

Cavitron RF Combination System Ultrasonic Scaler and Air Polishing Prophylaxis System

Directions for Use

-Draft Form-

Rev-1 04/26/05

Rev-2 06/27/05

Rev-3 06/29/05

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Introduction

Welcome to the world of ultrasonic scaling and air polishing as experienced with a Cavitron® combination ultrasonic scaling and air polishing prophylaxis system, the original brand of ultrasonic scaling and air polishing systems. Your decision to add the Cavitron® JET RF™ system from DENTSPLY Professional to your practice represents a wise investment in good dentistry. Congratulations!

For over four decades, dental professionals have discovered the clinical benefits and labor-saving advantages inherent in Cavitron ultrasonic scalers. Clinical studies and independent research have proven that no other method of supra- and subgingival calculus removal can surpass the speed, efficiency, and versatility of ultrasonic scaling.

With the addition of air polishing capabilities in the Cavitron JET RF combination system, your Cavitron JET RF system becomes a compact prophylaxis center that maximizes the time spent performing scaling and polishing procedures and minimizes the need for strenuous calculus and stain removal with hand instruments. Clinical studies have proven that air polishing is far superior to traditional cup and pumice for stain and plaque removal. With proper technique and simple daily maintenance, your Cavitron® JET RF™ combination system will immediately become an indispensable component in your practice of modern preventive dentistry.

DENTSPLY® Professional is an ISO 13485 registered company. All DENTSPLY Professional medical devices sold in Europe are CE marked in conformance with Council Directive 93/42/EEC.

Website: www.professional.dentsply.com

Caution: Federal law restricts this device to sale by or on the order of a Dentist.

Product Overview

The Cavitron® RF™ Combination System is a precision engineered and manufactured instrument. It contains controls and components for ultrasonic scaling and air polishing modes. Mode selection is automatic when you place the JET Air Polishing Insert or one of the interchangeable 30K™ ultrasonic inserts into the handpiece.

In the scaling mode, the system produces 30,000 strokes per second at the ultrasonic insert's working tip that when combined with the cavitation effect of the coolant lavage creates a synergistic action that literally "powers away" the heaviest calculus deposits while providing exceptional operator and patient comfort.

In the air polishing mode, the system delivers a precise air/water/powder mixture at the JET air polishing insert tip that polishes the tooth enamel without contact so there is less abrasion to enamel and no physical pressure or heat build-up to cause discomfort in sensitive patients.

Technological advances in the Cavitron JET RF system, including a wireless footswitch, easy to view illuminated display, 330° swivel handpiece cable with lavage control, JET-Mate™ detachable, sterilizable handpiece, rinse setting, automated purge function, and Expanded SPS™ Technology, combine with established features like The Blue Zone™ extended low power range and Hands-Free Boost mode, to provide the ultimate in ultrasonic scaling experiences for both you and your patient while still providing the quality and reliability you've come to expect from Cavitron Brand ultrasonic systems.

Your Cavitron® JET RF™ combination system is UL/CSA certified and approved. The Cavitron® RF Combination System is classified by Underwriters Laboratories Inc. with respect to electric shock, fire, mechanical hazards in accordance with IEC 60601 Standard. The Cavitron RF Combination System complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: 1) this device may not cause harmful interference, and 2) this device must accept any interference received, including interference that may cause undesired operation. Cavitron RF base FCC certification/registration number: FCC ID: TF3-DPD73227323; IC: 4681B-73227323. Cavitron RF footswitch FCC certification/registration number: FCC ID: TF3-DPD81675; IC: 4681B-81675. The term IC before the certification/registration number only signifies that the Industry Canada technical specifications were met.

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Technical Support

There are no user serviceable parts in this device except for filter maintenance. Refer to Section 9.0 System Care for Maintenance Instruction. Refer all service to a qualified service repair facility. For technical support and repair assistance in the U.S., call the DENTSPLY Professional Cavitron CareSM Factory Certified Service at 1-800-989-8826, Monday through Friday, 8:00 A.M. to 5:00 P.M. (Eastern Time). For other areas, contact your local DENTSPLY[®] Professional representative.

Supplies & Replacement Parts

To order supplies or replacement parts in the U.S., contact your local DENTSPLY[®] Professional Distributor or call 1-800-989-8826 Monday through Friday, 8:00 A.M. to 5:00 P.M. (Eastern Time). For other areas, contact your local DENTSPLY[®] Professional representative.

Section 1: Indications for Use

1.1 Ultrasonic Procedures

- All general supra and subgingival scaling applications
- Periodontal debridement for all types of periodontal diseases.
- For patients with a history of sensitivity to ultrasonic scaling.
- Endodontic procedures.

1.2 Air Polishing Procedures

- Removal of a variety of extrinsic stains, e.g. tobacco, coffee & tea, chlorohexidine.
- Prophylaxis of orthodontic patients.
- Preparing tooth surfaces prior to bonding and sealant procedures.

Section 2: Contraindications and Warnings

2.1 Contraindications

- Ultrasonic Systems should not be used for restorative dental procedures involving the condensation of amalgam.
- Use only Cavitron[®] Brand Prophy Powders
 - Cavitron[®] PROPHY-JET Prophy Powders is a water-soluble sodium bicarbonate powder. Therefore, this powder is not recommended for patients on a sodium restricted diet.
 - Cavitron[®] JET-Fresh Prophy Powder is a sodium free powder and can be used on patients who are on a sodium restricted diets.
- Patients who have severe respiratory illness should consult their physician before undergoing air polishing prophylaxis procedures.

2.2 Warnings

- Persons fitted with cardiac pacemakers, defibrillators and other active implanted medical devices, have been cautioned that some types of electronic equipment might interfere with the operation of the device. Although no instance of interference has ever been reported to DENTSPLY, we recommend that the handpiece and cables be kept at least 6 to 9 inches (15 to 23 cm) away from any device and their leads during use.

There are a variety of pacemakers and other medical implanted devices on the market. Clinicians should contact the device manufacturers or the patient's physician for detailed information about the device.

- The use of High Volume Saliva Evacuation to reduce the quantity of aerosols released during treatment is highly recommended.
- Do not direct the air polishing stream at soft tissue or into the sulcus. Tissue emphysema has been reportedly caused when the air/water/powder stream was directed at the soft tissue or into the sulcus.

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- It is the responsibility of the Dental Healthcare Professionals (DHCP) to determine the appropriate uses of this product and to understand the health of each patient, the dental procedures being undertaken, and industry and governmental agency recommendations, requirements, and regulations for safe practice of dentistry.
- Where asepsis is required or deemed appropriate in the best professional judgment of the DHCP, this product should not be used.
- During boil-water advisories, this product should not be operated as an open water system (e.g. connected to a public water system). DHCP should discontinue use on patients and contact the local water authority to determine when it is safe to continue use of this product. When the advisory is cancelled, the local water authority should provide guidance for flushing of waterlines. All incoming waterlines from the public water system inside the dental office (e.g., faucets, waterlines, and dental equipment) should be flushed in accordance with manufacturer's instructions for a period of 2 to 5 minutes.
- It is suggested that prior to beginning treatment, patients should rinse with a known antimicrobial such as Chlorhexidine Gluconate 0.12%. Rinsing with an antimicrobial reduces the chance of infection and reduces the number of microorganisms the patient might release in the form of aerosols during treatment.
- Per FCC Part 15.21, changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

Section 3: Precautions

3.1 Precautions for All Systems

Ultrasonics

- For optimum performance use only inserts manufactured by DENTSPLY® Professional.
- 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.
- The system is portable, but must be handled with care when moving.
- Equipment flushing and dental water supply system maintenance are strongly recommended. See the Water Supply Recommendations, Water Line Requirements and System Care sections.
- Close manual shut-off valve on the dental office water supply every night before leaving the office.
- The use of an in-line water filter is recommended.
- Never operate the scaling mode without fluid flowing through handpiece.

Air Polishing

- The use of an air dryer on the compressor line supplying the System will prevent condensation from forming in the air line which in turn may cause "caking" of the air polishing powder and clogging of the lines and air polishing nozzle.
- Cavitron® Prophy Powders are specially formulated for use in Cavitron® Air Polishing Systems. Do not use any other cleaning materials in the air polishing powder reservoir.
- Empty the air polishing powder bowl at the end of the day to prevent "caking" of the powder and clogging of the lines and air polishing nozzle.
- Never operate the air polishing mode without fluid flowing through the handpiece.

3.2 Precautions for Ultrasonic Prophylaxis Procedures

- Like a toothbrush, ultrasonic inserts "wear" with use. Inserts with just 2 mm of wear lose about 50% of their scaling efficiency. In general it is recommended that ultrasonic inserts be discarded and replaced after one year of use to maintain optimal efficiency and avoid breakage. A DENTSPLY® Professional insert efficiency indicator is enclosed for your use.
- If excessive wear is noted, or the insert has been bent, reshaped or otherwise damaged, discard the insert immediately.
- Ultrasonic insert tips that have been bent, damaged, or reshaped are susceptible to in-use breakage and should be discarded and replaced immediately.
- Retract the lips, cheeks and tongue to prevent contact with the insert tip whenever it is placed in the patient's mouth.

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3.3 Precautions for Air Polishing Procedures

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- Only set the air polishing powder flow control to the maximum position (H) when it is necessary to remove particularly difficult stains. Return the powder flow control to the medium position upon the completion of the procedure.
- Avoid use on restorative dental materials.
- Avoid prolonged use on cementum or dentin.
- Avoid prolonged use on polished metal surfaces as a matte finish may result.
- Patients who have severe respiratory illness should consult their physician before undergoing air polishing prophylaxis procedures.
- Patients wearing contact lenses should remove them prior to air polishing treatment.
- JET Air Polishing Insert nozzles that have been bent, damaged or re-shaped, are susceptible to in-use breakage and should be discarded and replaced immediately.
- Check O-ring and threads on powder bowl cap to ensure a tight seal. If O-ring or threads are worn, replace immediately.
- Residual prophy powder in threads can result in excessive wear and disengagement of the cap during unit operation. Be sure to clean threads regularly as per Section 9: System Care.

Section 4: Infection Control

4.1 Infection Control Information Booklet

For your convenience, an Infection Control Information booklet has been included with your Cavitron® RF™ Combination System. Additional booklets can be obtained by calling Customer Service at 1-800-989-8826 Monday through Friday, 8:00 A.M. to 5:00 P.M. (Eastern Time). For other areas, contact your local DENTSPLY® Professional representative.

4.2 General Infection Control Recommendations

- As with all dental procedures, use universal precautions (i.e., wear face mask, eyewear, or face shield, gloves and protective gown).
- For maximal operator and patient safety, carefully follow the Infection Control Information procedures detailed in the enclosed Cavitron Systems Infection Control Procedures booklet accompanying your System.
- As with high speed handpieces, and other dental devices, the combination of water and ultrasonic vibration from you Cavitron® RF™ Combination System will create aerosols. With proper technique, much of the Cavitron® RF™ Combination System's aerosol dispersion can be effectively controlled and minimized. Please carefully follow the procedural guidelines in this manual regarding the use of your system.

4.3 Water Supply Recommendations

- It is highly recommended that all dental water supply systems conform to applicable CDC (Centers for Disease Control and Prevention) and ADA (American Dental Association) standards, and that all recommendations be followed in terms of flushing, chemical flushing, and general infection control procedures. See Sections 5.2 and 9.0.
- As a medical device, this product must to be installed in accordance with applicable local, regional, and national regulations, including guidelines for water quality (e.g. drinking water). As an open water system, such regulation may require this device to be connected to a centralized water control device. The Cavitron® DualSelect™ Dispensing System may be installed to allow this unit to operate as a closed water system.

Section 5: Installation Instructions

5.1 General Information

If the installation of your Cavitron® RF™ Combination System is performed by someone other than trained DENTSPLY® Professional Distributor personnel, care should be taken to observe the following requirements and recommendations.

DRAFT**5.2 Water Line Requirements**

- A water supply line with user-replaceable filter is supplied with your system. See Section 9.0 System Care for replacement instructions.
- Incoming water supply line pressure to the system must be 20 psi (172kPa minimum) to 40 psi (275kPa maximum). If your dental water system's supply line pressure is above 40 psi, install a water pressure regulator on the water supply line to your Cavitron® RF™ Combination System.
- A manual shut-off valve on the dental water system supply line should be used so that the water can be completely shut-off when the office is unoccupied.
- In addition to the water filter supplied, it is recommended that a filter in the dental water system supply line be installed so that any particulates in the water supply will be trapped before reaching the system.
- After the above installations are completed on the dental water supply system, the dental office water line should be thoroughly flushed prior to connection to the system.

5.3 Air Line Requirements & Recommendations

- An air supply line with a user-replaceable filter assembly is supplied with your Cavitron® RF™ Combination System. A filter mounting bracket is included for hanging the air filter. The clear bowl should hang downward allowing for moisture separation and drainage of water from the air filter. See Section 9.0 System Care for replacement instructions.
- Incoming air supply line pressure to the system must be 65 psig (448kPa) to 100 psig (690kPa). If your office air line pressure is above 100 psig (690kPa), install an air pressure regulator on the supply line to your Cavitron® RF™ Combination System.
- A manual shut-off valve on the office air supply line should be used so that the air line can be completely shut-off, and the line pressure relieved when the office is unoccupied.
- The system must be supplied with clean, dry air to help prevent water condensation from forming in the air supply line which may cause the system to malfunction. In addition to the air filter supplied with your system, it is strongly recommended that an air dryer be used on the compressor line supplying the system.

5.4 Electrical Requirements

- Incoming power to the system must be 100 volts AC to 240 volts AC, single phase 50/60 Hz capable of supplying 1.0 amps.
- The system power should be supplied through the AC power cord provided with your system. The power cord should be attached to an approved hospital-grade AC wall outlet for safe and effective operation.

5.5 Unpacking the System

Carefully unpack your Cavitron® RF™ Combination System and verify that all components and accessories are included:

1. Cavitron® RF™ Combination System and factory installed handpiece cable assembly
2. Air Line Assembly (Black) with Filter and Quick Disconnect
3. Water Line Assembly (Blue) with Filter and Quick Disconnect
4. Additional Water Line Filter
5. Detachable AC Power Cord
6. Cordless Foot Control Assembly
7. "AA" Batteries
8. Auxiliary Cable for cordless Footswitch
9. Cavitron® JET Air Polishing Nozzle with cleaning tool
10. Jet-Mate Detachable Sterilizable Handpiece
11. Prophy Handpiece Cleaning Wire
12. Cavitron® Ultrasonic Inserts (quantity optional)
13. Efficiency Indicator for Cavitron Inserts
14. JetShield™ Aerosol Reduction Device Kit
15. Literature Packet
16. PROPHY-JET® Sodium Bicarbonate Prophy Powder
17. JET-Fresh® Aluminum Trihydroxide Prophy Powder

5.6 System Installation

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- The Cavitron® RF™ Combination System is designed for a level surface. Be sure unit is stable and resting on four feet.
- Placing unit in direct sunlight may discolor plastic housing.

5.7 Power Cord/Power Connection

(Picture)

- Verify the main Power Control ON/OFF switch, located at the center front underside of the system, is set to the OFF position before proceeding.
- Insert the detachable AC power cord into the power input on the back of the system.
- Insert the pronged plug into an approved AC wall outlet.

5.8 Water Supply Line Connection

(Picture)

- Grasp the Water Supply Line (blue hose) by the end closest to the water filter and insert it into the water receptacle located toward the bottom center of the back panel until the hose cannot be pushed in any further.
- Connect the free end of the water supply line to the office water supply line or a Cavitron® DualSelect™ Dispensing System. If your system's water supply line is provided with a quick disconnect, connect the quick disconnect to the dental office water supply line or a Cavitron® DualSelect™ Dispensing System.
- Inspect all connections to make certain there are no leaks.
- To remove the water line from the Cavitron® RF™ Combination System, turn off the dental office water supply. Disconnect the water supply line from the dental office water supply. If a quick-disconnect connector is attached to the end of the hose, relieve the water pressure by pressing the tip of the connector in an appropriate container and allow water to drain. To remove hose from the system, push on the outer ring of the systems water inlet and gently pull the water line out.

5.9 Air Supply Line Connection

(Picture)

- Grasp the Air Supply Line (black hose) into the air receptacle located at the lower left corner of the back panel until the hose cannot be pushed in any further.
- Connect the free end of the air supply line to the dental office air supply or a Cavitron® Dual Select™ Dispensing System. If your system's air supply line is provided with a quick disconnect, connect the quick disconnect to the dental office air supply or a Cavitron® DualSelect™ Dispensing System.
- Inspect all connections to make certain there are no leaks.
- To remove the air supply line from the Cavitron® RF™ Combination System, turn off the dental office air supply. Disconnect the air supply line from the dental office air supply, then push on outer ring of the system's air inlet and gently pull out air line.

5.10 Footswitch Battery Replacement

(Picture)

- Turn footswitch over and using a Philips screwdriver, carefully remove battery cover screw and battery cover.
- Remove used batteries and install two new "AA" batteries as shown. Discard used batteries in accordance with local, state and regional regulations.
- Replace battery cover and screw and hand tighten with Philips screwdriver.

5.11 Footswitch Synchronization

Your Cavitron® RF™ System comes equipped with a footswitch which has remote operation capabilities. To ensure that the particular footswitch sent with your Cavitron RF system works with the system base, a unique address has been programmed into both the system base and the footswitch. If for any reason address synchronization is required, your Cavitron RF System has been designed so that this can be performed in the operatory environment. Perform the following steps to synchronize the footswitch with the system base.

1. Turn the main Power Control switch located at the center front underside of the System to the OFF position.
2. Install a new set of "AA" batteries into the footswitch. (See Section 5.8) Leave the battery cover of the footswitch open so the red button switch is accessible.

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3. Maintain a distance of no more than 10 feet between the system base and footswitch during the synchronization process.
4. Turn the main Power Control switch to the ON position and wait for the Information Center graphics (refer to Section 6.2) to light.
5. While all graphics are lit, press the Purge button, also located on the Information Center. The graphics will begin to blink in a sequential pattern, representing the synchronization mode. This mode will last 5 to 6 seconds.
6. During this mode, press the red button located in the battery compartment of the footswitch. This will complete the synchronization process.
7. Synchronization is successful when all graphics blink at the same time.
8. To verify proper communication, press the footswitch to the Boost position (footswitch fully pressed – 2nd position) and ensure the Boost graphic on system base lights.
9. Replace battery cover.

Section 6: Cavitron® RF™ Scaler Description

6.1 System Controls

(Picture of Unit / Handpiece / Cable / Footswitch)

Main Power ON/OFF Switch

ON/OFF Switch located at the center front underside of the system. The ON/OFF switch disconnects power to all internal electrical circuits in the system base.

Ultrasonic Power Control

Turn knob to select ultrasonic power level for operation: clockwise increases system power, counter clockwise decreases system power. For Air Polishing Procedures, the knob must be set past the Blue Zone.

The Blue Zone is an extended low-power range providing effective subgingival debridement and greater patient comfort during definitive therapy. This zone cannot be used during air polishing procedures.

Rinse

Turn Ultrasonic Power Control knob fully counter clockwise until “click” is heard. Rinse mode is for use during an ultrasonic scaling procedure when lavage is wanted without ultrasonic tip action.

Information Center

See Section 6.2.

Handpiece

Accepts all Cavitron® 30K™ Ultrasonic inserts and transmits power and lavage from the System to insert. It also accepts the Cavitron® JET Air Polishing Insert which automatically selects air polishing mode.

Handpiece Holder

Securely holds the system’s Handpiece (with or without insert) when the system is not in use. Also holds cable connector when handpiece is not installed.

Powder Fill Cap

Removable cap for filling and emptying the powder bowl. An adjustable pointer increases or decreases powder flow rates.

Lavage Control (Flow Adjustment)

See Section 6.3

Foot Control

See Section 6.6

6.2 Information Center Graphic Displays and Control

(Picture)

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Power – (Display) Lights when the Power ON/OFF Control Switch is ON.

Low Battery – (Display) Lights when the footswitch battery power is approaching end of life. Replace batteries as instructed in Section 5.8.

Service – (Display) Lights when the system is not functioning properly. This display has two distinct modes. A **blinking light** indicates an incorrect set-up in the system, such as a missing handpiece. Correct the set-up and press the footswitch for a second to stop the blinking. The service light may blink briefly while installing or removing your insert. Should this occur, release and press the footswitch for a second and the light will stop blinking. A **steady light** indicates an internal operating parameter shift. The system will still function properly without harm to user or patient. Have your system serviced. Refer to Section 10.2 for Technical Support and Repairs.

Boost – (Display) Lights when the Boost Mode has been activated by the footswitch (fully depressed to 2nd position).

Blue Zone– (Display) Lights when the Ultrasonic Power Control knob is positioned in the blue zone of the power scale. (Use the Blue Zone extended low-power range for effective subgingival debridement and greater patient comfort during definitive therapy.)

Rinse – (Display) Lights when the Ultrasonic Power Control knob is turned fully counter clockwise. With an insert in the handpiece, activate the footswitch and lavage, with minimal cavitation will occur. (Use the Rinse mode when irrigation is wanted to flush the procedural area.)

Purge – (Display and Control) Lights when the Purge function is activated. To activate Purge, remove insert from the handpiece, press the Purge button and water will purge through system lines for 2 minutes. To deactivate mode during the 2 minute cycle, press Purge button again or press Foot Control.

6.3 Handpiece / Cable Connection

(Picture)

- The Cavitron® JET-Mate Sterilizable Handpiece accepts all Cavitron® 30K Ultrasonic Inserts and JET air polishing insert.
- Lavage Control – Turn the Lavage Control to select flow rate during system operation. Clockwise increases flow at insert tip, counter clockwise decreases flow. The flow rate through the handpiece also determines the temperature of the lavage. Lower flow rates produce warmer lavage. Higher flow rates produce cooler lavage. If the handpiece becomes warm, increase the flow rate. With experience you will be able to determine the best flow rate setting for optimum operating efficiency and patient comfort.
- Prior to connecting, align the handpiece and Cable Assembly electrical connections. If Cable Assembly does not seat into handpiece, gently rotate handpiece until contacts align.
- Powder Delivery Port – creates an airtight seal between the air polishing insert and the handpiece.
- Swivel Feature – reduces cable drag as handpiece rotates during procedures.
- Insert Port – creates a watertight seal between the insert and the handpiece.
- Soft Grip – provides an ergonomic and comfortable grasp of the handpiece.

6.4 Cavitron® 30K™ Ultrasonic Inserts

(Picture from current DFU's)

O-Ring

Provides a watertight seal when the insert is fully seated in the handpiece. O-ring should be replaced when worn.

Connecting Body

Transfers and amplifies mechanical motion of stack to insert tip.

Magnetostrictive Stack

Converts energy provided by the handpiece into mechanical oscillations used to activate the insert tip. Warms lavage for patient comfort.

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Insert Tip

Shape and size of tip determines access and adaptation.

Insert Marking

Manufacturer, Date (YYMM),

Frequency, Insert Type (E.g. DENTSPLY 0508 30K FSI-SLI-10S)

- Hold the handpiece in an upright position. Activate the Foot Control to bleed any air bubbles that might be trapped inside the handpiece. Lubricate the O-ring on the insert with water before placing it into the handpiece. Fully seat insert with a gentle push-twist motion. **DO NOT FORCE.**
- The many styles of Cavitron® 30K™ Ultrasonic Inserts are easily interchangeable for various procedures and applications. See enclosed booklet for specific information.

6.5 Cavitron® JET Air Polishing Inserts

(Picture from current DFU's)

Air Polishing Insert Nozzle

Tube-in-tube design delivers precise air/water/powder mixture at point of delivery.

Prophy Powder Delivery Tube

Directs air/water powder flow to nozzle

Insert Rod

Warms lavage for patient comfort.

O-Ring

Provides a watertight seal when the insert is fully seated in the handpiece. O-ring should be replaced when worn.

- The Air Polishing Insert automatically selects the Air Polishing mode when placed in the handpiece.
- Lubricate the rubber O-ring on the insert with water before placing it into the handpiece. Place the insert rod into the insert port of the handpiece. Align the powder delivery tube with the powder delivery port and gently push into handpiece until fully seated.

6.6 Foot Control Information and Operation

The Foot Control is a two-positioned momentary switch. The first position activates both ultrasonic energy and lavage at the insert tip for scaling procedures and lavage only (rinse) at the air polishing insert nozzle for air polishing procedures. The second position (fully depressed footswitch) activates Boost Mode while scaling and, with a JET insert present in the handpiece, enables air/powder/water slurry for air polishing procedures. The Boost Mode provides capability to briefly increase the system's ultrasonic power output for quick / efficient removal of tenacious deposits using only the foot control without touching the system base.

- Pressing anywhere on the top of the footswitch activates the base unit.
(Picture showing released, 1st position, 2nd position)
- In the event that the batteries do run low and new batteries are not available for replacement, an auxiliary cord is supplied to provide emergency control.
(Picture to show hook-up)

Section 7: Accessories and User Replaceable Parts

7.1 Accessories

1. AC Power Cord
2. Dual Position Foot Control (Cordless)
3. Auxiliary Footswitch Cable
4. Cavitron® JET-Mate Sterilizable Handpiece
5. Prophy Handpiece Cleaning Wire
6. Cavitron® Ultrasonic Insert

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7. Cavitron® DualSelect™ Dispensing system
8. Cavitron® JET Air Polishing Insert
9. Cavitron® JET Nozzle Cleaning Tool
10. JetShield® Aerosol Reduction Device

7.2 User Replaceable Part Kits

1. Powder Bowl Cap O-ring, Part Number 628052001
2. Powder Bowl Cap, Part Number 81728
3. Cavitron Insert Replacement O-ring 12/Pack, Part Number 62351
4. Handpiece Cable O-ring , Part Number 79357
5. Jet-Mate Handpiece Nozzle Grip, 81717
6. Lavage (Water) Filter, 10/Pack, Part Number 90158

For detailed information, contact your local DENTSPLY® Professional Representative or authorized DENTSPLY® Professional Distributor.

Section 8: Techniques for Use**8.1 Patient Positioning**

(Picture)

For optimal access to both the upper and lower arches, the backrest of the chair should be adjusted as for other dental procedures. This assures patient comfort and clinician visibility.

Have the patient turn his/her head to the right or left. Also position chin up or down depending upon the quadrant and surface being treated. Evacuate irrigant using either a saliva ejector or High Volume Evacuator (HVE).

8.2 Performing Ultrasonic Scaling Procedures

- Note: Refer to the Infection Control Information Booklet supplied with your system for general procedures to be followed at the beginning of each day and between patients.
- The edges of Cavitron® Ultrasonic Inserts are intentionally rounded so there is little danger of tissue laceration with proper ultrasonic scaling technique. Whenever the insert tip is placed in the patient's mouth, the lips, cheek and tongue should be retracted to prevent accidental (prolonged) contact with the activated tip.
- Hold the empty Handpiece in an upright position over a sink or drain. Activate the Foot Control until water exits.
- Lubricate the rubber O-ring on the insert with water before placing it into the handpiece. Fully seat insert with a gentle push-twist motion. **DO NOT FORCE.**
- Activate the System. Hold the handpiece over a sink or drain. (Check spray to verify fluid is reaching the working end of the insert tip). Adjust the water control to ensure adequate flow for the selected power setting. Greater flow settings provide cooler irrigation.
- It may be necessary to adjust lavage with the System in "Boost" mode (Foot Control fully depressed) so adequate fluid will be available to cool tip tooth interface.
- In general, it is suggested that a "feather-light-touch" be used for ultrasonic scaling. The motion of the activated tip and acoustic effects of the irrigating fluid, in most cases, are adequate to remove even the most tenacious calculus.
- Periodically check the Cavitron Ultrasonic Insert for wear with the Cavitron Insert Efficiency Indicator.
- The use of a saliva ejector or High Volume Evacuator (HVE) is recommended during all procedures.
- Set the System's Ultrasonic Power Control knob to the lowest efficient power setting for the application and the selected insert.

8.3 Patient Comfort Considerations

Reasons for sensitivity

- Incorrect tip placement. The point should never be directed toward tooth root surfaces.
- Not keeping tip in motion on tooth. Do not allow the insert to remain in a static position on any one area of the tooth. Change the insert's path of motion.

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- Applying excessive pressure. Use a very light grasp and pressure, with a soft tissue fulcrum whenever possible, especially on exposed cementum.
- If sensitivity persists, decrease power setting and/or move from the sensitive tooth to another and then return.

8.4 Air Polishing Powder bowl

- Use only Cavitron® Prophy Powder in your Cavitron® RF™ Combination System. Any other substance or additives may clog the system and will void the warranty. For your convenience, the prophy powders are supplied in bottles. Keep stored in a location that does not exceed 95°F.
- A special container is provided with your System for use in emptying the powder bowl.
- It is strongly recommended that the Powder bowl be emptied at the end of each day. This will reduce moisture absorption and minimize clogging.

To fill, or refill, the Powder bowl: (Picture)

- Turn the System OFF.
- Unscrew the Powder Fill Cap.
- With the cap of the powder bottle closed, shake the powder bottle vigorously to break up any lumps that may have formed from settling. Carefully pour powder into the bowl until the level reaches the top of the center tube.
- Replace the Powder Bowl Cap and tighten.
- Turn the System ON.

NOTE: Use only Cavitron® Prophy Powders in the system. Powder should be kept dry and stored in a location that does not exceed 95°F.

To adjust the flow of powder:

- Adjust the powder flow rate by positioning the control on the cap at H (12 o'clock), M (9 o'clock) or L (6 o'clock).
- For heavy stain removal set the control to H.
- For light stain removal set the control to L.
- The control can be set at any position between H and L.
- The view window at the center of the pointer lets you observe the powder flow (small white circle of powder) during operation. If no flow is seen, check for clogging or add prophy powder.

8.5 Air Polishing using the JetShield™ Aerosol reduction device Accessory

Jet-Shield Precautions:

The JetShield™ cup assemblies are designed for single use only. Use of chemical or heat sterilization will lead to poor performance and malfunction of product.

The reusable components are wipe-disinfectable, using clean cloths and appropriate non-immersion type disinfectant. Wipe once with disinfectant to remove bioburden, then use a fresh cloth and more disinfectant to clean surface. Dry with clean paper towel or air.

JET-Shield Set-Up Instructions:

1. Remove entire assembly from package.
2. Insert air polishing nozzle through cup and seat shoulder flush on nozzle. See Figure 2A.
3. Insert small barb from ejector tube into evacuation tube of cup assembly.
4. Insert large barb from ejector tube into operator saliva ejector.

Figure 1.

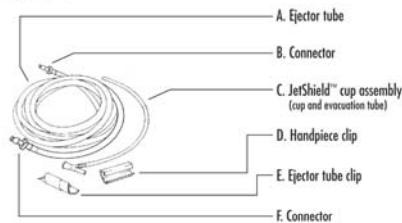


Figure 2A.

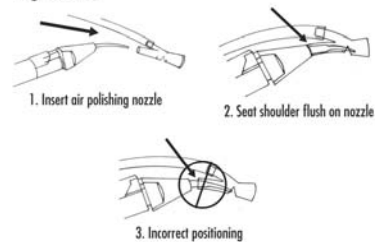
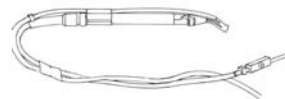


Figure 3A.



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5. Place ejector tube clip around ejector tube and handpiece cable such that the cables drape together for patient and clinician comfort.
6. (Optional) Place handpiece clip such that the clip is holding the JetShield™ evacuation tube in place along handpiece as shown in applicable Figure 3.

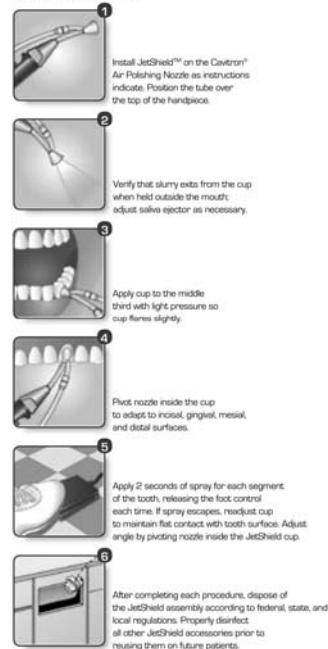
After completion of each procedure, remove JetShield™ cup assembly and dispose of according to applicable regulations. Wipe-disinfect all other components before next use.

8.6 Performing JET Air Polishing Procedures with JetShield™

NOTE: Refer to the Infection Control card supplied with your System for general procedures to be followed at the beginning of each day and between patients.

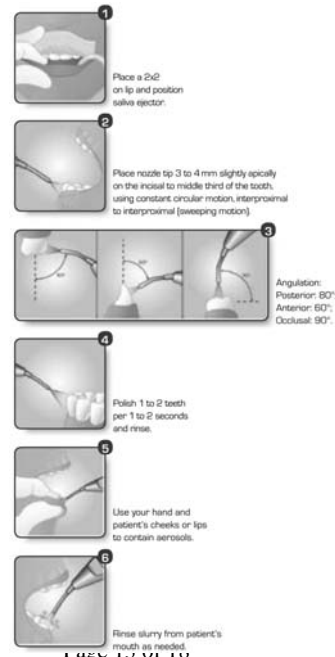
- Adjust JetShield™ on the Cavitron® Air Polishing Insert nozzle as indicated on instructions provided.
- Select the appropriate amount of powder using the dial on the air polishing systems' powder bowl.
- Verify that slurry exits from the cup when held outside the mouth; adjust saliva ejector as necessary.
- Divide the tooth visually into segments to polish (incisal, middle and gingival).
- Apply cup to middle third with light pressure so cup flares slightly.
- Pivot nozzle inside the cup to adapt to incisal, gingival, mesial and distal surfaces.
- Apply two seconds of spray for each segment of the tooth, releasing the Foot Control each time. If spray escapes, readjust cup to maintain flat contact with tooth surface. Adjust angle by pivoting nozzle inside the JetShield™ cup.
- The suction from the JetShield™ can be used to remove excess saliva from the patient's mouth.
- After completing each procedure, dispose of clear JetShield™ assembly according to Federal, State and local regulations. Properly disinfect all other JetShield™ accessories prior to reusing on future patients.

With JetShield™



8.7 Performing Air Polishing procedures without JetShield™

- The recommended normal procedure is to clean 2-3 teeth with the air polishing spray (Foot Control depressed to the second position) and then rinse the area with water only (Foot Control depressed to the first position) to inspect the work site before proceeding to the next 2-3 teeth. If desired, the bleed air (Foot Control released) passing through the air polishing insert tip can be used to dry the work site during inspection.
- Flushing the patient's tongue with water only (Foot Control depressed to first position) helps reduce the saline taste.
- Place a 2 x 2 gauze on lip and position saliva ejector.
- Maintain a 2 to 4 mm insert tip-to-tooth operating distance.
- The patient's lip should be held between the thumb and index finger of your free hand and pulled out and up, or down, to form a "cup". Do not retract the lips.
- Tilt the patient's head toward you to help prevent puddling in the cupped lip and minimize aerosol dispersion.
- Use saliva ejector or High Volume Evacuator (HVE).
- In the upper anterior region, use the upper lip and your hand as a shield to help contain the aerosol spray.
- In the posterior regions, use the cheek to help contain aerosol spray.
- When air polishing the facial surfaces of the anteriors, center the spray on the middle third of the tooth and use a constant circular motion. The edge of the spray will clean the teeth to the gingival.



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- Do not aim directly at the soft tissue.
- Avoid prolonged use on polished metal surfaces as a matte finish may result.

8.8 Proper Angulation of the Air Polishing Insert without JetShield™

- Recommended angulation on the anterior teeth is 60° with the tip aimed at the middle third of the tooth surface.
- Recommended angulation to occlusal surfaces is 90°.
- Recommended angulation on the buccal and lingual surfaces of posterior teeth is 80° with the tip aimed slightly distally.

Section 9: System Care

It is recommended that you perform the following maintenance procedures to help maximize water quality and to be in compliance with CDC guidelines for infection control.

9.1 Daily Maintenance**Start-Up Procedures at the beginning of the day:**

1. Open the manual shut-off valve on the dental office water supply system.
2. With the RF system OFF, unscrew the powder bowl cap. Verify the powder bowl is empty. Turn the system ON for 15 seconds to eliminate residual moisture in the lines. Turn the system OFF.
3. Shake the powder bottle well to create an even consistency of powder mixture.
4. Pour enough powder into the bowl for the procedure to be performed. With experience the Dental Health Professional will be able to determine the amount of powder required. Do not fill above the top of the center tube.
5. Secure the cap on the powder bowl.
6. Install a sterilized JET-Mate Handpiece onto the handpiece cable.
7. Set the Power Adjustment knob to the minimum and the Lavage Control knob to maximum.
8. Turn the system ON.
9. If powder fluffing is observed when Foot Control is not in use, this would indicate an air leak. To correct, turn the System OFF, remove the Powder Cap, clean any residual powder from the O-ring seal and threads, replace the Powder Cap, tighten, and turn the System back ON.
10. Hold the handpiece (without an insert or nozzle insert installed) over a sink or drain. Activate the Purge button with water flow set to maximum.
 - The Purge button will light for two minutes indicating proper activation of the purge function.
 - If the Purge button is activated with an insert present in the handpiece, the button will blink for 3 seconds and disable. Remove the insert from the handpiece and press the Purge button again.
 - The Purge function can be interrupted at any time during the two minute cycle by pressing the Purge button again or by pressing the footswitch.
11. After the purge cycle is complete, and when ready for use, place a sterilized 30kHz Cavitron® Ultrasonic Insert into the handpiece and set the Power and Lavage Control knobs to your preferred operating position for ultrasonic scaling. For air polishing, place a sterilized JET Air Polishing Insert into the handpiece and adjust the Powder Flow and Lavage Control knobs to your preferred positions.

Between Patients:

1. Remove the used Cavitron® Ultrasonic Insert or JET Air Polishing Insert. Clean and sterilize following the Infection Control Procedures that were enclosed with your insert.
2. Hold the handpiece over a sink or drain and activate Purge function as described in Step 10 of the Start-Up procedure.
3. After the purge cycle is complete, turn the System OFF.
4. Remove JET-Mate handpiece, clean and sterilize following the procedures outlined in the Cavitron Systems Infection Control Procedures booklet that was enclosed with your system.
5. Disinfect the surfaces of the cabinet, Power Cord, Handpiece Cable, and Foot Control and cable assembly (if applicable) by applying an approved non-immersion type disinfectant solution* carefully following the instructions provided by the disinfectant solution manufacturer. To clean System, generously spray disinfectant solution on a clean towel and wipe all surfaces. Discard used towel. To disinfect system, generously spray disinfectant on a clean towel and wipe all surfaces. Allow disinfectant solution to air dry. Never spray disinfectant solution directly on the System.

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6. Inspect the handpiece cable for any breaks or tears.
7. If using a closed water supply or DualSelect Dispensing System, check for adequate fluid volumes for next procedure.
8. Check the powder bowl for sufficient powder for the next procedure.
9. When ready to use, place a sterilized JET-Mate Handpiece onto the handpiece cable assembly and insert a sterilized ultrasonic insert or air polishing insert into the handpiece and adjust system controls as preferred.

Shut-Down Procedures at the end of the day

1. Remove the used Cavitron® Ultrasonic Insert or JET Air Polishing Insert. Clean and sterilize following the Infection Control Procedures that were enclosed with your insert.
2. Hold the handpiece over a sink or drain and activate Purge function as described in Step 10 of the Start-Up Procedures.
3. After the purge cycle is complete, turn the System OFF.
4. Remove JET-Mate handpiece, clean and sterilize following procedures outlined in the Cavitron Systems Infection Control Procedures booklet that was enclosed with your system.
5. Slowly unscrew the powder bowl cap and set aside.
6. Remove the powder bowl from the cabinet. Empty the powder from the bowl using the powder removal/storage jar. It is recommended that the unused powder be discarded to minimize the chance of moisture contaminated powder clogging your system.
7. Hold the open end of the powder bowl away from you. Activate the system for 15 seconds to clear the powder bowl. A high volume evacuator can be used to remove any residual powder.
8. Remove the o-ring seal from the powder bowl cap. Using a soft dry cloth, clean any residual powder from the o-ring and the cap. Ensure that the threads of the cap are clean. Be careful not to scratch or otherwise damage the plastic cap.
9. Using a dry cloth, remove residual powder from the powder bowl threads. Secure the cap on the powder bowl.
10. Disinfect the surfaces of the cabinet, Power cord, Handpiece cable assembly, Foot Control and cable assembly (if applicable) by applying an approved non-immersion type disinfectant solution* carefully following the instructions provided by the disinfectant solution manufacturer. To clean system, generously spray disinfectant solution on a clean towel and wipe all surfaces. Discard used towel. To disinfect system, generously spray disinfectant on a clean towel and wipe all surfaces. Allow disinfectant solution to air dry. Never spray disinfectant solution directly on the System.
11. Inspect the handpiece cable for any breaks or tears.
12. Close the manual shut-off valve on the dental water supply system.

*NOTE: Water-based disinfection solutions are preferred. Some alcohol-based disinfectant solutions may be harmful and may discolor plastic materials.

End of Week Procedures

If the System is connected to a DualSelect™ Dispensing System, follow the recommended procedures listed in the DualSelect™ manual.

9.2 Weekly Maintenance

Remove residual prophy powder from the cap and bowl threads using a soft brush (toothbrush). If not removed, caked powder in threads can result in thread wear and powder bowl cap disengagement.

9.3 Lavage Filter Maintenance

When the Lavage filter becomes discolored, the filter should be replaced to prevent reduced lavage flow to the system. A 10-pack of replacement filters is available by ordering Part Number 90158 from your local DENTSPLY® Professional distributor.

1. Verify that the system is turned OFF.
2. Disconnect the water supply line from the dental office water supply. If a quick disconnect connector is attached to the end of the hose, relieve the water pressure by pressing the tip of the connector in an appropriate container and drain the water.
3. Grasp the fittings on either side of the filter disk and twist counterclockwise. Remove the filter section from either side of the water hose.

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4. Install the replacement filter onto the water hose fittings. The filter should be positioned to match up with the correct hose fitting.
5. Hand tighten the two hose fittings in a clockwise direction. Reconnect the water supply line, turn the system ON and operate lavage flow to bleed the air and test for leaks.

9.4 Air Supply Line Air Filter Maintenance

Water build up in the air supply line filter should be drained. This can be accomplished by turning the knob on the bottom of the filter counter-clockwise to open. After draining, turn the knob fully clockwise to close. If the inner filter element becomes discolored or dirty, a new filter assembly should be installed. Replacement filter assemblies are available by ordering Part Number 90088 from your local DENTSPLY® Professional distributor.

1. Verify that the system is turned OFF.
2. Disconnect the air supply line from the dental office air source.
3. Using pliers or a wrench, loosen the nuts on the side fittings of the filter. Unscrew the nuts and slide them down the hose. Disconnect hoses from the filter and discard the used filter.
4. Insert the short hose into the input part of the filter and the long hose into the output port of the filter. Slide the nuts up the hoses and screw onto the fittings. Tighten using pliers or a wrench.
5. Turn the System ON, operate the system and check for leaks.

9.5 Powder Bowl Maintenance

1. Turn the System OFF.
2. Allow the powder bowl to depressurize and unscrew the Powder Cap.
3. Empty powder from the bowl and use the high suction to remove any residual powder in the bowl.
4. Turn System ON and check for strong air flow from the center tube of the powder bowl.
5. If no or low air flow is present, turn the System OFF.
6. Unscrew the knurled ring at the bottom of the bowl assembly and remove the fitting assembly.
7. Using the JET Air Polishing Insert nozzle cleaning wire tool, clean clogged powder from the fitting assembly. Turn the System ON and check for strong air flow.
8. Check that the o-ring is properly positioned in the groove of the fitting assembly and reassemble the fitting assembly to the bowl. Tighten knurled ring. Place powder bowl into System.
9. Fill the powder bowl with fresh prophylaxis powder and test for flow and leaks.

Section 10: Troubleshooting

Although service and repair of the Cavitron® RF™ Combination System should be performed by DENTSPLY® personnel, the following are some basic troubleshooting procedures that will help avoid unnecessary service calls. Generally, check all lines and connections to and from the System, a loose plug or connection will often create problems. Check the settings on the System's knobs.

10.1 Troubleshooting Guide

Symptom - System will not operate (no Power ON indicator):

1. Check that the ON/OFF switch is in the ON (I) position, and that the detachable Power Cord is fully seated in the receptacle on back of System.
2. Check that the system's pronged plug is fully seated in an appropriate AC wall outlet.
3. Check that the wall outlet is functional.

Symptom- System operates: (No water flow to insert Tip)

1. Assure that water control is properly adjusted.
2. Check that the dental office water supply valves are open.
3. If connected to DualSelect Dispensing System, check that fluid level in the selected bottle is sufficient. Make sure valves are open when using external water source.
4. Check that lavage filter is clean. Replace lavage filter if needed, refer to Section 9.3.

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Symptom – System operates: (No insert cavitation)

1. Check that the Ultrasonic Power Control knob is not in rinse mode.
2. Check that the Low Battery light is not lit.
3. Turn the system's main power switch OFF. Wait 5 seconds and turn the system back ON.
4. If problem still exists, replace both "AA" batteries in footswitch with new "AA" batteries. Refer to Section 5.8.
5. Connect the auxiliary footswitch cable to footswitch and system base.
6. Check the insert for damage and that it is properly installed in the handpiece.
7. Check that the handpiece is properly installed to the cable assembly.
8. Resynchronize the footswitch to the system base. Refer to Section 5.9.

Symptom – System operates: (Maintenance Mode will not function – icon flashing)

1. Check that handpiece has insert or nozzle insert removed.
2. Check that handpiece is properly installed to the cable assembly.

Symptom – System operates: (JET Air Polishing Insert nozzle blocks repeatedly)

1. Powder is contaminated (lumpy). Discard powder.
2. Air Supply Line Air Filter is contaminated. Refer to Section 9.4 Air Supply Line Air Filter Maintenance.

Symptom – System operates: (No bleed air.)

1. Blocked JET Air Polishing insert nozzle. Clean nozzle using supplied tool.
2. Blocked air bleed "duckbill" air filter. Have unit serviced by qualified service repair facility.

Symptom – System operates: (No or poor cleaning action.)

1. Very low powder level or empty Powder bowl. Fill Powder bowl.
2. Blocked JET Air Polishing insert nozzle. Clean nozzle using supplied tool.
3. Powder Cap loose. Tighten Powder Cap and turn System ON. If cap does not fit tightly, check for thread wear and replace cap or bowl assembly.
4. Clogged fitting assembly on Powder bowl. Refer to Section 9.5 Powder bowl Maintenance.

Symptom – System operates: (Continuous powder agitation.)

Powder Cap not securely sealed. Turn System OFF. Remove the o-ring seal from the Powder Cap and clean residual powder from the cap. Be careful not to scratch or otherwise damage the plastic cap. Wipe off the o-ring and place it in the Powder Cap and turn system ON. Worn caps and o-rings should be replaced when wear is noted.

10.2 Technical Support and Repairs

For technical support and repair assistance call DENTSPLY Professional Cavitron CareSM Factory Certified Service at 1-800-989-8826 Monday through Friday, 8:00 A.M. to 5:00 P.M. (Eastern Time). For other areas, contact your local DENTSPLY® Professional representative.

Section 11: Warranty Period

The Cavitron[®] RFTM Combination Ultrasonic Scaler and Air Polishing System is warranted for TWO YEARS from date of purchase. The JET-MateTM Handpiece enclosed with your system is warranted for SIX MONTHS from date of purchase. Refer to the Warranty Statement Sheet furnished with your system for full Warranty Statement and Terms.

In addition, the Printed Circuit Boards, or Micro Circuit Module, are warranted for a full FIVE YEARS from date of purchase.

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(Include required symbols)

Electrical Voltage	Continuous (100-240 VAC)
Current	1.0 Amperers, Maximum
Frequency	50/60 Hertz
Water Pressure	20-40 psig
Air Pressure	65-100 psig
Flow Rate	Minimum Setting (CCW) < 15 ml/min Maximum Setting (CW) > 55 ml/min
Weight	4.4 lbs (2 Kg)
Dimensions	Height 6 in (15,24 cm) Width 9.5 in (24,13 cm) Depth 8 in (20,32 cm) Handpiece Cable length: 6.5 ft. (2.0 M) Auxiliary Footswitch Cable length: 8 ft. (2.4 M) Water Supply Line length: 8 ft. (2.4 M) Air Supply Line length: 10 ft. (3.04 M)
Footswitch	Not for operating theatres. Protection Class IPX1
Operating Environment	Temperature: 15-40 Deg. Celsius Relative Humidity: 30% to 75% (non-condensing)
Transport and Storage Conditions	Temperature: -40 to 70 Deg. Celsius Relative Humidity: 10% to 100% (non-condensing) Atmospheric Pressure: 500 to 1060 hPa

Section 13: Classifications

- Type of protection against electric shock: Class 1
- Degree of protection against electric shock: Type B
- Degree of protection against the harmful ingress of water: Ordinary
- Mode of operation: Continuous
- Degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide: Equipment not suitable for use in the presence of flammable anaesthetic or oxygen.
- According to medical device directive: IIA (rule 9)

Section 14: Disposal of Unit

- Accordance with local and state laws.