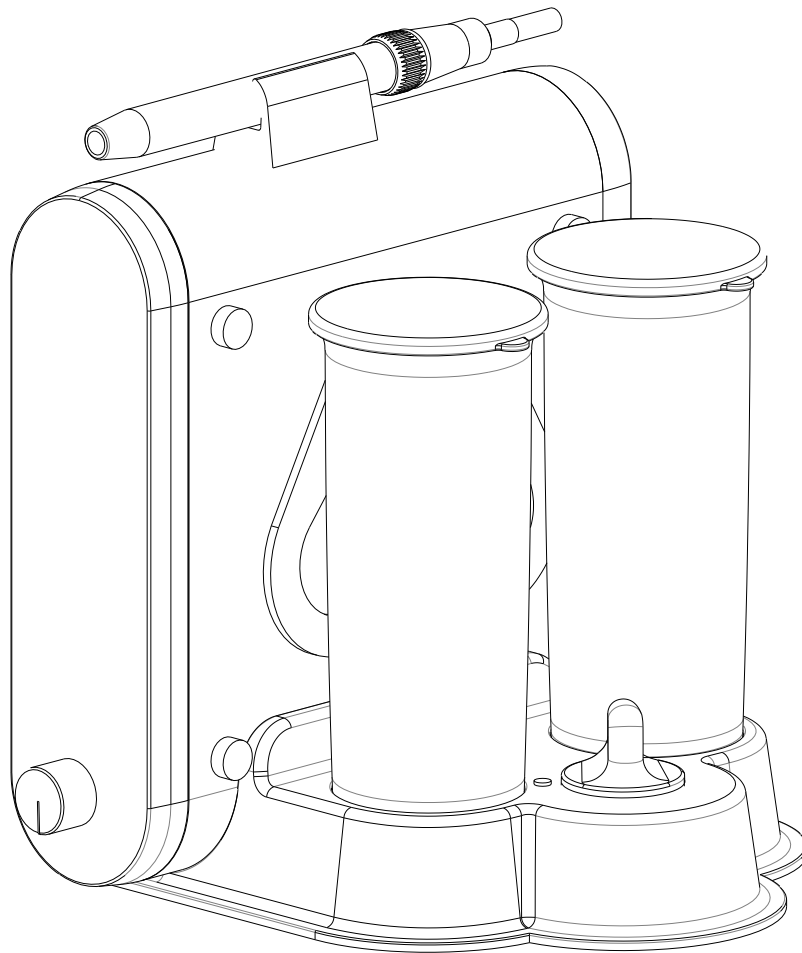


ROLENCE® ULTRASONIC SCALER

ELiTEDENT® MS-1 Dual Elite

(25K/30K)



Instructions For Use

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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. Place the ultrasonic scaler where air is free to circulate on all sides and beneath it.
-  **Never operate the ultrasonic scaler without water flowing through the handpiece.**
-  **Always flush your ELiTEDENT® ultrasonic system with clean water at least 30 seconds at highest flow after treatment.**
-  **Do not continuously operate the ultrasonic unit for more than 20 minutes; try 5 minutes down time before reserving.**
-  Equipment maintenance is strongly recommended. See Section 12: System Maintenance And Care.
-  Close the power switch every night before leaving the office.
-  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 ultrasonic inserts you wish to use with the ultrasonic scaler.
- Like a toothbrush, ultrasonic inserts "wear out" 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.
- Always examine the unit and ultrasonic insert tips before commencing treatment. If excessive wear is noted, or ultrasonic insert tips 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 insert whenever it is placed in the patient's mouth.

Section 2: Introduction

The Rolence ELITEDENT® 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.

Rolence Enterprise Inc. is an ISO 9001, ISO 13485 certified manufacturer of Ultrasonic Scaling System. The product is FDA registered and compliant with EN standards.

2.1 Conformance to Standards:

The ELITEDENT® ultrasonic scaler conforms to IEC60601-1-2:2014 and IEC60601-1-1:2012(Reprint).

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













2.2 Supplies and Replacement Parts

Contact your local Rolence Enterprise Inc. dealer to order supplies or replacement parts.

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: Glossary of Symbols

	Caution, Consult accompanying Documents		Type BF Applied Part; Type BF Equipment - Protection against electric shock
	Read usage instructions		Equipment class: Class II (IEC601-1) - double insulated
	Alternating Current		The equipment complies with the requirements in the MDD 93/42/EEC.
	Manufacturer		Icon to identify electric and electronic devices. The unit must be collected and disposed of separately.
	Date of manufacture		Power off
	Catalogue number		Power on

Remark : Cavitron® is the registered trademark of Dentsply Sirona®

Section 4: Intended Use

Ultrasonic procedure

- All general supra and subgingival scaling applications.
- Periodontal debridement for all types of periodontal diseases.

Section 5: Specifications

The ELiTEDENT® MS-1 Dual Ultrasonic Scaler is a multi-voltage 100V~240V unit.

5.1 Electric Voltage:

VOLTAGE:	CURRENT
100VAC-240VAC 50/60Hz	2.3-1.1A (MAX)

WATTAGE CONSUMPTION: MAX. 90W

5.2 Dimension:

HEIGHT:	23 CM
WIDTH:	21.5 CM
DEPTH:	22.0 CM
WEIGHT:	2.3 KG

5.3 Operation Environment:

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

5.4 Transportation And Storage Environment:

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

Section 6: Contraindications and Warnings

6.1 Contraindications

- Ultrasonic systems should not be used for restorative dental procedures involving the condensation of amalgam or porcelain.
- 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 Enterprise Inc.
- Do not use this device if the patient or operator is wearing a pacemaker.

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

6.2 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 Cable 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 Sterilizable Sleeve of handpiece overheats please check the water supply, and stop using the unit for a while.

Section 7: Infection Control

7.1 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 12 system maintenance and care information.
- 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 direction manual regarding the use of your ultrasonic scaler.
- **Always flush your ELiTEDEnt® Ultrasonic Scaler with clean water at least for 30 seconds with highest flow after treatment.**
- Clean and disinfect the Sterilizable Sleeve of handpiece and ultrasonic insert after use. The handpiece sleeve can be autoclaved in 135°C for at least 5 minutes.

7.2 Sterilizing:


1. Place Sterilizable Sleeve of handpiece 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 10 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.

Please note liquid tank can not be sterilized.

7.3 Replacement of tubing pump set

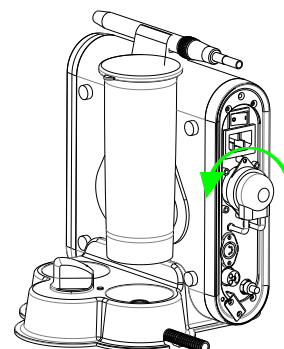
 **Important:** The pump of the unit is a wear part. It is recommended to replace it while the water

pumping is slow or every 12 (twelve) months after normal usage.

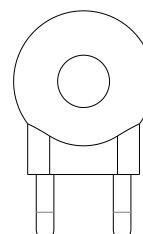
1. Switch off the system. Disconnect power cord on the back of the system.



2. Turn the pump set moderately in the direction of counterclockwise at about 30 degree. Then pull out the complete used pump set with tubing.



3. Reverse the procedure above, replace with a new tubing pump set.



Note: Please contact the dealer you purchased this device for the replacement tubing pump set and assistance.

Section 8: Installation Instructions

8.1 General Information

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

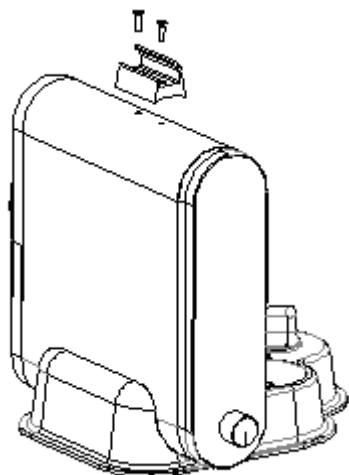
8.2 Unpacking the System

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

1. Rolence ELiTEDENT® Ultrasonic scaler main unit with factory installed PS Sterilizable handpiece with PS handpiece cable
2. Power Cord
3. Foot Pedal.
4. 2 Bottles
5. Handpiece holder with screws
6. User Manual.

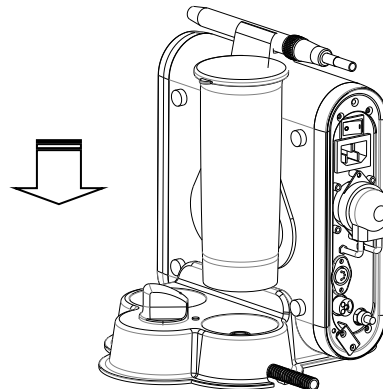
8.3 System Installation

- Place the system on a level surface. Be sure unit is stable and resting on four feet.
- Placing unit in direct sunlight may discolor plastic material.
- Install handpiece holder on the top of main unit by fixing 2 screws.



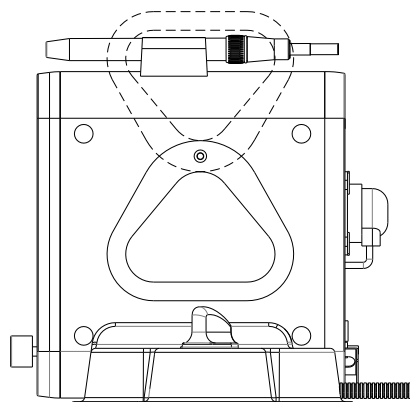
Install Bottles

Insert the bottles downward into the base until feeling a gentle "click".



Use Of Handle

Rotate the handle making it ready for hand carry.



8.4 Electrical Requirements

Refer to Section 3: Specifications.

8.5 Power Connection

- The ON/OFF Control Switch and power indicator is located on the Front Panel of the ELiTEDENT® Ultrasonic Scaler. (See Section 9.1)
- Verify the ON/OFF Control Switch located on the front panel of the Rolence ELiTEDENT® ultrasonic scaler is in the OFF position before proceeding.
- Plug the detachable AC Cord into the back of the ultrasonic scaler and into an approved outlet.

Section 9: ELiTEDENT® Ultrasonic Scaler Description

9.1 System Controls Rear Panel

Sterilizable Sleeve of Handpiece Holder

Securely holds the Sterilizable Sleeve of Handpiece when system is not being used.

Power Switch / AC Power Indicator Light

Illuminates when POWER ON/OFF control switch is on.

Foot Pedal Connector

Connect foot pedal here, ensure it is firmly seated.

Power Socket

Connect with power cord; ensure it is firmly seated.

Bottles switch

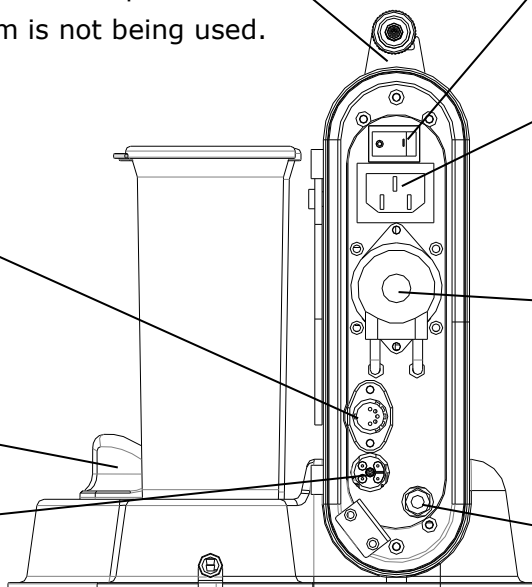
Choose liquid source from the bottles.

Tubing pump

Drive liquid from the bottles into ultrasonic scaling system.

Handpiece Cable Quick Connector

Solenoid Water Inlet



Front Panel

Sterilizable Sleeve of Handpiece

Operates 25Khz or 30Khz Ultrasonic inserts and transmits power and water flow from the scaler to the insert.

Purge

Used for flush water lines. Runs automatically for 2 minutes.

Rinse

Use during an ultrasonic scaling procedure when lavage is desired with no cavitation.

Lock

Press and hold to lock or unlock screen. Logo will appear brighter when locked.

Turbo Indicator Light

Illuminates when foot switch is deeply pressed, and it is functioning in "Turbo" mode.

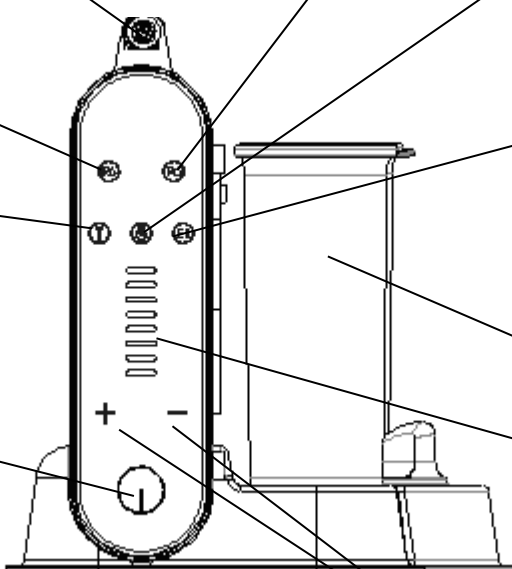
Handpiece Cable Indicator

Indicator will light up automatically if the handpiece cable is not connected properly.

Water Flow Adjustment

Turn knob to select Water Flow level for operation. Clockwise increases water flow, while counterclockwise decreases water flow.

The rate of flow through the Hand piece determines the temperature of the water flow. Lower flow rate produces warmer temperature; higher flow rate produces cooler temperature.



Bottles

Allow to fill in medicament for treatments.

Intensity Display

Indicates the power level, total 8 LEDs display.

Intensity Control

Increase or decrease power level for operation: "+" increases power, "-" decreases power.

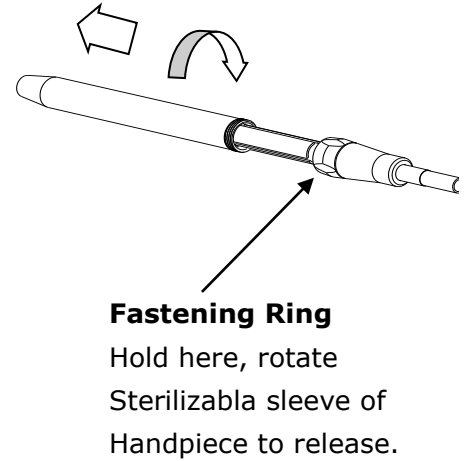
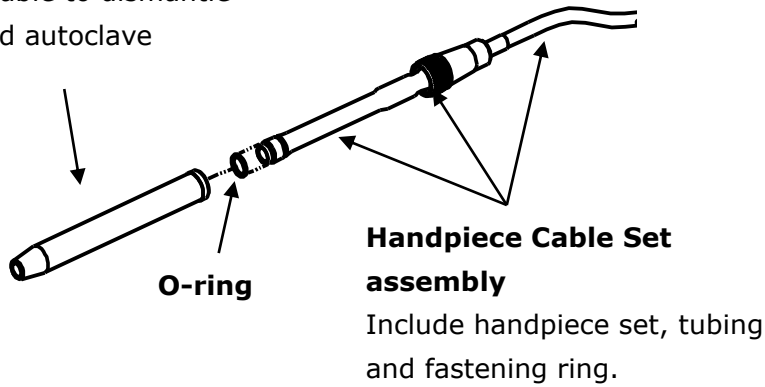
9.2 Handpiece Assembly / Handpiece Sleeve

The ultrasonic scaler is dual-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 better oral hygiene care, the handpiece sleeve can be dismantled and autoclaved in 135°C. See below:

Sterilizable Sleeve of Handpiece

Enable to dismantle and autoclave



To take off the Sterilizable sleeve of handpiece, please hold the fastening ring, and rotate the sleeve counterclockwise from handpiece cable set assembly. **Note: Avoid rotate or twist the handpiece Cable .**

9.3 Foot switch Controls and Operation

The Foot switch is a two-position momentary switch, which activates both Ultrasonic energy and water flow at insert tip.

<p>Foot Pedal Released... Both ultrasonic activation and irrigating flow stop.</p>	<p>Foot Pedal Depressed Half Way (1st position) The ultrasonic insert tip is activated and irrigating water flow under normal function.</p>	<p>Foot Pedal fully depressed (2nd position) This activates the "Turbo" mode increasing extra power.</p>

Section 10: Accessories

1. Sterilizable Sleeve of Handpiece
2. 2 bottles with caps
3. Power Cord
4. Foot Pedal
5. Replacement tubing pump set (optional).
6. Ultrasonic inserts (optional).

Section 11: Techniques For Use

11.1 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).

11.2 Performing ultrasonic scaling procedures

- Note: Refer to section 12 for general procedures to be followed at the beginning of each day and between patients.
- The edges of scaling tips are intentionally rounded so there is little danger of tissue laceration with proper ultrasonic Scaling technique. Whenever the 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 sterilizable sleeve of 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 sterilizable sleeve of handpiece. Fully seat insert with a gentle push-twist motion. DO NOT FORCE IT INTO PLACE.
- Activate the System. Hold the sterilizable sleeve of 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 Pedal 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 tips for wear with Insert Efficiency Indicator in tip package.
- The use of a saliva ejector or High Volume Evacuator (HVE) is recommended during all procedures.
- If water leakage found in sterilizable sleeve of handpiece, check the handpiece and handpiece o-ring to eliminate.

11.3 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 tip to remain in a static position on any one area of the tooth. Change the tip'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 12: 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 inserts, and scaling performance.

Preparation prior to the treatment:

1. Clean and fill up the liquid tank.
2. Turn the system ON using the Power ON/OFF switch. Verify the Power Indicator Light is on.
3. Set the Water Control knob to maximum.
4. Set power minimum. Hold the Sterilizable Sleeve of 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 sterilizable sleeve of Handpiece and set the water control knob to your preferred operating position.

Between Patients:

1. Remove ultrasonic insert and sterilizable sleeve of handpiece sleeve used, clean and sterilize.
2. Place a sterilized sterilized handpiece sleeve power to minimum. Hold the sterilizable sleeve of handpiece over a sink or drain and flush the water line at maximum water flow for 30 seconds.
3. When ready, place a sterilized insert into the handpiece.

Shut-down procedures at the end of day:

1. Remove ultrasonic insert and handpiece sleeve used, clean and sterilize.
2. Set power to minimum. Hold the handpiece over a sink or drain and flush the water line with clean water at maximum water flow for 2 minutes.
3. Turn the system OFF.
4. Clean and disinfect the surfaces of the cabinet, Power Cord, Handpiece cable set assembly, control knobs, Foot Pedal cable assembly 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, 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. Clean and disinfect the liquid tank. The bottle can be washed in a dishwasher and disinfected at up to 95 °C in a washer disinfector.

Please note liquid tank can not be sterilized.

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

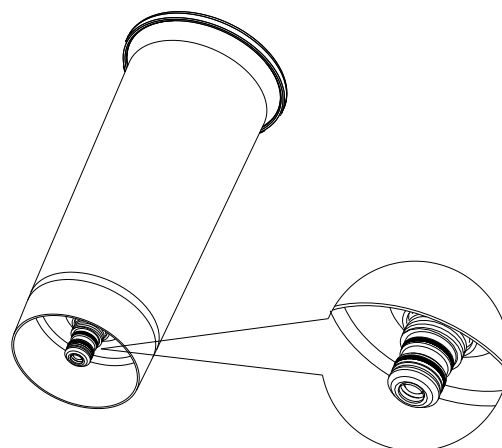
Sterilizing:

1. Place sterilizable sleeve of handpiece and pouched ultrasonic inserts into steam autoclave. After warm-up is completed, operate at a sterilizing temperature and pressure of 273° F/31 psi (134°C/216 kPa) for 10 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.

Replacement of O-rings

A damaged or worn out O-ring must be replaced immediately.



Section 13: Trouble shooting

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

13.1 Troubleshooting Guide

Problem: System will not operate: (Power Indicator Light is not lit.)

1. Check that the Power switch is in the ON position, and that the detachable Power Cord is fully seated in the receptacle on back of System.
2. Check that the System's plug is fully seated in an appropriate AC receptacle, and that AC current is present.

(Power Indicator Light is lit.)

1. Check that the Foot Pedal Connector is fully seated in the Foot Pedal Receptacle on the back of

the System.

System operates:

(No water flow to the insert.)

1. Assure that water control is properly adjusted.
2. Check tubing pump on the back of main unit, there should be water flow running inside water tubing. If not,
3. Check that bottle is filled and fully mounted on its base.

(Instrument stops vibrating)

1. Deactivate foot pedal.
2. Verify ultrasonic instrument is properly installed.
3. Depress foot pedal to try again.

Water Leakage at the bottom of the Detachable Internal Water Supply System

1. Check the o-rings at the bottom of bottles. A damaged or worn out o-ring must be replaced immediately. Please refer to section 12.
2. Verify that the pump tubing is firmly connected to connector which is located on the back of main unit. If broken tubing is found, replace the pump tubing. Please refer to Section 7.3

Section 14: Disposal of Unit

- Keep original packaging until the Rolence ELiTEDENT® Ultrasonic Scaler is to be disposed of permanently. You can use it for shipping or storing your ELiTEDENT® Ultrasonic Scaler at any time.
- Dispose of the Rolence ELiTEDENT® Ultrasonic Scaler in accordance with local and national laws.

Section 15: 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 Enterprise Inc.
- The electrical installation of the relevant room complies with the requirements.
- The equipment is used in accordance with these instructions for use.

Section 16: Warranty

16.1 Malfunction

Rolence Enterprise Inc. 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 Enterprise Inc. will offer service of free maintenance and parts for replacement.

16.2 Repair

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

16.3 Warranty Exception


The warranty stated herein is the sole warranty applicable to Rolence products. Rolence Enterprise Inc. 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 fields specified in this instruction.
- (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.

(This instruction subjects to change without pre-notice.)

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



 **Rolence Enterprise Inc.**
No. 18-3, Lane 231, Pu Chung Rd.,
Chungli, Taoyuan 32083, Taiwan.

EU authorized representative name and address

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