Veterinary Services and Supplies, LLC

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Instructions for Use

VSS[®] 25/30 Ultrasonic Scaler VSS2000



MD

Rx ONLY

This manual, in whole or in part, should not be considered a substitute for formal training in ultrasonic scaling. Appropriate dental professional education is strongly recommended prior to using this device clinically.





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What's Included

- (1) Magnetostrictive Scaler Control Unit with attached hard-wired handpiece, removable, autoclavable sheath (VSS2010), foot controller and water line with male quick-connect coupler.
- (1) "SS" #10 30K Insert (VSS4068).
- (1) Universal Power Adapter with attached cable (4 ft / 2.5 mm jack).
- (1) Power Adapter Line Cord (6 ft).
- (2) Inline water filters (1) attached to water line).(3-pack Replacement VSS2040).
- (1) Operator's Manual / Instructions for Use

This precision dental device was designed, manufactured and is serviced in the United States of America for:



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Specifications

Power:	Input: 100-240 VAC, 1.0-2.0 A, 50/60 Hz; Output: 24 VDC, 3.0 A, 2.5mm, Center Positive
Weight:	0.73 Kg / 1.60 lbs.
Size:	1½" H x 5½" W x 7½" D
Weight of Transformer:	0.6 lbs. (270g)
Length of Handpiece Cable:	7' (215cm)
Length of Foot Pedal Cable:	7' (215cm)
Length of Water Hose:	7'6" (230cm)
Length of Power Cord:	110V: 12'6" (380cm)
Handpiece Operating Frequency:	25/30KHz
Protection Against Electric Shock:	Class 1, Type B applied part
Protection Against Ingress of Liquids:	Foot Switch & Scaler: IPX1 (drip proof); Power Supply: IPX0 (Ordinary)
Mode of Operation of Equipment:	Intermittent – 10 minutes on, 5 minutes off
Operating Conditions:	15 - 30°C, 20 - 70% RH (non-condensing)
Transport and Storage Conditions:	-17°- 40°C, 20 - 70% RH (non-condensing)



TURBO Light— Indicates the device is operating on high-power TURBO mode (footswitch fully depressed)

Device Description

The VSS® Millennium is a magnetostrictive ultrasonic scaler (VSS2000) that operates at a frequency of either 25KHz or 30KHz, which translates to the insert tip vibrating 25,000 or 30,000 times per second during active scaling. It also features an IntelliSense™ processor for ensuring top-level, consistent performance with all Veterinary Services and Supplies, LLC and market-leading 25/30 KHz inserts. For more information about usage with non-Veterinary Services and Supplies, LLC inserts, please see Veterinary Services and Supplies, LLC's warranty information.

The VSS® Millennium also features: a "priming" mode for preparing the handpiece to begin scaling with the first compression of the foot pedal; a "press and hold" turbo feature for assistance in removing challenging deposits if required; and a more precise water flow system for heightened aerosol control.

Indications for Use

For removal of calculus, plaque, and oral debris from teeth during dental prophylaxis/scaling.

Contraindications to Use

Because of the potential for electromagnetic interference, this device should not be used on patients or by clinicians with cardiac pacemakers, internal defibrillators, intracorporeal fluid pumps or any other implantable electronic devices, or in close proximity to sensitive patient monitoring devices such as pulse oximeters.

If patient or operator is pregnant or has any medical condition which might be affected by this device during treatment, consult a physician prior to use.

In case of an adverse event, discontinue the scaling procedure.

Warnings

- Close manual shut-off valve on the dental office water supply every night before leaving the office.
- The water / fluid supply line to the scaler should always be turned off whenever the device is being connected, disconnected, or when not in use.

- Turn the scaler power off every night before leaving the office with the rocker switch on the back. When power is off, the green LED on the front panel will turn off.
- Locate the scaler and power adapter above and away from sources of fluid that may enter them. Always ensure that the electrical connections on the handpiece cable and the handpiece are clean and dry before assembling them for use.
- As with all electrical devices, the unit should not be immersed in fluids, and fluids should not be allowed to enter the unit through front or rear panel slots. Do not reach for the device if it has fallen into liquid until power is disconnected and do not use the device. Return it to Veterinary Services and Supplies, LLC for servicing. Modifying device violates safety codes, endangers patients and operators, and voids the warranty.
- Use of this equipment adjacent to or stacked with other equipment should be avoided.
- Only use the provided power supply by the manufacturer along with the unit.
- This equipment produces electromagnetic energy and may cause interference with other electronic devices. Should this occur, changing the position or location of the unit may be necessary.
- Use of accessories other than those specified / provided by the manufacturer of this equipment could result in increased electromagnetic emissions, decreased electromagnetic immunity or improper operation.
- The system is portable but must be handled with care when moving. Do not place the system on or next to a radiator or other heat source. Excessive heat may damage the system's electronics. Place the system where air is free to circulate on all sides and beneath it.
- Failure to follow properly validated sterilization processes and approved aseptic techniques for Veterinary Services and Supplies, LLC inserts or handpieces may result in cross contamination.
- Insufficient water flow could result in elevated water and the tip as
 well as insert stack temperature. When operated with sufficient
 water flow, the water and tip temperature should not exceed 50°C
 (122°F). Failure to follow recommendations could result in injury to
 patients or users. If temperature is elevated, increase water flow. If
 temperature remains elevated, discontinue use and contact
 Veterinary Services and Supplies, LLC.
- Portable RF communications equipment (including peripherals

such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

 This equipment is not suitable for use in the presence of a flammable anesthetic gas mixture (when used along with air or oxygen).

Clinical Precautions

- Although the following precautions may be common sense to the experienced user of ultrasonic scalers, they bear repeating in the interest of safety, and the management of unnecessary risk.
- Ultrasonic scalers should only be used by trained, veterinary professionals.
- Use of appropriate personal protection equipment and highvolume intraoral suction is strongly recommended when operating this device, to avoid exposure to contaminated aerosols.
- DO NOT OPERATE UNIT WITHOUT WATER FLOWING. Water flow through tip during use must always be enough to cool handpiece and insert.
- Do not allow prolonged contact of insert tip with lips, cheek, tongue, or other soft tissues. Insert tips are sharp and should be used carefully.
- Handpiece and inserts supplied along with the unit are not sterile and needs to cleaned and sterilized in autoclave by the user prior to the first use and before each use, as specified on the insert package instructions and in Infection Control procedure specified in this instruction manual.
- To keep heat generation to minimum, use the lowest scaling power that is effective.
- Before using the insert in the oral cavity, adjust water mist by varying the POWER & WATER settings.
- For patient comfort, use a generous flow of water as a coolant, lubricant, and debris flush.
- When done properly, the patient should not experience any uncomfortable heat. If patient shows signs of discomfort, adjust POWER and WATER accordingly, or examine inserts for wear or damage.
- Do not test a scaler tip on your fingers while operating, as this is not a valid test of how scaling feels to the patient. If you touch the tip, it will feel uncomfortably hot to your fingers.
- Hold the handpiece in a comfortable pen-grasp. Elevated heat may be felt if the lighted handpiece is gripped where the insert meets the handpiece.
- Keep the long axis of the insert tip parallel to the long axis of the tooth to wipe deposits from the tooth with a light, brushing stroke with the side of the insert. Do not gouge the tooth with the point of the tip.
- Excess pressure will not improve scaling efficiency and may cause overheating of the tooth and pain to the patient. Keep the scaler insert in motion always, using repeated gentle strokes to remove all tenacious deposits.
- Occasionally pause during scaling by removing foot from pedal to evaluate deposit removal. Exercise caution near ceramic or resin restorations, as they can fracture if stressed.

Inserts

One VSS4068 #10 30K Insert is included with the basic scaler. Additional Magnetostrictive Inserts for the scaler are available. The unit is designed to work with all Veterinary Services and Supplies, LLC 25/30 KHz inserts. Brand new inserts may fit very tightly in the handpiece initially and may be inserted and removed more easily by using a slight twisting motion, and by lubricating the insert "O" ring with water. Old, worn, or blunt inserts will perform poorly, generate excess heat, and should be replaced when necessary.

Installing Your Scaler

- Veterinary Services and Supplies, LLC, VSS® Millennium System is designed to rest on a level surface. Be sure the unit is stable. This will assure that an accidental pull on the handpiece or corded foot pedal does not cause the unit to fall onto the floor.
- The scaler requires access to a source of drinking-quality water and a grounded electrical outlet.
- Locate the control unit such that it can be easily disconnected form the mains power line in case it needs to be disconnected for any reasons. Disconnection form the mains power line can be accomplished by removing the power cord from the wall plug, removing the power cord from the in-line "power supply adapter" or by removing the 2.5 mm metal plug connector from the back of the scaler.
- Install the scaler where control panel and foot pedal will be easy to reach during scaling procedures.
- The rear of the unit requires access so the water filter may be changed periodically without difficulty.
- The device and its separate power adapter generate a minimal amount of heat. Avoid covering them to allow normal cooling.

Water Connection

Before plugging in the device, connect the scaler's water line to a drinking-quality water supply (15-35 psi optimal), free of sediment. An external, office-wide water filter is recommended to minimize frequent changes of the device's in-line water filter.



The male quick-connect that comes on the end of the water hose is the standard fitting presently used in the dental industry. If you are replacing a scaler that uses an Adectype or other type of connection, remove the old fitting from the unit hose and attach it to the new water line. Check for leaks at all hose and filter connections before use, and tighten if necessary.

Controlling the Water Flow



Observing the arrow printed on the control panel, turn the water control counter- clockwise to increase the flow, or clockwise to decrease water flow. If water does not flow through the insert when the foot pedal is depressed, the water passage in the scaling insert may be clogged.

Electrical Connection

The scaler must only be powered via the power supply assembly that is supplied with the device by Veterinary Services and Supplies, LLC. Power supply provided by Veterinary Services and Supplies, LLC is a Medical-Grade, IEC 60601 compliant, TUV approved switching power supply adapter with Input being 100-240 VAC, 1.0-2.0 Amp, 50/60 Hz and Output being 24 VDC, 3.0 Amp.





- Insert the 2.5 mm metal plug from the Power Adapter into the back of the scaler.
- Insert the supplied AC cord female plug into the Power Adapter.
- Plug the male AC power cord into any grounded electrical outlet.

Use of Autoclavable Sheaths and Ultrasonic Inserts

The VSS® Millennium handpiece is provided with the autoclavable handpiece sheath attached. Prior to use, the sheath should be sterilized. To remove it, hold the handpiece at the base with one hand and turn the sheath counter-clockwise with the other, taking care not to twist the hose. The sheath will unscrew and slip off.



Turning on the Scaler and Controlling the Power Output

The unit provides a rocker switch on the rear panel for Main Power Control. UP position of the switch turns the device ON. Green LED on the front panel would illuminate indicating powered ON status of the device. DOWN position of the switch on the rear panel would turn the device and Green LED indicator OFF.

Scaling will be activated upon pressing the foot switch once the device is turned ON. The pedal should be placed where it will not accidentally be pressed when the device is not in use. The orange LED will illuminate when foot pedal is pressed to indicate the scaler is active.



The VSS® Millennium gives you two ways to adjust the scaling power, by using the Power Control Knob for normal operation, or by depressing the Foot Pedal to enter the "Turbo Mode".

Use the Power Control Knob to set the initial scaling power. Rotate the knob in a clockwise direction to increase the power, or counterclockwise to decrease the power.

When starting a procedure, use the Power Control Knob to set the power to "Medium". When the foot pedal is slightly depressed to the first position, the insert will begin vibrating at medium power. Then adjust the power up or down based the specific needs for the case being treated

Use the "Turbo Mode" for short-term increases in power during scaling. Using increased foot pressure, fully depress the foot pedal to the floor to enter "Turbo" mode. A yellow indicator light will illuminate on the front panel to confirm the scaler is operating at "Turbo" power. Scaling power to a point midway between the current setting and the scaler's maximum power.

Engaging the Turbo feature at a low power setting causes a significant boost in power.

Engaging the Turbo feature at high power will produce very little change.

Since water flow is not affected by "Turbo Mode", extended procedures may require a water adjustment.

Partially lifting your foot off the pedal will return the scaler to normal, "non- Turbo" mode. Releasing your foot completely off the pedal will deactivate scaling. Green LED indicator will NOT turn OFF, as it indicates device ON status.

Priming the Handpiece

- Confirm the unit is ON and that the green LED on the front panel is illuminated. Make sure there is no insert connected to the handpiece.
- 2. Hold the handpiece in an upright position.
- 3. Depress the foot pedal.
- 4. Water will begin to flow and fill the handpiece. Priming of the handpiece should be done with a water setting between medium and maximum flow. (The lower the setting the longer it will take to prime and fill the handpiece with water.)
- 5. Press foot pedal and orange LED light will illuminate.
- To stop water flow into the handpiece, remove foot from foot pedal.
- 7. An insert may now be placed into the handpiece for scaling.
- 8. **Safety feature:** Priming is limited for 2 minutes to prevent accidental flooding.

Clinical Suggestions on Tooth Scaling

- Ultrasonic scalers should only be used by trained, veterinary professionals.
- Protect patient's eyes, lips, cheek, tongue or other vulnerable soft tissues when using this device. Inadvertent contact with Insert tip may cause a slight burn.
- Inserts and removable sheath must be sterilized before each use
- Use of a face mask by the clinician, and high-volume intraoral suction, is strongly recommended when operating this device to avoid inhalation of contaminated aerosols.
- To prevent a possible slight burn to the patient or clinician, NEVER OPERATE UNIT WITHOUT WATER FLOWING.
- Use the lowest effective scaling power for the case at hand. This keeps heat generation to a minimum.
- Before using the insert in the oral cavity, adjust the water spray following the graphics on the faceplate of the scaler over a sink or cuspidor until desired mist is obtained. Good water flow will act as a coolant and aid in flushing out debris to maximize patient comfort.

- Do not test a scaler tip for vibration on your fingers while the unit is operating. This is not a valid test of how scaling feels to the patient.
- Hold the handpiece in a comfortable pen-grasp. To remove deposits from teeth, always use a light brushing stroke with the side of the insert tip, in contact with and parallel to the root surface. Excess pressure will not improve scaling action but may cause heating and pain to the patient. Keep the scaler insert in motion, using repeated gentle strokes to remove all tenacious deposits.
- Do not use the point of the insert on the tooth surface. You may gouge the tooth.
- Pause occasionally during scaling by removing foot from pedal to evaluate deposit removal.
- Exercise caution near ceramic restorations, as they can discolor or fracture if stressed.

Common Operator Errors that May Result in Poor Clinical Performance

- Failure to keep insert tip parallel to the long axis of the tooth.
- · Excessive use of hand pressure.
- Failure to use the lowest effective power setting for the case at hand
- · Insufficient water flow.
- Scaling with the point of the insert instead of the side.
- · Inserts that are damaged, bent or worn out.

Cleaning and Infection Control

- Consult www.CDC.gov for the "Guidelines for Infection Control in Dental Health - Care Settings" and "Statement on Reprocessing Dental Handpieces".
- DO NOT AUTOCLAVE the VSS® Millennium control unit, as autoclave heat will destroy it. The control unit should be cleaned of debris with a water-damp paper towel, disinfected by wiping with a paper towel that has been saturated with an EPAregistered low-level (HIV/HBV claim) to intermediate-level (tuberculocidal claim) hospital disinfectant, wiped of chemical residue with a water- damp paper towel, and dried. Utilize the surface disinfecting protocol of the disinfectant manufacturer.
- Autoclaving does not remove debris that has accumulated on the sheath or the insert. Failure to adequately remove debris will result in inadequate sterilization. Rinse the sheath, and the insert under warm running water for 30 seconds to remove any external or internal soil or debris. Using a soft soapy cleaning brush to assist in the cleaning, if necessary. Use non-ammoniated detergent or dishwashing soap. Do not use ammoniated cleansers or disinfectants. Rinse the devices again under warm running water for 30 seconds to remove any residual soap and blot dry with a dry lint-free towel. Wipe Insert with a lint free towel that has been saturated in an EPA-approved, hospitalgrade intermediate or high-level disinfectant (minimum 2.5% Glutaraldehyde solution), following the instructions for use provided by the disinfectant manufacturer. Dry the devices with a dry lint-free towel.
- The sheaths and inserts may be sterilized in any conventional steam autoclave following manufacturer's instructions. A typical steam sterilization cycle is 132 +/- 2°C for 4 mins. (Vacuum) or 132 +/- 2°C for 15 mins. (Gravity), followed by a 15-minute minimum cool-down period. Use a steam sterilization pouch that is compliant with ISO 1140-1 Type 4 and 11607

- standards. Once items are sterilized, adhere to the shelf-life specified by the pouch manufacturer. After sterilization, inspect the device in the autoclave bag for integrity. If suspicion about the item exists, discard it and order a replacement from Veterinary Services and Supplies, LLC or your dealer.
- DO NOT USE DRY HEAT OR CHEMCLAVE on the sheath or the insert.
- The handpiece sheaths are designed to withstand a minimum of 250 autoclaving cycles when reprocessed.
- The ultrasonic inserts from Veterinary Services and Supplies, LLC are designed to withstand a minimum of 500 autoclaving cycles when reprocessed.

How to Replace the Filter Disk

The water filter disk coming off the rear hose of the unit should be replaced when it becomes dark or clogged with debris so that water flow is not blocked (1-3 months).





Replacement Filters are available from Veterinary Services and Supplies, LLC (package of 3 filters—VSS2040).

- Close any water valves and bleed all water lines of residual water pressure.
- Disconnect the scaler water supply hose from the water supply at the quick-connect.
- 3. Remove the old filter disk by holding it in one hand and loosening it by twisting it off the hose connectors on either side. They rotate in opposite directions.
- 4. Install the new filter disk in the same position as the old one and tighten the connectors in reverse.
- 5. Reconnect the scaler water supply hose to the water supply via the quick-connect and check for leaks.

Note: If the filter becomes clogged and you do not have a replacement disk, the hose connectors may be locked together TEMPORARILY without the filter disk to allow emergency operation only. Water Filter is a single use part. Once replaced, the old water filter should be properly disposed in trash and must not be reused.

Troubleshooting

Unit does not operate ("power on" indicator does not light)

- Main ON/OFF switch is not set to on; Check that switch on rear panel is in up position.
- Power Adapter cable is disconnected from wall outlet or scaler. Reconnect properly.
- Wall outlet is not powered. Use different wall outlet.
- Unit fuse has failed. Contact Veterinary Services and Supplies, LLC.

Insert does not vibrate properly

- Faulty, damaged, or worn insert. Replace.
- Insert not correctly seated in handpiece. Reinsert properly.
- Use a new Veterinary Services and Supplies, LLC® brand insert.
- Power control not correctly adjusted. Readjust.

Excess heat at handle or tip of insert

- Faulty, damaged, or worn insert. Replace.
- Too little water flow. Insert may be blocked. Inspect & clear blockage or replace insert.
- · Power too high for water. Increase water flow.
- Excessive hand pressure applied. Correct technique.

No water spray when foot pedal is depressed

- Water line blocked or kinked. Correct.
- Water passage in the scaling insert clogged. Inspect and clear blockage or replace insert.
- · Water filter clogged. Replace.
- No water supply connected. Correct.

Insert does not go into handpiece

- Insert stack is bent. Straighten plates carefully by hand and reinsert.
- O-ring is too tight. Lubricate O-ring with water and use twisting motion to seat insert.
- · Autoclavable handpiece sheath is not attached to handpiece.

Insert falls out of handpiece or water leaks from front of handpiece

• O-ring damaged or worn. Replace O-ring on the insert.

Water leaks at base of handpiece

• Orange O-ring at end of handpiece missing or damaged.

Insert comes out of handpiece when pedal is depressed

 Water pressure is too high. Adjust water pressure to 15-35 psi at dental unit connection or in floor junction box or replace insert O-ring.

Scaling Power has reduced to minimum automatically

- Foot switch remained pressed continuously for more than 3 minutes. To avoid any accidental damage, scaling power was reduced to minimum after 3 minutes of continuous foot switch press. Scaling and water flow will be disabled completely after 10 minutes of continuous usage. This is normal.
- Release foot switch and press again. Contact Veterinary Services and Supplies, LLC for additional assistance.
- Upon activation, VSS® Millennium detects if there is no insert connected into the handpiece. VSS® Millennium then; disables output oscillator reducing power consumption and heat generation.
- VSS® Millennium detects insert stall and instantly recovers upon release of the tip preventing damage to the teeth / gum line / other anatomical structure during a clinical procedure by momentarily shutting down the oscillator and reducing power output significantly.
- Always Awake. Without a "Sleep" mode, VSS® Millennium always remains ready for activation while powered on. Position the foot pedal to avoid accidental activation.

User Maintenance and Authorized Service

The Veterinary Services and Supplies, LLC VSS® Millennium requires very little maintenance for years of trouble-free operation. There are no user-serviceable parts inside the control unit or the foot pedal. Opening the cases will void all warranties. Authorized Veterinary Services and Supplies, LLC personnel must make all internal repairs. Veterinary Services and Supplies, LLC urges all scaler users to monitor the condition of the water filter periodically and change the filter whenever noticeable darkening of the disk occurs, or when water flow decreases. The most common reason for service for ultrasonic scalers is failure by the user to periodically change the water filter. This will result in contamination and clogging of the internal water components.

The ultrasonic inserts, removable sheath, power supply, water filter and water hose are all detachable and may be replaced by the user. Contact Veterinary Services and Supplies, LLC for a list of authorized inserts and available replacement parts.

Within the US, all repairs must be made by authorized Veterinary Services and Supplies, LLC personnel. We maintain a complete service and parts facility in our factory at 415 State Route 34, Suite 210, Colts Neck, NJ 07722. Equipment needing service in the US should be returned, freight pre-paid, via approved common carrier (e.g., USPS, UPS, FedEx), and adequately insured. Return all accessories with the unit and include an explanation of the problem. Pack in the original box, add plenty of cushioning material, and over box the unit during shipping. Transit should maintain a dry temperature of 0°F-110°F. You will be contacted for your approval of the repair, along with any associated costs, prior to any work. The unit will be repaired and returned to you.

Outside the US, repairs must be made by a Veterinary Services and Supplies, LLC-authorized facility.

If you have any questions or problems with the installation or use of your VSS* Millennium, call 908-309-6272.

Warranty and Terms of Use

Please consult technical support at Veterinary Services and Supplies, LLC:

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Phone: 848-482-7201 Tech Support: 908-309-6272 **Email:** veterinaryservicesandsupplies@gmail.com

Conformance to Standards

The Veterinary Services and Supplies, LLC VSS® Millennium is TUV listed and conforms to IEC 60601-1, 60601-1-2 (Electromagnetic Compatibility of Medical Devices) and CAN/ CSA C22.2 No. 601.1. Veterinary Services and Supplies, LLC's quality system is certified to ISO13485.



Explanation of Symbols Used

(3)	Follow instructions for use
	Package contents
	Manufacturer
R	Qualified User Symbol
†	Medical Safety Classification Symbol
1	Temperature limitations
	Do not use if package is damaged
Ť	Keep dry
REF	Catalogue / stock number
UDI	Unique Device Identifier
MD	Medical Device
(Protective Earth Connection
Z	Do not dispose this product into the ordinary municipal waste or garbage system
2	Single use only
132 +1- 2°C	Sterilizable in a steam sterilizer (autoclave) at the temperature specified
2	Footswitch Connection
=== ♦•••	AC Power Connection
	Water Connection

