Cavitron® Built-In

Ultrasonic Scaler with
Cavitron® Steri-Mate® Handpiece

Directions For Use
Introduction

The Cavitron Built-In Ultrasonic Scaler is equipped with a Sustained Performance System™ (SPS), which offers a constant balance between scaling efficiency and patient comfort by maintaining the unit's power level when the insert tip encounters tenacious deposits allowing the clinician to effectively scale even at a decreased/lower power setting.

The System operates by converting an SELV source current into high frequency current. The ultrasonic system consists of two parts: an insert and the SPS™ electronic system. The SPS™ system incorporates two closed loops. One loop provides automatic tuning (operating frequency is adjusted to be at resonance for each insert), the second loop automatically controls the tip stroke over different working conditions. The DENTSPLY Cavitron® Built-In scaler produces 30,000 microscopically small strokes per second at the insert’s working tip. This, combined with acoustic effects of the coolant water, produces a synergistic action that literally “powers away” the heaviest calculus deposits while providing improved operator and patient comfort.
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Product Overview
This product is intended for installation into a dental system. The end users are dental professionals. The devices are used to debride light to heavy calculus deposits from the tooth and root surfaces.

Technical Support
For technical support and repair assistance in the U.S., call a Cavitron CareSM representative at 1-800-989-8826 or 717-767-8502 Monday through Friday, 8:00 AM to 5:00 PM (Eastern Time). For other areas, contact your local DENTSPLY representative.

Section 1: Indications for Use
Ultrasonic Procedures
• All general supra and subgingival scaling applications.
• Periodontal debridement for all types of periodontal diseases.

Section 2: Contraindications
• Ultrasonic Systems should not be used for restorative procedures involving condensation of amalgam.
• Not for use on children under the age of 3.

Section 3: 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 specific recommendations. This unit complies with IEC 60601 Medical Device Standards.

• It is the responsibility of the Dental Healthcare Professional to determine the appropriate uses of this product and to understand: • the health of each patient,
• the dental procedures being undertaken,
• and applicable industry and governmental agency recommendations for infection control in dental healthcare settings,
• requirements, and regulations for safe practice of dentistry; and
• these Directions for Use in their entirety, including Section 4 Precautions, Section 6 Infection Control, and Section 10 System Care.

• This product is designed to assist in eliminating susceptibility to retraction of oral fluids. To ensure adequate protection from cross-contamination from other devices connected to the Dental Unit, it is highly recommended that the Dental Unit be installed with anti-retraction features. Additionally, the Dental Unit, including the anti-retraction features, must be properly maintained and periodically tested. For more information, please contact your Dental Unit manufacturer.

• Where asepsis is required or deemed appropriate in the best professional judgment of the Dental Healthcare Professional, this product should not be used, unless used in combination with a Sterile Lavage Kit, (P/N 81340).

• During boil-water advisories, this product should not be operated as an open water system (e.g. connected to a public water system). Dental Healthcare Professionals 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 minimum of 5 minutes.

• 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 released in the form of aerosols during treatment.

• The use of High Volume Saliva Evacuation to reduce the quantity of aerosols released during treatment is highly recommended.

• Failure to follow recommendations for environmental operating conditions, including input water temperature, could result in injury to patients or users.

• Handle Cavitron insert with care. Improper handling of insert, specifically the insert tip, may result in injury and/or cross contamination.

• Failure to follow properly validated sterilization processes and approved aseptic techniques for Cavitron inserts may result in cross contamination.

• DO NOT mount the Cavitron Built-In Scaler outside of the Dental Unit; doing so will void the warranty.
Section 4: Precautions

- Equipment flushing and dental water supply system maintenance are strongly recommended. See Section 10: System Care.
- Verify handpiece fits properly in the dental delivery system holder. If not properly seated, there is a potential for the handpiece to slip out of the holder and be damaged or contaminated. Contact a service technician for proper fit.
- 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 system without fluid flowing through handpiece.
- Always ensure that the electrical connections on the handpiece cable and the Steri-Mate® Handpiece are clean and dry before assembling them for use.
- Cavitron ultrasonic scaling units and Cavitron ultrasonic inserts are designed and tested for safety and efficacy as a system. Use of any other brand ultrasonic equipment with Cavitron equipment has not been tested and may have a negative effect on the safety and effectiveness of your Cavitron equipment and their warranties. Please review the warranty statement enclosed before use.
- Like bristles of a toothbrush, ultrasonic insert tips “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 Wear 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.
- Water should be used for all scaling procedures. Water flow is adjustable from less than 10 to greater than 60 ml per minute.
- Only adjust the systems’s power adjustment knob with the insert outside the patients mouth.
- As with all dental procedures, use universal precautions (i.e., wear face mask, eyewear, or face shield, gloves, and protective gown).

Section 5: Adverse Reactions

None known.
Section 6: Infection Control

6.1 General Information

• For operator and patient safety, carefully practice the infection control procedures detailed in the Infection Control Information Booklet accompanying your 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 areas outside the U.S., contact your local DENTSPLY Professional representative.

• As with high speed handpieces and other dental devices, the combination of water and ultrasonic vibration from the Cavitron Built-In Scaler will create aerosols. Following the procedural guidelines in Section 9 of this manual can effectively control and minimize aerosol dispersion.

6.2 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, and general infection control procedures (See Sections 7 and 10). Knowledge of and compliance with agency guidelines, standards and recommendations is the sole responsibility of the Dental Healthcare Professional.

• As a medical device, Cavitron® products need to be installed in accordance with local or national regulations, including guidelines for water quality (e.g. drinking water). As an open water system, such regulation may require your Cavitron product to be connected to a centralized water control device that prevents water containing contaminants from back-flow into the water supply.

Section 7: Water Line Requirements

• Incoming water supply line pressure to the ultrasonic scaler must be 25 psi (172kPa) minimum to 60 psi (414 kPa) maximum. If your dental water system's supply line pressure is above 60 psi, install a water pressure regulator on the water supply line to your Ultrasonic Scaler.

• Incoming water temperature to the Cavitron System should not exceed 25˚C (77˚F). If needed device should be installed to maintain a temperature within this specification, or a Cavitron DualSelect Dispensing System attached to allow this system to be operated as a closed water 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.

• A filter in the dental water system supply line is recommended so that the particles in the water supply will be trapped before reaching the ultrasonic scaler.

• After the above installations are complete on the dental water supply system, the dental office water line should be thoroughly flushed prior to connection to the ultrasonic system.

• After flushing system, verify there are no leaks.
Section 8: Ultrasonic Scaler System

Description

8.1 System Controls
The DENTSPLY Cavitron® Built-In module is enabled whenever the clinician removes the handpiece from the handpiece holder.

ON/OFF Function
The Ultrasonics is switched ON and OFF using the treatment unit’s foot control.

Power Adjustment
There are 2 options for adjusting the power to your Cavitron Built-In Ultrasonic Scaler.

Option 1: Power is adjusted by turning the Power Control Knob located on the treatment unit head that has been installed by your service technician. Stickers have been provided for application to the treatment unit to denote the Cavitron Ultrasonic Scaler power range (see image). These stickers are not required and may or may not have been applied by your technician. If they have not been applied or left behind by the technician and you would like to apply them to your treatment unit, contact DENTSPLY Customer Service to order them.

Option 2: If you are using a treatment unit equipped with a touch pad, your service technician will wire the power adjustment to the appropriate buttons on the treatment unit. Power can be adjusted using these buttons.

Lavage Flow Adjustment
Water flow through the handpiece is adjusted by rotating a control element on the cable connector (blue).
8.2 Steri-Mate® Handpiece

The Steri-Mate handpiece accepts all Cavitron 30K Ultrasonic Inserts. The Cavitron Steri-Mate 360 Handpiece accepts all Cavitron 30K plastic grip type Ultrasonic Inserts. It is not compatible with the Cavitron 30K Slimline metal grip type inserts (30K SLI-10S, SLI-10L and SLI-10R).

**Handpiece Connector**
(Handpiece & Mating Assembly are keyed)

**Steri-Mate® 360 Handpiece**

**360 Rotating Handpiece Nose**

**Cable Assembly**

**Date Codes**

**Insert Port**

**360 Rotating Handpiece Nose**

To rotate the insert, place fingers on the nose of the handpiece and rotate to desired position. This allows adjustable hand positioning, free flowing movement and access within the anterior and posterior of the oral cavity.

**Lavage Flow Adjustment**

Holding open end of handpiece upright, lavage can be increased by holding the handpiece and gently twisting the blue lavage adjustment knob clockwise. The rate of flow through the Handpiece determines the temperature of the lavage. Low flow rates produce warmer temperatures, high flow rates produce cooler temperatures.
8.3 DENTSPLY Cavitron® 30K™ Ultrasonic Inserts

The many styles of DENTSPLY Cavitron® Ultrasonic Inserts are easily interchangeable for various procedures and applications.

Hold the handpiece in an upright position. Activate to fill the handpiece with water. 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.

O-Ring
Provides seal for handpiece coolant

Connecting Body
Transfers and amplifies mechanical motion of the stack to insert tip.

Insert Tip
Shape and size of tip determine access and adaptation. Preheated lavage is directed to the tip.

Finger Grip

Insert Marking
Manufacturer, Date (YDDD = single year and three digit day of year), Frequency, and Type (e.g., DENTSPLY 7346 30K FSI-SLI-10S)

Magnetostrictive Stack
 Converts energy provided by the handpiece into mechanical oscillations used to activate the insert tip.
8.4 Foot Control Information & Operation

- The dental unit manufacturer provides the Foot Control. Refer to their directions for use for operating characteristics.

Section 9: Techniques for Use

9.1 Patient Positioning

- The backrest of the chair should be adjusted for optimal access to both the upper and lower arches. This assures patient comfort and clinician visibility.
- Have the patient turn head to the right or left.
- Position chin up or down depending on the quadrant and surface being treated.
- Evacuate irrigant using either a saliva ejector or High Vacuum Evacuator (HVE).

9.2 Performing Ultrasonic Scaling Procedures

- The edges of DENTSPLY Cavitron® Ultrasonic Inserts are intentionally rounded so there is little danger of tissue laceration with proper ultrasonic scaling techniques. The lips, cheek and tongue should be retracted to prevent accidental prolonged contact with the activated tip whenever the insert is placed in the mouth.
- Always adjust the lavage so adequate fluid will be available to cool the tip-tooth interface.
- In general, it is suggested that a “feather light touch” be used both supra- and subgingivally. The motion of the activated tip and acoustic effects of the irrigating fluid, in most cases, is adequate to remove even the most tenacious calculus.
• Set the System’s power adjustment knob to the lowest power setting for the application and the selected insert.
• Only adjust the System’s power adjustment knob with the insert outside the patients mouth.

3. Connect Steri-Mate® handpiece to the cable connector assembly (refer to the Infection Control information booklet for sterilizing instructions).

4. Adjust the lavage control to maximum.

5. Hold the handpiece (without an insert installed) over a sink or drain. Activate the foot control and flush water through handpiece for at least two minutes.

6. Place a sterilized insert into the handpiece using a gentle push-twist motion. Refer to the Cavitron Ultrasonic Inserts Directions for Use for cleaning and sterilizing instructions.

7. Activate the ultrasonics and adjust the power and lavage control to your preferred operating positions.

Between patients
1. Remove any ultrasonic inserts and the Steri-Mate® handpiece. Clean and sterilize the handpiece and all inserts used during the procedure (refer to the Infection Control information booklet and the Cavitron Ultrasonic Inserts Directions for Use for cleaning and sterilizing instructions).

2. Clean and disinfect the handpiece cable assembly by applying a medically approved non-immersion type disinfectant solution* carefully following the instructions

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9.3 Patient Comfort Considerations

Reasons for sensitivity
• Incorrect tip placement. Point should be directed away from root surfaces.
• Not keeping the tip in motion on the 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 pressure. Use extremely light grasp and pressure, especially on exposed cementum.
• If sensitivity persists, decrease power setting and/or move from the sensitive tooth to another and then return.

Section 10: System Care

10.1 Daily Protocol

Start-up procedures at the beginning of the day
1. Switch ON the dental treatment unit (refer to instruction manual of treatment unit).
2. Remove the DENTSPLY Cavitron® cable connector assembly from handpiece holder and set power adjustment to 30% of maximum.

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provided by the solution manufacturer. To clean the cable, generously spray disinfectant solution on a clean towel and wipe the cable and connector. Discard used towel. To disinfect the system, generously spray disinfectant on a clean towel and wipe the cable and connector. Allow the disinfectant solution to air dry.

3. Clean and disinfect all surfaces of the dental treatment control head according to the manufacturer’s instructions.

4. Connect a sterilized Steri-Mate® handpiece onto its mating cable connector.

5. Hold the handpiece (without an insert installed) over a sink or drain. Activate the foot control and flush water through handpiece for at least thirty seconds.

6. Place a sterilized insert into the handpiece.

*NOTE: Water-based disinfection solutions are preferred. Some alcohol-based disinfectant solutions may discolor the handpiece cable and connector.

Shut down at the end of the day
1. Flush the DENTSPLY Cavitron Built-In ultrasonic system according the dental treatment unit manufacturer’s instructions.

2. Remove any ultrasonic inserts and the Steri-Mate® handpiece. Clean and sterilize the handpiece and all inserts used during the procedure (refer to the Infection Control information booklet and the Cavitron Ultrasonic Inserts Directions for Use for cleaning and sterilizing instructions).

3. Clean and disinfect the handpiece cable assembly by applying a medically approved non-immersion type disinfectant solution* carefully following the instructions provided by the solution manufacturer. To clean the cable, generously spray disinfectant solution on a clean towel and wipe the cable and connector. Discard used towel. To disinfect the system, generously spray disinfectant on a clean towel and wipe the cable and connector. Allow the disinfectant solution to air dry.

4. Clean and disinfect all surfaces of the dental treatment control head according to the manufacturer’s instructions.

5. Place the cable connector into the handpiece holder for storage.

6. Turn OFF the power and water to the dental treatment unit.
Some basic troubleshooting procedures that will help avoid unnecessary service calls are listed below.

1. Bleed any air trapped in the handpiece.
2. Check if the power dial is in the blue zone.
3. If low vibrations are detected, check the wear using the wear indicator.
4. If the insert is worn or defective, replace it. Otherwise, service the scaler.
5. If all checks fail, the system is OK.
No vibrations; no water flow

Is scaler active?

No

Is scaler energized?

No

Check handpiece holder switch

Yes

Adjust scaler power control

Is insert worn?

No

Turn system off. After 20 seconds turn system on.

Yes

System performs normally

Replace insert

Yes

Service scaler

Is handpiece fully attached to cable?

No

Properly connect handpiece

Replace Steri-Mate® handpiece

Yes

System OK
Scaler handpiece gets too hot; output water is too hot

Bleed any trapped air from the handpiece

Verify input water temperature is not higher than 77°F (25°C)

Change insert

Temperature normal

Yes → System OK

No → Change handpiece

Temperature normal

Yes → Faulty insert

No → Increase water flow or set power lower

Temperature normal

Yes → Faulty handpiece

No → Service system

Temperature normal

Yes → System OK
Section 12: Warranty Period

The Cavitron® Built-In G139 Ultrasonic Scaler is warranted for TWO YEARS from date of purchase. The Steri-Mate® 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.

Section 13: Specifications

Operating Conditions:
Ambient temperature: 15 – 40°C
Humidity: 30 – 75 %RH

Input for Optional Power Supply if used:
APX Model AP7948DR
Voltage 120 VAC
Power 60 Watts
Frequency 60 Hz
Output Voltage 24 VAC
Output Current 2.5 Amps

Input for Model G139 Scaler Unit
Voltage 24 VAC
Current 2.5 Amps
Rated Power 60 VA
Frequency 50/60 Hz
Water Temperature 41 – 77°F (5 – 25°C)
Water Pressure 25 – 60 psi (172 – 414 kPa)

Water Flow Rate 10 > flow > 60 ml/min

Output Frequency 30 kHz
Power 3 – 30 Watts

Storage and Shipping Conditions:
Ambient temperature range: -40 – 75°C
Relative Humidity range: 10 – 95 %RH (non-condensing)
Atmospheric pressure range: 7 – 15 psi (50 – 106 kPa)

Section 14: Classifications

Input Voltage supplied by SELV
Degree of protection against electric shock: Type B
Degree of protection against harmful ingress of water: Ordinary
Mode of operation: Continuous
Equipment is not suitable for use in the presence of flammable mixtures
Medical Device Directive Classification: IIa

• Input Voltage to the Cavitron Built-In Ultrasonic Scaler G139, when not supplied by the dental unit, may only be supplied by the specified power supply from APX, Model AP7948DR.
Section 15: Symbol Identification

Type B Equipment
Consult Instructions
For Use
AC power
(AC 24~)

MEDICAL EQUIPMENT
WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1/CAN/CSA-C22.2 No. 601.1,
CAN/CSA-C22.2 No. 60601-1 (2008),
13VA

This symbol is a mandatory marking for devices entering the European market to indicate conformity with the essential health and safety requirements set out in European Directives. The symbol may be accompanied by a four-digit identification number of the notified body.