Cavitron RF Ultrasonic Scaler

Directions for Use

-Draft Form-

Rev-1 04/26/05

Rev-2 06/24/05

Rev-3 06/27/05

Rev-4 06/28/05

Rev-5 07/07/05

Rev-6 07/13/05

Rev-7 07/18/05

Rev-8 07/22/05

Rev-9 07/25/05

Rev-10 08/01/05

Introduction

Welcome to the world of ultrasonic scaling as experienced with a Cavitron[®] ultrasonic scaling system, the original brand of ultrasonic scaling systems. Your decision to add the Cavitron[®] RFTM Ultrasonic Scaler 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.

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® RFTM ultrasonic scaling system is a precision engineered and manufactured instrument. It contains controls and components for ultrasonic scaling.

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

Technological advances in the Cavitron RF system, including a wireless footswitch, easy to view illuminated display, 330° swivel handpiece cable with lavage control, Steri-MateTM Plus detachable sterilizable handpiece, rinse setting, automated purge function, and Expanded SPSTM Technology, combine with established features like The Blue ZoneTM 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® RFTM 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.

Technical Support

For technical support and repair assistance in the U.S., 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.

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

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.

Section 2: Contraindications and Warnings

2.1 Contraindications

 Ultrasonic Systems should not be used for restorative dental procedures involving the condensation of amalgam.

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 medically implanted devices on the market. Clinicians should contact the device manufacturer 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.
- 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

- 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 Section 9: System Care.
- 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 scaler without fluid flowing through handpiece.

3.2 Precautions for Ultrasonic Prophylaxis Procedures

- For optimum performance use only inserts manufactured by DENTSPLY® Professional.
- 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.

Section 4: Infection Control

4.1 Infection Control Information Booklet

For your convenience, an Infection Control Information booklet has been included with your Cavitron® RFTM 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 on the reference card accompanying your System.
- As with high speed handpieces, and other dental devices, the combination of water and ultrasonic vibration from you Cavitron® RFTM System will create aerosols. With proper technique, much of the Cavitron® RFTM 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 Dual Select™ 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® RFTM System is performed by someone other than trained DENTSPLY® Professional Distributor personnel, care should be taken to observe the following requirements and recommendations.

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® RFTM Ultrasonic Scaling 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 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.

5.4 Unpacking the System

Carefully unpack your Cavitron® RFTM System and verify that all components and accessories are included:

- 1. Cavitron® RFTM System and factory installed handpiece cable assembly
- 2. Detachable AC Power Cord set
- 3. Cordless Foot Control Assembly
- 4. "AA" Batteries
- 5. Auxiliary Cable for cordless Footswitch
- 6. Water Line Assembly (Blue) with Filter and Quick Disconnect
- 7. Additional Water Line Filter
- 8. Steri-Mate Plus Detachable Sterilizable Handpiece
- 9. Cavitron® Ultrasonic Inserts (quantity optional)
- 10. Efficiency Indicator for Cavitron Inserts
- 11. Literature Packet

5.5 System Installation

- The Cavitron® RFTM 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.

5.6 Power Cord/Power Connection

(Picture)

- Verify the Power Control ON/OFF switch, which is 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.

5.7 Water Supply Line Connection

(Picture)

- Grasp the Water Supply Line (blue hose) by the end nearest 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 opposite end of the water supply line to the dental office water supply 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 or a Cavitron® DualSelect™ Dispensing
 System.
- Inspect all connections to make certain there are no leaks.
- To remove the water line from the Cavitron® RFTM 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.

5.8 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 regulations.
- Replace battery cover and screw and hand tighten with Philips screwdriver.

5.9 Footswitch Synchronization

Your Cavitron® RFTM System comes equipped with a footswitch which has remote operation capabilities. To ensure 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 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.
- 3. Maintain a distance of no more that 10 feet between the system base and footswitch during the synchronization process.
- 4. Turn the 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.

Section 6: Cavitron® RFTM 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.

The Blue Zone is an extended low-power range providing effective subgingival debridement and greater patient comfort during definitive therapy.

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

Operates all Cavitron® 30KTM Ultrasonic inserts and transmits power and lavage from the system to insert.

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.

Lavage Control (Flow Adjustment)

See Section 6.3

Foot Control See Section 6.5

6.2 Information Center Graphics Displays and Controls

(Picture)

Power – (Display) Lights when the main 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 2^{nd} 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 will occur with minimal cavitation. (Use the Rinse mode when lavage 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® Steri-Mate Plus sterilizable handpiece accepts all Cavitron® 30K Ultrasonic Inserts.
- 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 the Dental Health Care Professional will be able to determine the best flow rate setting for optimum operating efficiency and patient comfort.
- Prior to connecting, align Handpiece and Cable Assembly electrical connections. If Cable Assembly does not seat into the handpiece, gently rotate the handpiece until contacts align, then fully insert 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® 30KTM 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.

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

Magnetostrictive Stack

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

- 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® 30KTM Ultrasonic Inserts are easily interchangeable for various procedures and applications. See enclosed booklet for specific information.

6.5 Foot Control Information and Operation

The Foot Control is a two-positioned momentary switch. The first activates both ultrasonic energy and lavage at the insert tip and the second position activates Boost Mode. The Boost Mode (fully depressed footswitch) 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 system base. *Picture showing released*, I^{st} *position*, 2^{nd} *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 Foot Control Power Cord
- 4. Cavitron® Ultrasonic Inserts
- 5. Cavitron® DualSelectTM Dispensing system
- 6. Cavitron Steri-Mate Plus Sterilizable Handpiece

7.2 User Replaceable Part Kits

- 1. Cavitron Insert Replacement O-ring 12/Pack, Part Number 62351
- 2. Steri-Mate Handpiece Cable O-ring, Part Number 79357
- 3. 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.
- Hold the handpiece over a sink or drain. Activate the System. (Check spray to verify fluid is reaching the working end of the insert tip). Adjust the Lavage 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 to 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.
- 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.

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. Turn ON/OFF Switch to the ON position. Verify the ON/OFF indicator light is lit.

- 3. Set the Power Adjustment knob to the minimum setting.
- 4. Set the Lavage Control on the handpiece cable to maximum.
- 5. Hold the Handpiece (without an insert installed) upright 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.
- 6. After a completed purge cycle and when ready for use, place a sterilized insert into the Handpiece and set the Ultrasonic Power Control knob and Lavage Control knob to your preferred operating position.

Between Patients:

- 1. Remove ultrasonic insert used. Clean and sterilize the ultrasonic insert(s) following the procedures outlined in the Cavitron Ultrasonic Insert Infection Control Direction for Use enclosed with every insert.
- 2. Hold the handpiece over a sink or drain and activate Purge function as described in Step 5 of the Start-Up Procedures.
- 3. After the purge cycle is complete, turn the system OFF.
- 4. Remove the Steri-Mate Plus handpiece, clean and sterilize procedure outlined in the Cavitron Systems Infection Control Procedures booklet enclosed with your unit.
- 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.
- 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 volume for the next patient.
- 8. When ready for use, place sterilized Steri-Mate Plus handpiece on the handpiece cable and a sterilized insert into the handpiece and adjust system control as preferred.

Shut-Down Procedures at the end of the day:

- 1. Remove ultrasonic insert from handpiece. Clean and sterilize the ultrasonic insert(s) following the procedures outlined in the Cavitron Ultrasonic Insert Infection Control Direction for Use enclosed with every insert.
- 2. Holding the handpiece (without an insert) over a sink or drain, activate the Purge function as per Step 5 of the Start-Up procedures.
- 3. After the purge cycle is completed, turn the System OFF.
- 4. Remove the Steri-Mate Plus handpiece from the cable. Clean and sterilize the Steri-Mate Plus handpiece following the procedure outlined in the Cavitron Systems Infection Control Procedures booklet enclosed with your unit..
- 5. Disinfect the surfaces of the cabinet, Power Cord, Handpiece Cable, Handpiece, 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.
- 6. Inspect the handpiece cable for any breaks or tears.
- 7. 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.

9.2 Weekly Maintenance

End of Week Procedures

If the system is used with a DualSelectTM Dispensing System, follow the end of the week procedures listed in the DualSelect Dispensing Systems Directions for Use manual.

9.3 Water Line Filter Maintenance

When the water line filter becomes discolored, the filter should be replaced to prevent reduced water flow to the Cavitron® RFTM Ultrasonic Scaler. A 10-pack of replacement filters is available by ordering Part Number 90158 from your local DENTSPLY® Distributor.

- 1. Disconnect the water supply hose from the water source. 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.
- 2. Grasp the fitting on either side of the filter disk and twist counterclockwise. Remove the filter section from either side of the water hose.
- 3. Install the replacement filter onto the water hose fittings. The filter should be positioned to match up with the correct hose fitting.
- 4. Hand tighten the two hose fittings in a clockwise direction. Reconnect the water supply hose, operate the unit to bleed the air and test for leaks.

Section 10: Troubleshooting

Although service and repair of the Cavitron® RFTM Ultrasonic Scaler should be performed by DENTSPLY® personnel, the following are some basic trouble shooting 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 (l) 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 lavage control is properly adjusted.
- 2. Check that dental office water supply valves are open.
- 3. If the system is 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 the water line filter is clean. Replace filter if needed.

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: (Purge Mode will not function – icon flashing)

- 1. Check that there is no insert in the handpiece.
- 2. Check that handpiece is properly installed to the cable assembly.

3.

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 Ultrasonic Scaler is warranted for TWO YEARS from date of purchase. The Steri-Mate Plus 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.

Section 12: Specifications

(Include required symbols)

Electrical Voltage Continuous (100-240 VAC)
Current 1.0 Amperes, Maximum

Phase Single Frequency 50/60 Hertz Water Pressure 2040 psig

Flow Rate Minimum Setting (CCW) < 15 ml/min

Maximum Setting (CW) > 55 ml/min

Weight 3.3 lbs (2 Kg)

Dimensions Height: 5 in (12,7 cm)

Width: 9.5 in (24,13 cm) Depth: 8 in (20,32 cm)

Handpiece Cable length: 6.5 ft. (2.0 M) Auxillary Footswitch Cable length: 8ft. (2.4 M) Water Supply Line length: 8 ft. (2.4 M)

Footswitch Not for operating theatres. Protection Class IPX1

Remote Communication Frequency: 2405-2480 MHz

Power: < 1mW Channels: 16

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.