



Ultrasonic Scaling System

Détartreur ultrasonique

Escarificador ultrasónico

Ultraschall-Zahnsteinentfernungsgerät

Scaler ultrasonico

Ультразвуковая система для удаления зубного камня



Directions For Use

Mode d'emploi

Instrucciones de uso

Gebrauchsanweisung

Istruzioni per l'uso

Указания по применению



Please read carefully and completely before operating unit.

Prière de lire attentivement et complètement avant la première utilisation de l'appareil.

Por favor lea cuidadosamente y en su totalidad antes de operar la unidad.

Bitte vor Inbetriebnahme der Einheit sorgfältig und vollständig durchlesen.

Si prega di leggere attentamente e completamente prima di utilizzare l'apparecchio.

Пожалуйста, внимательно и полностью прочтите перед использованием устройства.

TABLE OF CONTENTS

PRODUCT OVERVIEW	3
-------------------------	---

TECHNICAL SUPPORT	3
--------------------------	---

SUPPLIES & REPLACEMENT PARTS	3
---	---

INDICATIONS FOR USE	3
----------------------------	---

CONTRAINDICATIONS	3
--------------------------	---

WARNINGS	3-4
-----------------	-----

PRECAUTIONS

4.1 System Precautions	4
4.2 Procedural Precautions	4

ADVERSE REACTIONS	4
--------------------------	---

INFECTION CONTROL

6.1 General Infection Control	4
6.2 Water Supply Recommendations	4-5

INSTALLATION INSTRUCTIONS

7.1 Water Line Requirements	5
7.2 Electrical Requirements	5
7.3 Unpacking the System	5
7.4 System Installation	5
7.5 Power Cord Connection	5-6
7.6 Water Supply Line Connection	6
7.7 Tap-On™ Foot Pedal Synchronization	6
7.8 Recharging Tap-On Foot Pedal	6
7.9 Powering On/Off Tap-On Foot Pedal	6

CAVITRON TOUCH SCALER DESCRIPTION

8.1 System Controls	7
8.2 Diagnostic Display Indicators and Controls	8-9
8.3 Handpiece/Cable	10
8.4 Cavitron® 30K™ Ultrasonic Inserts	10
8.5 Tap-On™ Wireless Foot Pedal Operation	11
8.6 Accessories and User Replaceable Parts	11
8.6.1 Accessories	11
8.6.2 User Replaceable Part Kits	11

SYSTEM SETUP, OPERATION AND TECHNIQUES FOR USE

9.1 Handpiece Setup	11
9.2 Boost Mode	12
9.3 Patient Positioning	12
9.4 Performing Ultrasonic Scaling Procedures	12
9.5 Patient Comfort Considerations	12

SYSTEM CARE

10.1 Daily Maintenance	12
Start-up procedures at the beginning of the day	12-13
Between patients	13
Shut-down procedures at the end of the day	13
10.2 Weekly Maintenance	13
10.3 Monthly Maintenance	13
Water Line Filter	

TROUBLESHOOTING

11.1 Troubleshooting Guide	14
11.2 Technical Support and Repairs	15

WARRANTY PERIOD	15
------------------------	----

SPECIFICATIONS	15
-----------------------	----

SYMBOL IDENTIFICATION	16
------------------------------	----

CLASSIFICATIONS	16
------------------------	----

DISPOSAL OF UNIT	16
-------------------------	----

CAUTION: United States Federal Law restricts this device to sale by or on the order of, a licensed dental professional.

For dental use only.

PRODUCT OVERVIEW

The Cavitron Touch™ Ultrasonic Scaling System offers an advanced experience at your fingertips. The unit features a modern touch screen interface for ease of use with added memory presets and customizable power settings for improved efficiency. The system also features a lightweight, detachable handpiece cord for improved ergonomics.

TECHNICAL SUPPORT

For technical support and repair assistance in the U.S., call the DENTSPLY Cavitron Care 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® representative.

SUPPLIES & REPLACEMENT PARTS

To order supplies or replacement parts in the U.S., contact your local DENTSPLY 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 Representative.

SECTION 1: Indications For Use

USED FOR 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 dental procedures involving the condensation of amalgam.
- Not for use on children under the age of 3.

SECTION 3: Warnings

- The use of High Volume Saliva Evacuation to reduce the quantity of aerosols released during treatment is highly recommended.
- Prior to beginning treatment, patients should rinse with an 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.

- 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.
- 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).
- 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 or handpieces may result in cross contamination.
- 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 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.

- Insufficient water flow could result in elevated water and tip temperature. When operated at the input water temperature specified in the Water Line Requirements Section 7.1 and with sufficient water flow, the water and tip temperature should not exceed 50° C (122° F). Failure to follow recommendations for environmental operating conditions, including input water temperature, could result in injury to patients or users. If temperature is elevated, increase water flow. If temperature remains elevated, discontinue use.
- During boil-water advisories, this product should not be operated as an open water system (e.g. connected to a public water system). A Dental Healthcare Professional should disconnect the system from the central water source. The Cavitron DualSelect™ system can be attached to this unit and operated as a closed

* data on file

system until the advisory is cancelled. When the advisory is cancelled, flush all incoming waterlines from the public water system (e.g. faucets, waterlines and dental equipment) in accordance with the manufacturer's instructions for a minimum of 5 minutes.

- 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.
- This portable transmitter with its antenna complies with FCC/IC RF exposure limits for general population / uncontrolled exposure.
- This Device complies with Industry Canada License-exempt RSS standard(s). Operation is subject to the following two conditions: 1) this device may not cause interference, and 2) this device must accept any interference, including interference that may cause undesired operation of the device.

SECTION 4: Precautions

4.1 System Precautions

- Close manual shut-off valve on the dental office water supply every night before leaving the office.
- 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 10: System Care.
- Never operate system without fluid flowing through the 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.

4.2 Procedural Precautions

General

- As with all dental procedures, use universal precautions (i.e., wear face mask, eyewear, or face shield, gloves and protective gown).

Ultrasonics

- The Cavitron Touch Ultrasonic Scaling System works with Cavitron inserts as a system, and was designed and tested to deliver maximum performance for all currently available Cavitron brand ultrasonic inserts. Companies that manufacture, repair or modify inserts carry the sole responsibility for proving the efficacy and performance of their products when used as a part of this system. Users

are cautioned to understand the operating limits of their insert before using in a clinical setting.

- Like bristles of 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.
- 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 5: Adverse Reactions

None Known.

SECTION 6: Infection Control

6.1 General Infection Control

- For operator and patient safety, carefully practice the infection control procedures detailed in the Cavitron Systems Infection Control Procedures 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 representative.
- As with high speed handpieces and other dental devices, the combination of water and ultrasonic vibration from the Cavitron Touch Ultrasonic 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, chemical flushing, and general infection control procedures. See Sections 7.1 and 10.

- As a medical device, this product must 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 7: Installation Instructions

Anyone installing a Cavitron Touch System should observe the following requirements and recommendations.

7.1 Water Line Requirements

- A water supply line with user-replaceable filter is supplied with your system. See Section 10 System Care for replacement instructions.
- Incoming water supply line pressure to the system must be 20 psi (138 kPa) to 40 psi (275 kPa). 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 Touch Ultrasonic Scaler.
- 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 Cavitron 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 Cavitron system.
- Incoming water temperature to the Cavitron System should not exceed 25°C (77°F). If needed a 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.

7.2 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.
- WARNING:** To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

7.3 Unpacking the System

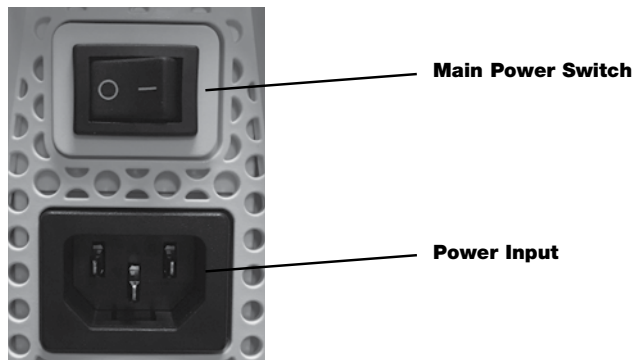
Carefully unpack your Cavitron Touch Ultrasonic Scaling System and verify that all components and accessories are included:

- Cavitron Touch System with Detachable Featherweight Handpiece Cable
- Water Line Assembly (Blue) with Filter and Quick Disconnect
- Additional Water Line Filter
- Detachable AC Power Cord
- Cavitron® Tap-On™ Wireless Foot Pedal
- Auxiliary Cable for Rechargeable Foot Pedal
- Steri-Mate® 360 Detachable Sterilizable Handpiece
- Literature Packet

7.4 System Installation

- The Cavitron Touch System is designed to rest on a level surface. Be sure unit is stable and resting on four feet.
- The Cavitron Touch System should not be positioned such that access to the power input and AC power cord are limited.
- Placing unit in direct sunlight may discolor plastic housing.
- The system has been equipped with a Tap-On Wireless Foot Pedal which was factory synchronized to operate with the system's base unit. If your office has more than one Cavitron system with Tap-On Technology, it is recommended that you mark the Tap-On Foot Pedal and base unit for easy reference as to which Tap-On Foot Pedal operates with which base unit. Should resynchronization be necessary, follow the instructions in section 7.7.

7.5 Power Cord Connection



- Verify the Main Power ON/OFF switch, located at the rear of the System, is set to the OFF (O) position before proceeding.
- Insert the AC power cord into the power input on the back of the System.
- Insert the pronged plug into an AC wall outlet.

7.6 Water Supply Line Connection

- Grasp the Water Supply Line (blue hose) by the end opposite the quick-disconnect and insert it into the water inlet connector until fully seated.



**Press ring to
release water
supply tube.**

- 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 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 into an appropriate container and allow water to drain. To remove the hose from the system, push on the outer ring of the system's water inlet and gently pull out the water line.

7.7 TAP-ON™ FOOT PEDAL SYNCHRONIZATION

The Tap-On Wireless Rechargeable Foot Pedal supplied with your system has been factory synchronized with the base unit. Should a replacement Foot Pedal be necessary, synchronization will be required prior to system operation. Perform the following steps to synchronize the Foot Pedal with the base unit.

- Turn the Main Power switch located at the rear of the system to the ON (I) position. The Main screen will appear. This is also referred to as the Scale screen.
- Press and hold the Settings icon until the Settings screen appears.
- Maintain a distance of no more than 10 feet (3 meters) between the base unit and Tap-On Foot Pedal during the synchronization process.
- Remove any inserts from the handpiece.
- Ensure the foot pedal power is ON.
- Press the Sync icon on the Settings screen.
- Press the red sync button on the bottom of the foot pedal - hold for at least three seconds.
- Synchronizing is complete when the Sync icon has

stopped rotating and sound indication occurs.

- To verify proper communication, press the Scale icon to return to the Main screen (scale screen). Depress the foot pedal to the second position and ensure that Boost is activated (seen in Power Level icon).

7.8 RECHARGING THE TAP-ON FOOT PEDAL

Ensure the foot pedal power is ON. With the unit ON, plug the Auxiliary foot pedal cable into the foot pedal and the USB port on the front of the unit. Allow to charge for 2 hours for a full battery charge.

The unit will operate with the foot pedal while the battery is charging.

Battery Icon (Foot Pedal Charge)

- 100% - 75% =
- 75% - 50% =
- 50% - 25% =
- 25% - 0% =

7.9 POWERING ON/OFF THE TAP-ON FOOT PEDAL

- The foot pedal is packaged with the power OFF. The foot pedal must be turned on prior to use. (The foot pedal will not charge in the OFF state).
- The Power button is used to disconnect the battery from the circuitry for shipping purposes.
- The Power button must be pressed and held for 4 seconds to disconnect the battery. Likewise the Power button must be pressed and held for 4 seconds to reconnect the battery.
- If the Foot Pedal power is OFF, pressing the Sync button or trying to Sync with the Scaler will not turn the Foot Pedal on.



SECTION 8: Cavitron Touch™ Ultrasonic Scaler Description

8.1 System Controls

Ultrasonic Power Level Control

Slide to select the desired ultrasonic power level for operation. Sliding up increases the power level and sliding down decreases the power level.

Rinse

Rinse mode is for use during an ultrasonic scaling procedure when lavage is desired with no cavitation (Page 8).

Purge

Purge mode is used to flush water lines. Runs automatically for 2 minutes (Page 8).

Diagnostic Display

See section 8.2 for more details.

Handpiece Holder

Securely holds the system's handpiece, or cable connector when handpiece is not installed.

Preset Power Modes

Lock / Unlock

Press and hold to lock or unlock the screen. Screen will appear dimmed when locked.

Detachable Featherweight Handpiece Cable

Cable can easily be detached from unit as needed for replacement.

Settings Icon

Allows you to adjust settings for the foot pedal and screen brightness. Press and hold until the Settings screen appears.

Main Power ON/OFF Switch

ON/OFF Switch located on the rear of the system.

Tap-On™ Wireless Rechargeable Foot Pedal

Eliminates the need to hold down or pump foot pedal. See section 8.5 for more details.

Steri-Mate® 360 Handpiece

Accepts all Cavitron® 30K™ Ultrasonic inserts. See section 8.3 for more details.

8.2 Diagnostic Display Indicators and Control



Service

- 1 - Cable or handpiece issue.
- 2 - Unit overheating. Stop use and contact Cavitron Care.



Icon will appear when water filter needs to be replaced. Once replaced, press and hold to reset indicator.



Purge mode is used to flush water lines. Runs automatically for 2 minutes.

This screen shows when purge is activated.



- Scale Icon - press to return to main screen
- Depress foot pedal to return to main screen
- Main screen will appear when countdown is complete



Rinse mode is for use during an ultrasonic scaling procedure when lavage is desired with no cavitation.

This screen shows when rinse is activated. Depress foot pedal to begin rinse mode cycle.



- Scale Icon - press to return to main screen



Press & hold until settings screen appears (see pg.9).



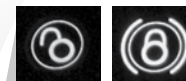
Foot Pedal Battery

Indicates battery life of foot pedal.



Preset Power Modes-Programmable

Press and hold until sound indicator is heard.



Lock / Unlock Icons

Press and hold to lock or unlock screen. Screen appears dimmed when locked.



Power Level Icon

Adjust number to desired power level by swiping in an upward or downward motion.



- Power levels set between 05 and 35 are within Blue Zone range

8.2 Diagnostic Display Indicators and Control, continued



Scale

Press to return to main screen



Tap-On

Press to activate or inactivate
Tap-On™ Technology

*Note: Tap-On is inactivated at the
factory.*



Sync

Press to synchronize foot pedal
and unit

*Note: If the foot pedal is synced to
the unit, pressing the sync icon will
unlink the foot pedal from the unit.*



Brightness

Sliding up and down will increase
or decrease brightness level

Settings Screen



8.3 Handpiece / Cable

Lavage Control

Turn the Lavage Control to select flow rate during system operation. Flow rate is based on a scale from 1 to 6. Turn clockwise toward 6 to increase flow at insert tip. Turn counter-clockwise toward 1 to decrease flow. The flow rate through the handpiece also determines the temperature of the lavage. Lower flow rates produce warmer lavage. Higher water flow rates produce cooler lavage.

360° Rotating Handpiece Nose

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

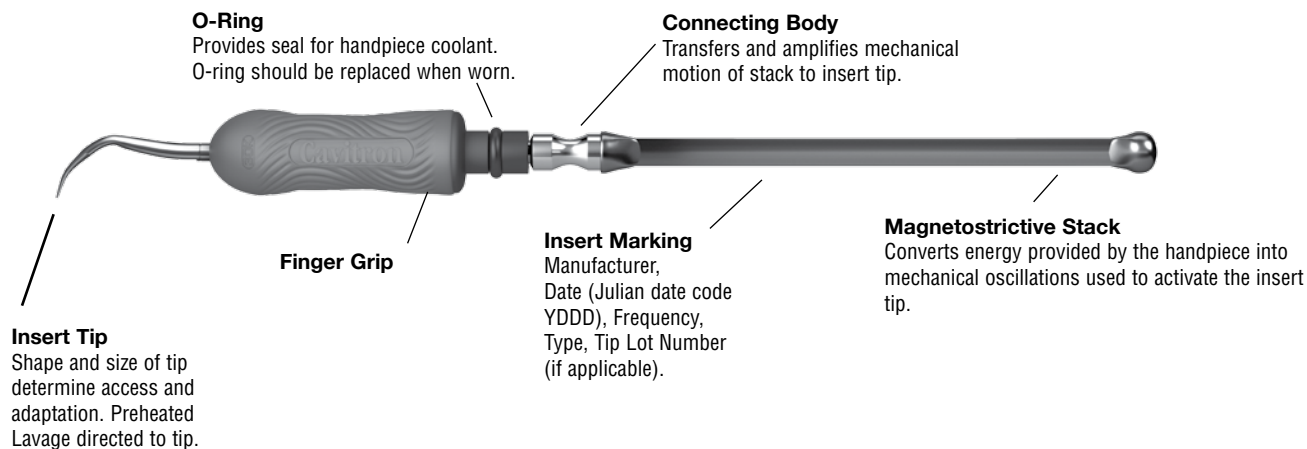
Note: The design of the Steri-Mate 360 provides a smooth transition to Cavitron FitGrip inserts (shown).

Featherweight, Detachable Handpiece Cord

Lightweight handpiece cable easily detaches from the unit, also detaches from the Steri-Mate 360 handpiece for cleaning and replacement needs. Swivel feature reduces cord drag as handpiece rotates during procedures.

8.4 Cavitron 30K Ultrasonic Inserts

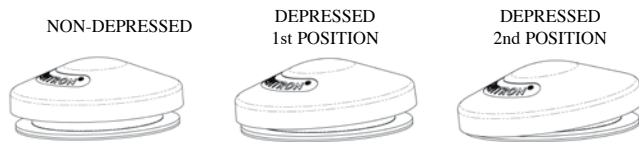
The many styles of Cavitron 30K Ultrasonic Inserts are easily interchangeable for various procedures and applications.






8.5 Tap-On Technology Wireless Foot Pedal Operation

Using Foot Pedal in Tap-On Mode

For scaling procedures, Tap-On Technology eliminates the need to hold the pedal down. Tapping the foot pedal once activates ultrasonic power for approximately 4 minutes. Tapping the foot pedal while in Tap-On mode disables the ultrasonic power and water flow. Boost is still available while scaling in Tap-On mode. To use Boost, simply depress the foot pedal to the second position (all the way to the floor) to activate and hold as long as Boost is desired. Release foot pedal to return to Tap-On mode.



TIPS:

-  Tap-On Technology will not run water unless an insert is in the handpiece
-  A sensor in the handpiece holder will prevent Tap-On Technology from operating when the handpiece is in the holder.
-  If the foot pedal is not tapped quickly, it will function in a conventional manner.

How to Enable and Disable Tap-On Technology

The Tap-On Technology feature can be enabled by pressing the Tap-On icon in the Settings Screen. From the main screen, press the Settings icon then press the Tap-On icon. The parenthesis lines around the icon will show as white when Tap-On is activated and when you return to Scale (Main screen) TAP ON will appear in the top of the Power Level bubble.

The Tap-On Technology feature can be disabled by pressing the Tap-On icon in the settings. From Scale (Main Screen) press the Settings icon then press the Tap-On icon. The icon will show as grayed out.

Using Foot Pedal without Tap-On Mode

For scaling operation, the first position activates both the ultrasonic energy and lavage at the insert tip. The second position activates the Boost Mode. The Boost Mode (fully depressed Foot Pedal) increases the ultrasonic power level for quick removal of tenacious deposits without adjusting the power level knob. To deactivate Boost Mode, release the Foot Pedal to the first position.

8.6 Accessories and User Replaceable Parts

8.6.1 Accessories

1. AC Power Cord
2. Wireless, Rechargeable Foot Pedal (with Tap-On Technology)
3. Auxiliary Foot Pedal Power Cable
4. Cavitron Steri-Mate® 360 Sterilizable Handpiece
5. Cavitron 30K Ultrasonic Inserts
6. Cavitron DualSelect Dispensing system

7. Detachable Featherweight Handpiece Cord
8. Cavitron Steri-Mate Sterilizable Handpiece

8.6.2 User Replaceable Part Kits

1. Cavitron Insert Replacement O-ring Kits, 12/packs
Part Number 62351 (black) for plastic and soft grips
Part Number 62605 (green) for metal grips
2. Handpiece Cable O-Ring, Part Number 79357
3. Lavage (Water) Filter, 10/Pack, Part Number 90158

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

SECTION 9: System Setup, Operation and Techniques for Use

9.1 Handpiece Setup

- This handpiece is sterilizable. Refer to Cavitron Systems Infection Control Procedure booklet for sterilization instructions prior to using handpiece.
- Connect the Handpiece to the Cable Assembly by aligning the electrical connections. If Cable Assembly does not seat into the handpiece, gently rotate the handpiece until contacts align, then fully insert handpiece. NOTE: Steri-Mate 360 and Steri-Mate are compatible with this system.
- Hold empty handpiece in a semi-upright position over a sink or drain. Activate the Tap-On Foot Pedal until water exits to release any air bubbles that might be trapped inside the handpiece. NOTE: Tap-On Technology only operates when an insert is in 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.
- Turn the Lavage Control to select flow rate during system operation. Flow rate is placed on a scale from 1 to 6. Turn control clockwise toward 6 to increase flow at insert tip. Turn control counter-clockwise toward 1 to decrease flow. The flow rate through the handpiece also determines the temperature of the lavage. Lower water flow rates produce warmer lavage. Higher flow rates produce cooler lavage. If the handpiece becomes warm, increase the flow rate. With experience the Dental Healthcare Professional will be able to determine the best flow rate setting for optimum operating efficiency and patient comfort.



9.2 Boost Mode

Boost provides a temporary increase in ultrasonic scaling power for quick removal of tenacious calculus without touching the unit. Boost is activated by fully depressing the Tap-On Foot Pedal to second position (all the way to the floor). When boost is activated, the Boost icon will illuminate on the Power Level bubble. Boost remains on as long as the clinician has the foot pedal pressed all the way down. In order to deactivate boost, release the Tap-On Foot Pedal to first position.

9.3 Patient Positioning

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).

9.4 Performing Ultrasonic Scaling Procedures

Note: Refer to the *Infection Control Information booklet supplied with your system and Section 10 of this manual for general procedures to be followed at the beginning of each day and between patients.*

- Follow precautions listed in the General and Ultrasonic sections of 4.2 Procedural Precautions.
- The edges of Cavitron Ultrasonic Inserts are intentionally rounded so there is minimal 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.
- Slide Power Level Control to select ultrasonic power level for operation. Upward increases system power. Power level will increase throughout the full range of the control. Hold the handpiece over a sink or drain. While in Tap-On mode, simply tap the Tap-On Foot Pedal to activate the system. (If Tap-On mode is turned off, press and hold the Tap-On Foot Pedal down to activate the system.) Check water spray to verify fluid is reaching the working end of the insert tip. Adjust the water lavage control until the water (lavage) flows with a rapid drip or small spray. Higher water flow settings provide cooler irrigation.
- It may be necessary to adjust lavage with the system in "Boost" mode (Tap-On Foot Pedal 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 Wear Indicator.
- The use of a saliva ejector or High Volume Evacuator (HVE) is recommended during all procedures.
- Set the system's Power Level Control to the lowest efficient power setting for the application and the selected insert.
- Keep the foot pedal near your foot to make it convenient to access.

9.5 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 10: System Care

It is recommended that you perform the following maintenance procedures.

10.1 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. Install a sterilized Steri-Mate Handpiece onto the handpiece cable.
3. Set the Power Level Control to minimum and the Lavage Control to maximum.
4. Turn the system ON.
5. Hold the sterilized handpiece (without insert installed) over a sink or drain. Activate the Purge Mode by pressing the Purge icon.
 - The Purge screen will appear indicating proper activation of the purge function. Time icon will count down indicating completion of purge cycle.
 - The Purge function can be interrupted at any time during the two minute cycle by pressing the Scale

icon or by pressing the Foot Pedal.

6. After completing the purge cycle, place a sterilized 30kHz Cavitron Ultrasonic Insert into the handpiece and set the Power Level Control and Lavage Control to your preferred operating position for ultrasonic scaling.

BETWEEN PATIENTS:

1. Remove the used Cavitron Ultrasonic 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 5 of the Start-Up procedure.
3. After the Purge cycle is complete, turn the System to the OFF (O) position.
4. Remove the Steri-Mate handpiece, clean and sterilize following the procedures outlined in the Cavitron Systems Infection Control Procedures booklet that was enclosed with your system.
5. Before disinfecting surface of cabinets, lock the touch screen by pressing the Lock icon. Disinfect the surfaces of the cabinet, Power Cord, Handpiece Cable, Tap-On Foot Pedal and Cable assembly (if applicable), Water Supply lines as instructed in the Cavitron Systems Infection Control Procedures booklet. **DO NOT SPRAY DISINFECTANT SOLUTION DIRECTLY ON SYSTEM SURFACES***.
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 the next patient.
8. When ready to use, press the unlock icon, place a sterilized Steri-Mate Handpiece onto the handpiece cable assembly and insert a sterilized ultrasonic insert into the handpiece and adjust system controls as preferred.

SHUT-DOWN PROCEDURES AT THE END OF THE DAY:

Follow the "Between Patients" maintenance procedures, Steps 1 through 6. In addition, it is recommended to close the manual shut-off valve on the dental water supply system.

***NOTE: Broad spectrum hospital grade water-based disinfection solutions are preferred, such as Lysol IC. Some alcohol-based disinfectant solutions may be harmful and may discolor plastic materials.**

10.2 Weekly Maintenance

It is strongly recommended that this system be disinfected by chemically flushing the waterlines with a 1:10 Sodium Hypochlorite solution (NaOCl) at the end of each week. This can be accomplished by connecting this device to the Cavitron DualSelect Dispensing System or a number of other devices available from your local distributors. Where this device is connected to the Cavitron DualSelect Dispensing System, please follow the DualSelect system's Directions for Use manual. If connected to another device, please follow those directions for use, keeping in mind that a chemical flush should be performed at maximum water flow for at least 30 seconds. The system should be left undisturbed for 10 minutes but no more than 30 minutes to allow the sodium hypochlorite solution to soak in the lines. As a suggestion, it is recommended that a sign be placed on the system stating that the SYSTEM IS BEING DISINFECTED WITH A STRONG DISINFECTANT AND SHOULD NOT BE USED. When ready, flush system with clean water for at least 30 seconds or until sodium hypochlorite odor disappears. **ALL CHEMICALS MUST BE FLUSHED FROM THE SYSTEM BEFORE IT IS READY FOR PATIENT USE.**

10.3 Monthly Maintenance

WATER LINE FILTER MAINTENANCE: When the water line filter becomes discolored or the filter icon illuminates, the filter should be replaced to prevent reduced water flow to the Cavitron Touch system.

1. Verify that the system is turned OFF.
2. Disconnect the water supply hose 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.
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 one hose fitting onto filter in a clockwise direction. Tighten second hose onto filter in clockwise direction. Reconnect the water supply line, operate unit to bleed the air and test for leaks.
6. Turn the unit back ON, press and hold filter icon until it disappears to reset filter maintenance icon.

SECTION 11:

Troubleshooting

Although service and repair of the Cavitron Touch Ultrasonic Scaler 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 controls.

11.1 Troubleshooting Guide

Symptom:

System operates: Tap-On Technology is not working

1. Tap-On Technology might be disabled. Refer to section 8.5.
2. Check to see if handpiece is in holder. Tap-On Technology is disabled when handpiece is in holder.
3. Check to see if the insert is secured inside the handpiece. Tap-On Technology is disabled when there is no insert in the handpiece.

Symptom:

System will not operate: No Power ON indicator (green light is not on)

1. Check that the Main Power 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 power cord plug is fully seated in an approved AC wall outlet.
3. Check that the wall outlet is functional.

Symptom:

System will not operate: Power ON Indicator is illuminated

1. If the office has more than one Tap-On Foot Pedal, test each to ensure that the proper Tap-On Foot Pedal is being used. With a handpiece and insert installed, depress the Tap-On Foot Pedal to the first position. The system should dispense water. If none of the Tap-On Foot Pedals operate the system, continue to the next step.
2. Ensure the foot pedal power is ON. Resynchronize one Tap-On Foot Pedal to the system (see Section 7.7 Tap-On Foot Pedal Synchronization).

Symptom:

System operates: No water flow to insert tip or handpiece overheats

1. Assure that handpiece lavage control is properly adjusted.
2. Check for clogged insert. Replace insert if necessary.
3. Check that dental office water supply valves are open.
4. 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.
5. Check that the water line filter is clean. Replace filter if needed.

Symptom:

System operates: No insert cavitation

1. Check the insert for damage and that it is properly installed in the handpiece.
2. Check that the handpiece is properly installed to the cable assembly.
3. Verify that the soft nozzle grip is flush with the hard plastic of the insert port.
4. Turn the system's Main Power Switch to the OFF (O) position. Wait 5 seconds and turn the system back ON.
5. If problem still exists, connect the Auxiliary Foot Pedal Cable.

Symptom:

System operates: Purge Mode will not function – Service Icon 1

1. Check that handpiece is properly installed to the cable assembly and the purge screen is visible.

Symptom:

System operates: Service Indicator Illuminated

- Service Icon 1 Illuminated – Indicates improper set-up
 1. If insert is in the handpiece, remove. Verify the handpiece is properly seated and hold the foot pedal for 2 seconds. If icon turns off, the system is ready for use. If icon remains lit, continue to the next step.
 2. Attach a NEW handpiece and hold Foot Pedal for 2 seconds. If icon turns off, the system is ready for use. Discard the old handpiece or return if within warranty. If icon remains lit, continue to the next step.
 3. If icon remains lit, refer to Section 11.2 Technical Support and Repairs to have unit serviced as soon as possible.

System operates: Service Indicator illuminated

- Service Icon 2 Illuminated
 1. Ensure that the base unit has adequate ventilation and is not near a heat source (i.e. radiator, heat lamp, sunlight or other heat producing operatory equipment).
 2. Turn Main Power Switch to the OFF (O) position. Allow system to cool for 10 minutes and turn system to the ON (I) position. Verify Service Icon 2 is not illuminated.
 3. If icon is still illuminated, refer to section 11.2 Technical Support and Repairs to have unit serviced as soon as possible.

11.2 Technical Support and Repairs

For technical support and repair assistance call DENTSPLY Cavitron Care Factory Certified 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 representative.

SECTION 12: Warranty Period

The Cavitron Touch Ultrasonic Scaler is warranted for TWO YEARS from date of purchase. The Steri-Mate 360 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

Electrical Voltage	Continuous (100-240 VAC)
Current	1.0 Amperes, Maximum
Phase	Single
Frequency	50/60 Hertz
Water Pressure	20 to 40 psig (138 to 275 kPa)
Water Temperature	< 25°C (77°F)
Water Flow Rate	Minimum Setting (CCW) < 15 ml/min Maximum Setting (CW) > 55 ml/min
Weight	4.4 lbs (2 Kg)
Dimensions	Height: 9 in. (23 cm) Width: 6 in. (15.25 cm) Depth: 9 in. (23 cm) Handpiece Cable length: 6.5 ft. (2.0 M) Auxillary Footswitch Cable length: 6 ft. (1.8 M) Water Supply Line length: 8 ft. (2.4 M)
Footswitch	Protection Class IPX1. Not for operating theatres.
Remote Communication	Frequency: 2.4 GHz Power: < 1mW
Operating Environment	Temperature: 15 to 40 Deg Celsius (59 to 104 Deg Fahrenheit) Relative Humidity: 30% to 75% (non-condensing)

Transport and Storage Conditions

Temperature: -40 to 70 Deg. Celsius
(-40 to 158 Deg. Fahrenheit)

Relative Humidity:
10% to 95% (non-condensing)

Atmospheric Pressure: 500 to 1060 hPa

SECTION 14: Symbol Identification



AC POWER



TYPE B APPLIED PART EQUIPMENT



PROTECTIVE EARTH (GROUND)

IPX1

Footswitch not for operating theatres
Protection Class- IPX1
IPX1 Classification of ingress of water



Consult Instructions for Use

0/I

AC Power Switch (0 = Off, I = On)



Footswitch



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.



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,
ANSI/AAMI ES60601-1 (2005, 3rd ed.)
CAN/CSA-C22.2 No. 60601-1 (2008),
13VA

This device 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.

FCC ID:TFB-BT2
IC: 5969A-BT2



WEEE

Dispose of in accordance with the Waste Electrical and
Electronic Equipment Directive 2002/96/EC of the
European Parliament and the Council of the European
Union



This is a wireless device.

SECTION 15: Classifications

- Type of protection against electric shock:
- Degree of protection against electric shock:
- Degree of protection against the harmful ingress of water:
- Mode of operation:
- Degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide:
- According to medical device directive:

Class 1
Type B
Ordinary
Continuous

Equipment not suitable for use in the presence of
flammable anaesthetic or oxygen.
IIA (rule 9)

SECTION 16: Disposal of Unit

U.S. - Dispose of the system components in accordance with state and local laws.

EU - Dispose of in accordance with the Waste Electrical and Electronic Equipment Directive 2002/96/EC of the European Parliament and the Council of the European Union.