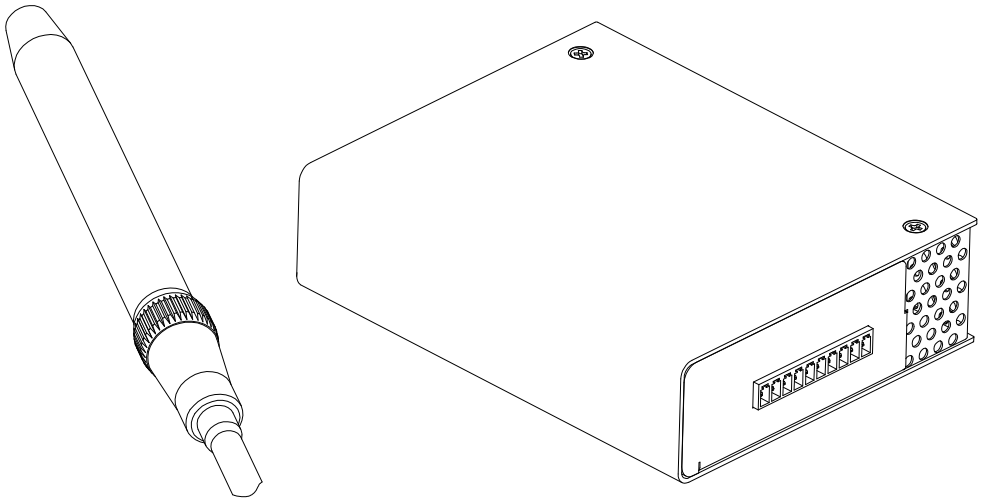
User Manual

ROLENCE ULTRASONIC SCALER ELiTEDENT® MS-10B

(Built-in type)



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S-19-01-1211-U0001 V4.3

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Section 1: Safety Precautions

Prior to installation and start-up of the ultrasonic scaler, carefully read the instructions provided herein!

1.1 Precautions for All Systems

 Do not place the ultrasonic scaler on or next to a radiator or other heat source. Excessive heat may damage the ultrasonic scaler's electronics.

 Equipment and dental water supply system maintenance are strongly recommended. See Section 10: System Maintenance And Care.

 Close the water shut-off valve in the dental water supply system every night before leaving the office.

 The use of an in-line water filter is recommended.

 Used for the intended purpose only. The ultrasonic scaler must be used by other than qualified and trained personnel, in medical facilities.

 Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked Hospital Only or Hospital Grade.

1.2 Precautions for Ultrasonic Prophylaxis Procedures

- Before first use, clean, disinfect and sterilize new or repaired handpieces and instruments you wish to use with the ultrasonic scaler.
- Always examine the unit and ultrasonic tips before commencing treatment. A damaged ultrasonic scaler or damaged tip must not be used.
- Ultrasonic 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 ultrasonic tip whenever it is placed in the patient's mouth.

Section 2: Introduction

Rolence Enterprise Inc. is an ISO 9001(2008), ISO 13485(2003) certified manufacturer of Ultrasonic Scalers. All the products are FDA registered and compliant with EN standard (CE Marking).

2.1 Conformance to Standards:

The Rolence® ELiTEDENT® MS-10B Ultrasonic Scaler conforms to IEC60601-1-2:2001 and IEC60601-1-1:2000. (Refer to Appendix I)

The device is CE marked corresponding to European **Medical Device Directive (93/42/EEC)**

2.2 Function

The ultrasonic scaler is designed for use in prophylaxis treatments periodontia, and other areas of operative dentistry. When used in prophylaxis treatment, the unit operates with a fine warm water spray, requiring little of the physical exertion necessary with hand instruments. It easily and effectively removes stubborn calculus and stains both supragingivally and subgingivally, leaving crown and root surfaces clean and smooth.

2.3 Supplies and Replacement Parts

Contact your local Rolence dealer to order supplies or replacement parts. There are no serviceable parts included in this device. Please contact your dealer to acquire all repairing service and technique supports.

CAUTION: EQUIPMENT NOT SUITABLE FOR USE IN THE PRESENCE OF FLAMMABLE ANESTHETIC MIXTURE WITH AIR OR WITH NITROUS OXIDE.

CAUTION: U.S FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A DENTAL PROFESSIONAL.

Section 3: Application

The Ultrasonic Scaler procedures

- All general supra and subgingival scaling applications.
- Periodontal treatment for all types of periodontal diseases.
- Endodontic procedures, preparation of root canals, etc.

Section 4: Specifications

Rolence® ELiTEDENT® MS-10B Ultrasonic Scaler requires 24V AC power supply from dental unit.

4.1 Electric Voltage:

VOLTAGE:	CURRENT
24V AC 50/60Hz	4.0A(MAX)
WATTAGE:	MAX.60W
WATER PRESSURE:	20-40 psi

4.2 Main Control Unit Dimension:

HEIGHT :	34 mm
WIDTH :	127 mm
DEPTH :	100 mm
WEIGHT :	340 g

4.3 Operation Environment:

AMBIENT TEMPERATURE	:+10℃ ～ +40℃
RELATIVE HUMIDITY	:30%～75%
ATOMOSPHERIC PRESSURE	:700 hPa～1060hPa

4.4 Transportation And Storage Environment:

AMBIENT TEMPERATURE	: －10℃～+70℃
RELATIVE HUMIDITY	: 10%～90%
ATOMOSPHERIC PRESSURE	: 500 hPa～1060hPa

Section 5: Contraindications and Warnings

5.1 Contraindications

- Ultrasonic systems should not be used for restorative dental procedures involving the condensation of amalgam.
- This device is designed to work with all Cavitron® (remark) insert with 25Khz or 30Khz frequency automatically. For optimum performance please use only qualified inserts supplied by Cavitron® or Rolence®.
- Do not use this device if the patient or operator is wearing a pacemaker.

  Remark: Cavitron® is a registered trademark of Dentsply® International, Inc.

5.2 Warnings

- Persons who are 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. We recommend that the handpiece and tubing be kept at least 6 to 9 inches (15 to 23 cm) away from any device and their leads during use.

- During using the unit, make sure that water is flowing continuously. If the handpiece overheats please check the water supply, and stop using the unit for a while.

Section 6: Infection Control

6.1 General Infection Control Recommendations

- As with all dental procedures, the use of standard personal protection equipment (i.e., wearing a face mask, eyewear, or face shield, gloves and protective gown) is recommended.
- For maximal operator and patient safety, carefully follow section 10 system maintenance and care information detailed in the operating instruction.
- As with high speed handpieces, and other dental devices, the combination of water and ultrasonic vibration from your ELiTEDENT® Ultrasonic Scaler will create aerosols. With proper technique, much of the aerosol dispersion can be effectively controlled and minimized. Please carefully follow the procedural guide lines in this manual

regarding the use of your ultrasonic scaler.

- Always flush your ELiTEDENT® Ultrasonic Scaler with highest flow before treatment. Refer to more information in section 10.
- Clean and disinfect the handpiece sleeve between patients. The handpiece sleeve can be autoclaved up to 135℃ for at least 3 minutes.

Sterilizing:

1. Place handpiece sleeve and pouched ultrasonic insert into a steam autoclave. After warm-up is completed, operate at a sterilizing temperature and pressure of 273° F/31 psi (134°C/216 kPa) for 12 minutes, followed by a 20-30 minute drying time.
2. To maintain sterility, the insert should remain in the sealed pouch until it is ready for use.

DO NOT USE Cold sterilization solution.

6.2 Water Supply Recommendations

- It is highly recommended that all dental water supply systems should 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 6.1 and 10

Section 7: Installation Instructions

7.1 General Information

If the installation of your ELiTEDENT® MS-10B ultrasonic scaler is performed by someone other than trained Rolence® distributor personnel, care should be taken to observe the following requirements and recommendations.

7.2 Water Line Requirements

- Incoming water supply line pressure to the ultrasonic scaler must be 25 psi (172 kPa minimum) to 40 psi (276 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.
- 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 any particles in the water supply will be trapped before reaching the ultrasonic scaler.

7.3 Electrical Requirements

Refer to Section 3: Specifications.

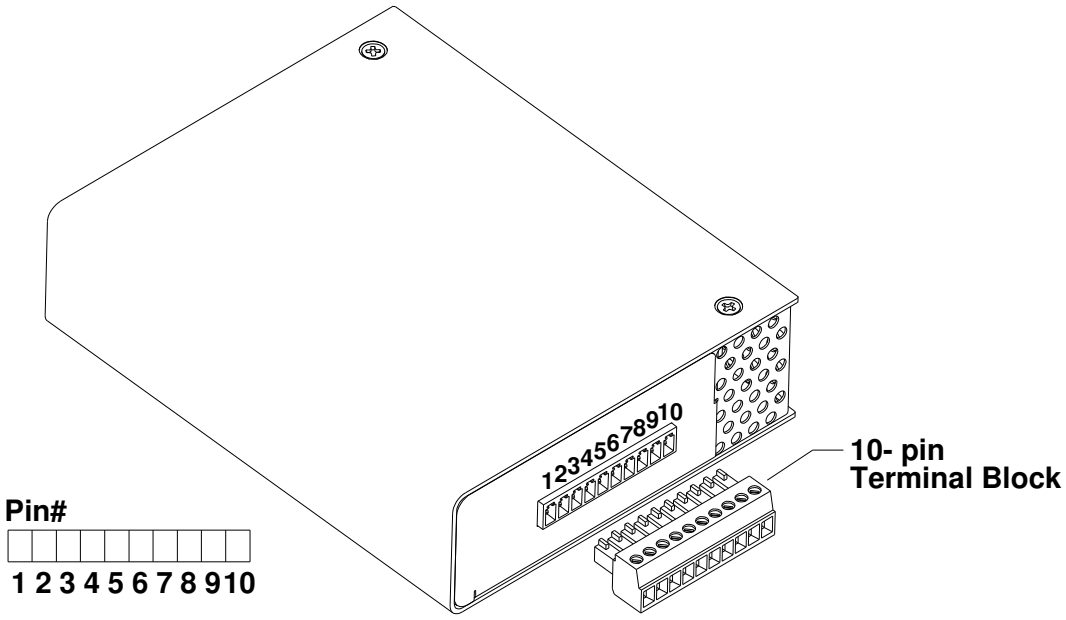
7.4 Unpacking the System

Carefully unpack your ELiTEDENT® ultrasonic scaler and verify that all components and accessories are included:

1. ELiTEDENT® MS-10B Ultrasonic scaler main control unit.
2. Handpiece set with tubing.
3. Variable Resistor with knob
4. Users Manuals.
5. Solenoid and mounting bracket (Optional)

7.5 Installation Instruction of MS-10B

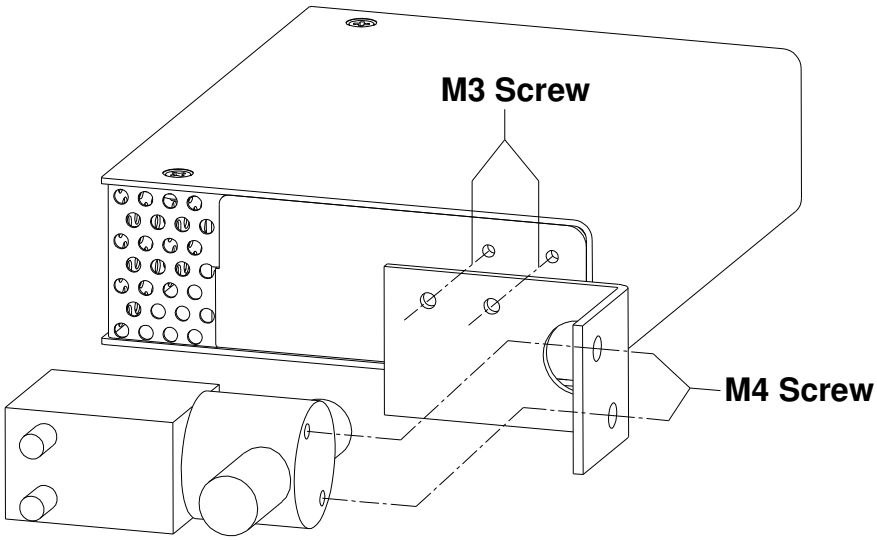
1. The main control unit should be fixed inside the dental unit where is free from water.
2. Connect handpiece water supply tube to the water control valve in the dental unit.
3. Following below pin definition for the wire connection to set up the system.
4. 24V, 3A AC power is required for this system.
5. Please connect the dental unit holder switch and power input of this system (Pin 1 & 2) in series connection.



Pin Definition
1,2 - 24V AC, 3A
3,4 - Open or Solenoid, if solenoid is applied, be sure to use Rolence's solenoid***(optional)***.
5,6 - Switch, Short circuit is ON, It could be Foot Padel Switch or other switch.
7,8 - Variable Resistor, 5KΩ
9,10 - Handpiece Wires

Optional : Solenoid Assembly

If you need Solenoid, the assembly is as below, be sure to use the solenoid from Rolence.



Important Notice:

1. This built-in scaling system is equipped with microprocessor which could be interfered and malfunctioned by outer electromagnetic noise. Most motors of dental units produce large number of electromagnetic noise while operating, such noise could result in the scaler out of order. In order to prevent the built-in scaler from shutting down (mostly known as fail to detect and lock working frequency correctly), the handpiece should be hang back to the holder where should function a safety switch to cut off the 24V AC power supply.

2. Unknown /uncertified scaling inserts may easily cause extra heat on handpiece when in operation, due to improper materials or imprecise tip dimension. To ensure safe and guaranteed practice, only certified Cavitron® and Rolence inserts are recommended to be used.

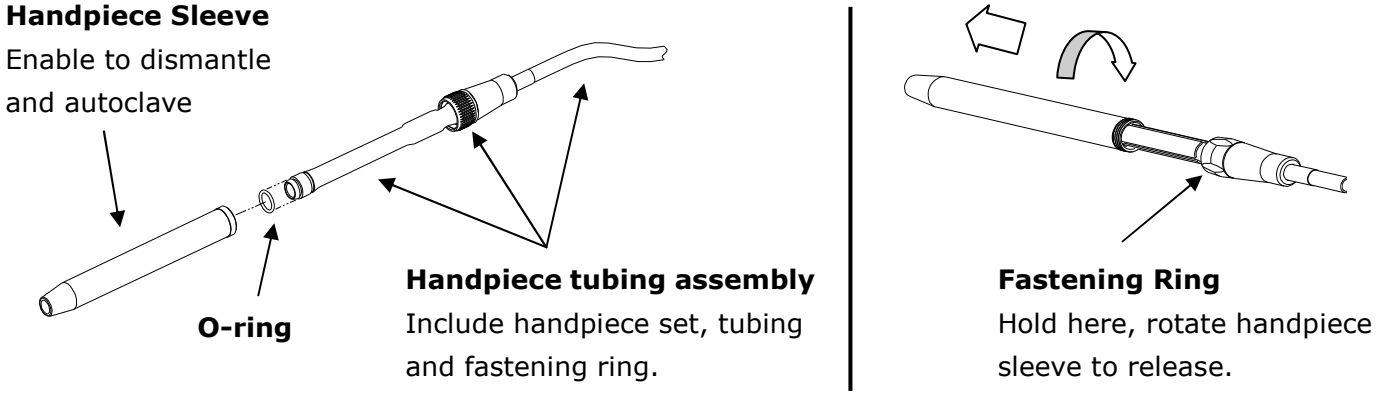
3. Please note that power supply AC 24V, 3A is required for this system. If the power supply current is less than 3 Ampere, it may lead the handpiece work at weak vibration.

4. Make sure the Handpiece working with continuous water irrigation spray during operation. Do not run the system without water. The Handpiece would overheat easily with risk of plastic Handpiece melting.

Section 8: ELiTEDENT® Ultrasonic Scaler Description

8.1 Handpiece Assembly / Handpiece Sleeve

The ultrasonic scaler is multi-frequency unit compatible with all Cavitron® 25Khz or 30 Khz inserts. The system will automatically detect the insert frequency, no need to switch any button.
For more oral hygiene care, the handpiece sleeve can be dismantled and autoclaved. See below:



To take off the handpiece sleeve, please hold the fastening ring, and rotate the sleeve counterclockwise from handpiece tubing assembly. **Note: Avoid rotate or twist the handpiece tubing.**

Section 9: Techniques For Use

9.1 Patient Positioning

- For optimal access to both the upper and lower arches, the backrest of the chair should be adjusted to a 45° degree angle. 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 irrigate using either a saliva ejector or High Volume Evacuator (HVE).

9.2 Performing Ultrasonic Scaling Procedures

- Note: Refer to the Section 6 and 11 for general procedures to be followed at the beginning of each day and between patients.

- The edges of 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. Activate the Foot Control until fluid 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 IT INTO PLACE.

- Activate the System. Hold the handpiece over a sink or drain. Check spray temperature to verify fluid is reaching the working end of the insert tip. Adjust the water cooler irrigate. Control knob to ensure adequate flow for the selected Power setting. Greater flow settings provide cooler irrigation.

- It may be necessary to adjust water flow larger under "Turbo" mode (Foot Control fully depressed) so adequate fluid will be available to cool tip and tooth interface.

- In general, it is suggested 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.

- Periodically check the ultrasonic insert for wear with the Insert Efficiency Indicator.
- The use of a saliva ejector or High Volume Evacuator (HVE) is recommended during all procedures.
- Set the System's Power Adjustment knob to the lowest power setting for the application and the selected insert.
- If water leakage found in handpiece, replace sleeve or o-ring on handpiece cable assembly to eliminate.

9.3 Patient Comfort Considerations

Reasons for sensitivity

- Incorrect tip placement. Point should be directed away from 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 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 Maintenance and Care

Daily Maintenance

It is recommended that you perform the following maintenance procedures to help minimize bio-film formation in the water path of your ELiTEDENT® ultrasonic scaler which could affect the water flow to the ultrasonic insert, and scaling performance.

Start-Up Procedures at the beginning of the day:

1. Open the manual shut-off valve on the dental office water supply system.
2. Set the Power Control knob to minimum setting.
3. Set the Water Control knob to maximum.
4. Hold the Handpiece (without an insert installed) upright over a sink or drain. Activate the Foot Control and flush the water line for at least 2 minutes.
5. Place a sterilized insert into the Handpiece and set the water control knob to your preferred operating position.

Between Patients:

1. Remove ultrasonic insert and handpiece sleeve used, clean and sterilize.
2. Clean and disinfect the surfaces of the cabinet, Handpiece cable assembly*, control knobs 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. Do not spray disinfectant solution directly on the ultrasonic scaler.
3. Place a sterilized handpiece sleeve. Set power to minimum. Hold the handpiece over a sink or drain and flush the water line at maximum water flow for 30 seconds.
4. When ready, place a sterilized insert into the handpiece.
5. Please consider use a FDA approved sheath to for the cable and entire handpiece or at least to cover the handpiece from the fastening ring to cable when sleeve is sterilized between patients.

Shut-Down Procedures at the end of the day:

1. Remove ultrasonic insert and handpiece sleeve used, clean and sterilize.

2. Turn the System OFF.
3. Clean and disinfect the surfaces of the cabinet, Handpiece cable assembly, control knobs, Foot Control 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 dean towel and wipe all surfaces. Discard used towel. To disinfect system,
4. generously spray disinfectant on a clean towel and wipe all surfaces. Allow disinfectant solution to air dry. Do not spray disinfectant solution directly on the ultrasonic scaler.
5. Close the manual shut-off valve on the dental water supply system.

*__Note__: Those Water-based disinfection solutions are preferred, due some alcohol-based disinfectant solutions may be harmful and may discolor plastic materials.

__*Note__: The electric wire winding covered by heat shrinkage tube which protected by handpiece sleeve is very sensitive to the disinfectant solution and water. After the disinfection, wipe surface of shrinkage tube with a slightly damp cloth and dry thoroughly before use.

Section 11: Trouble shooting

Although service and repair of the ELiTEDENT® Ultrasonic Scaler should be performed by ROLENCE dealer 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.

Problem: Insert stops vibrating

1. Deactivate foot control.
2. Verify insert is in good condition.
3. Depress foot control to try again.

Section 12: Disposal of Unit

Dispose of the ELiTEDENT® Ultrasonic Scaler in accordance with local and national laws.

Section 13: Disclaimer

ROLENCE Enterprise Inc. considers itself responsible for the effects on safety, reliability and performance of this product only if:

- Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by ROLENCE.
- The electrical installation of the relevant room complies with the requirements.
- The equipment is used in accordance with these instructions for use.

Section 14: Warranty

15.1 Malfunction

Rolence hereby warrants that for a period of one year from the delivery date, this device shall be free from

defects in material and workmanship. In case the machine is found malfunctioned under normal use, Rolence will offer service of free maintenance and parts for replacement.

15.2 Repair

Repairs must be only carried out by an authorized Rolence engineer/dealer. If repairs during warranty period are not carried out by an authorized engineer/dealer, warranty will expire immediately.

15.3 Warranty Exception

The warranty stated herein is the sole warranty applicable to Rolence products. Rolence expressly disclaims the liability for warranty even within warranty period, if

(1) Damages caused by natural disaster.
(2) Operator's fault or wrong operation.
(3) Application use other than curing light-cured material purpose.
(4) A malfunction or damage caused by repair, adjustment, modification which is not carried out by Rolence authorized technicians/dealers.
(5) A malfunction caused by abnormal power source or voltage.
(6) It is a consumption part.

Section15: Additional Symbols

 **BF Type.**

 **Attention, refer to accompanying documents.**

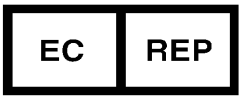
 **Power off**

 **Power on**

CE 1434

The equipment complies with the requirements in the Medical Device Directive 93/42 EEC.

EU authorized representative name and address



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