serious damages to the water valve.

6. Power control knob

The Power Control Knob allows you to control the power intensity. When turned clockwise, the power intensity increases. When turned counter-clockwise, the power intensity decreases.

7. Micro-Motor Socket

The micro-motor socket is where you connect the micro-motor to the main unit. It is located on the back of the main unit at the bottom left.

8. Footswitch Socket

The foot switch socket is where you connect the foot switch to the main unit. It is located next to the water hose input on the back of the main unit.

9. Water hose input connector

The water hose input connector is the contact point for the water tube and the main water supply line. Use either a male or female quick connect to connect the water tube to the water supply. The KRUUSE-SP1 comes with a male quick connect attached to the water tube.

10. Power cord socket

The power cord socket is where you connect the power cord to the main unit.

11. Forward / Reverse switch

The Forward/Reverse switch allows you to control the direction of the micro-motor. It is located on the back of the main unit.

Section VII: Techniques

7-A: Performing Ultrasonic Scaling Procedures

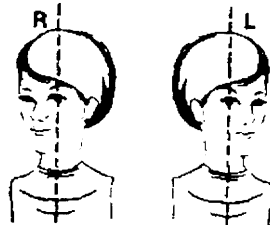
1. Use purified or distilled water to prevent infection when patients experience tissue laceration during treatment
2. Keep the power cord tidy to avoid tripping and other accidents.
3. Position the footswitch in an easily accessible spot for the user. Keep the footswitch cord tidy to avoid tripping and other accidents.
4. Hold the empty hand piece in an up right position when testing to see if the scaler is working properly. Tap the footswitch until water appears. **Do not repeatedly tap or hold the footswitch down. The empty hand piece will melt!**
5. Lubricate the rubber O-ring on the insert with water before placing it into the hand piece. **Install the insert by firmly pushing until seated.**
6. Hold the hand piece over a sink or drain with an insert installed. Verify that water is reaching the tip.
7. Check your scaling inserts for wear and replace as needed.
8. Use your foot to press down on the foot switch to allow water to reach the hand piece. Release the foot switch to stop the water.
9. Control the amount of water that flows through the hand piece by using the water control knob. Turn counter-clockwise to increase water flow and clockwise to decrease water flow.

NOTE : To lower the temperature of the hand piece, increase the water flow.

CAUTION : A continuous flow of water is required to keep the hand piece cool during use.

7-B: Patient Comfort Considerations

1. Position the patient comfortably on the patient chair. Adjust the chair angle and position to access the patient's oral cavity with ease and comfort.
2. Put the saliva ejector into the patient's mouth to remove excess saliva and debris.
3. Rotate the patient's head gently so that the oral cavity can be easily accessed without causing discomfort to the patient (see figure below).



4. During treatment, try to keep the angle between the surface of the tooth and scaling insert at 15 degrees. If the patient experiences any discomfort during treatment, follow the suggestions below:
 - Increase the hand piece movement speed on the surface when treating sensitive areas.
 - Treat less sensitive area first, and then return to sensitive areas.
 - If the problem persists, reduce the power output intensity of the hand piece.

Section VIII: System Maintenance

Daily start-up

1. Open the water supply valve.
2. Turn the KRUUSE-SP1 on using the main power switch. Verify that the LED power indicator (LED) is lit.
3. Set the power control knob to full power.
4. Turn the water control knob counter-clockwise to the maximum setting.
5. Hold the empty hand piece upright over a sink or drain.
6. Depress the footswitch and flush the water line for at least 2 minutes.
7. Place a scaling insert (or a compatible insert) into the hand piece and adjust the water level as desired.

NOTE : If no water is detected, check the water supply and the water control knob.

NOTE : If the power LED is not lit, contact a local authorized agent.

Preparations for treating each patient

1. Remove, clean, and sterilize all used ultrasonic inserts.
2. Make sure the scaling insert/tip has been sterilized before treating the next patient.
3. Clean and disinfect the surface of the power cord, hand piece, and cable assembly.

Daily shutdown

1. Use the power switch to turn the KRUUSE-SP1 off.
2. Close the water supply valve.

Daily Maintenance

The suggestions below will help maximize the lifespan of the scaler.

- A. The KRUUSE-SP1 should be used in a well-ventilated room
- B. Handle the KRUUSE-SP1 with care when moving it.
- C. Before leaving the operation room, make sure that the KRUUSE-SP1 is turned off and the water faucet is tightly closed.
- D. If you find that the power output to the hand piece is insufficient, the insert is probably worn out. Inserts should typically be replaced after six months or when worn out.
- E. Please contact a local authorized agent for technical support.

Section IX: Troubleshooting

While Bonart offers repair service, the following trouble shooting procedures can help you save time.

9-A Troubleshooting Guide

Basic procedures:

1. Check all lines and connections to and from the system. A loose plug or connection is the most common cause of problems.
2. Check the setting of all control knobs.

System will not operate:

LED power indicator is not lit

1. Check that the three-prong power plug is fully seated in the AC receptacle on the back of the KRUUSE-SP1, and that the voltage is supported.
2. Check that the power plug is plugged into the wall outlet.

LED power indicator is lit

1. Check that the footswitch connector is fully seated in the foot control receptacle on the back

of the system.

System operates:

No water reaches the tip (scaling mode)

1. Assure that the water control knob is turned on or adjusted to allow water to flow (turning counter-clockwise allows for more water).
2. Check that the water supply control valve (dental office water supply) is open.
3. Check that the external water tube is properly connected.

9-B Technical Support and Repairs

For technical support and assistance call 1-888-526-6278 or 626-600-5330 Monday through Friday, 9:00 AM to 5:00 PM (Pacific Time). For other areas, contact your local Bonart representative..

X: Specifications

Classification

- Protection against electric shock : Class I
- Degree of protection against electric shock : Type BF
- Mode of operation : Continuous
- Medical device directive : IIa

Standards Followed

- ISO13485:** Medical Devices, Quality Management Systems, Requirements for regulatory purposes
- 93/42/EEC:** MDD CE Directive
- EN60601-1:** Medical Electrical Equipment, General Requirement for Safety
- EN60601-1-2:** Medical Electrical Equipment, Electromagnetic Compatibility, Requirements and Tests

● Specification

- Power supply 115V ±5% ~50/60Hz 160VA
230V ±5% ~50/60Hz 160VA
 - Working frequency 24.5KHz ±5% (for 25KHz Insert)
 - Polisher speed 2000~30000 R.P.M
 - Water supply 25~60 PSIG(172~414KPa)
 - Dimension 24.5cm(L) x 22.5cm(W) x 8.5cm(H)
 - Weight 4 Kg(include hand piece)
 - Hand piece Cable 250 cm
 - Footswitch Cable 250 cm
- Operation environment
- Temperature 0°C~40°C
 - Relative Humidity 10% ~ 90% (non-condensing)
- Transport and storage conditions
- Temperature 0°C~60°C
 - Relative Humidity 10% ~ 90% (non-condensing)
 - Atmospheric pressure 860~1060 hPa

Section XI: Disposal

Please follow county and state regulations for disposal of the KRUUSE-SP1.