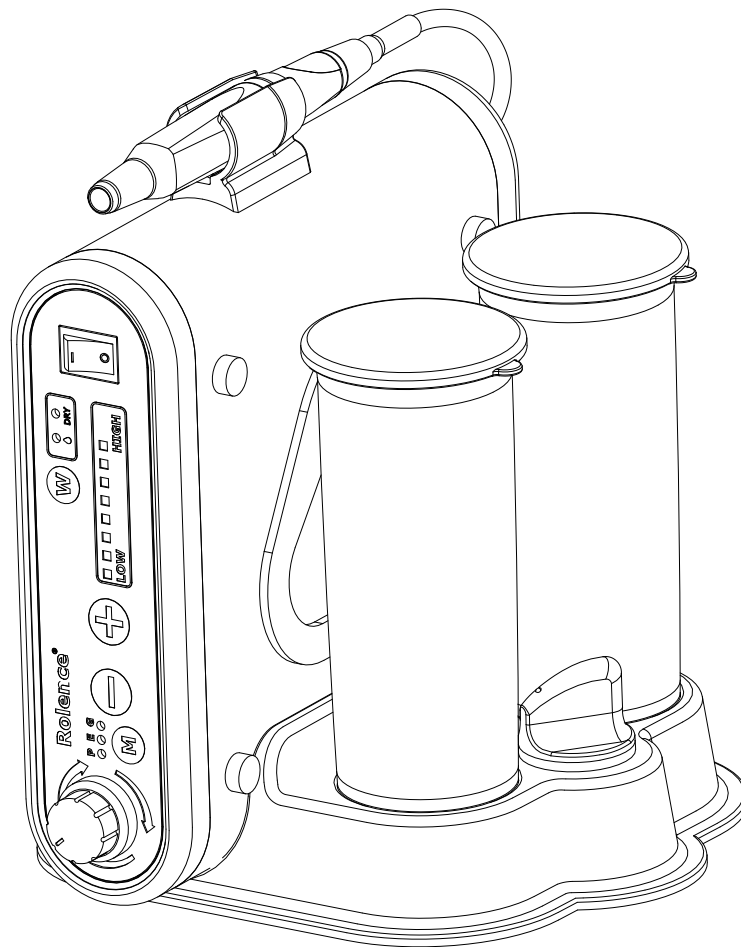


**ROLENCE<sup>®</sup>**  
**ULTRASONIC SCALER (Piezo)**  
**ELiTEDENT<sup>®</sup> PS-1 Dual / PS-1(LED) Dual**



***Instructions For Use***

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# ***Section 1: Safety Precautions***

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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.

 **Always set the system's power adjustment to the lowest power setting for the application of a new or special instrument.**


 **Always flush your ultrasonic system at least 30 seconds with highest clean water flow after treatment.**


 **Do not continuously operate the system in "Turbo" mode for more than 20 minutes! Try a 10 minute break before re-use the system.**

 **Do not continuously operate the unit in "DRY" mode for more than 4 minutes! Leave at least 8 minutes down time before reserving. This can extend handpiece lifetime.**

 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 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

---

The Rolence ELITEDENT® ultrasonic scaling system is designed for use in prophylaxis treatments periodontia, and other areas of operative dentistry. Rolence Enterprise Inc. is an ISO 9001(2008), ISO 13485 (2003) certified manufacturer of Ultrasonic Scaling System. The product is FDA registered and compliant with EN standards.

### 2.1 Conformance to Standards:

Ultrasonic Scaler ELITEDENT® PS-1 Dual / PS-1(LED) Dual conforms to IEC60601-1-2:2001 and IEC60601-1-1:2000.

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

### 2.2 Supplies and Replacement Parts










Contact your local Rolence 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

---

	<b>Attention, Consult accompanying Documents</b>
	<b>Alternating Current</b>
	<b>Power off</b>
	<b>Power on</b>
	<b>Manufacturer</b>
	<b>Type BF Applied Part; Type BF Equipment - Protection against electric shock</b>
	<b>Equipment class: Class II (IEC601-1) - double insulated</b>
	<b>The equipment complies with the requirements in the Medical Device Directive 93/42 EEC.</b>
	<b>Icon to identify electric and electronic devices. The unit must be collected and disposed of separately.</b>

## Section 4: Application

---

The Ultrasonic Scaler is designed for use in dentistry for the following applications:

### - General Scaling (G)

Removal of supragingival calculus

Removal of stains

### - Endo (E)

Preparation, cleaning and irrigation of root canals

Retrograde preparation of root canals

### - Perio (P)

Scaling and root planing

Periodontal treatments

## Section 5: Specifications

---

The ELITEDENT® PS-1 Dual/PS-1(LED) Dual voltage optional: 100V, 120V, 230V, 240V

### 5.1 Electric Voltage:

VOLTAGE:	CURRENT
100VAC 50/60Hz	0.38A (MAX)
120VAC 50/60Hz	0.32A (MAX)
230VAC 50/60Hz	0.17A (MAX)
240VAC 50/60Hz	0.16A (MAX)

Wattage Consumption: MAX.38W

### 5.2 Dimension:

HEIGHT:	23.0 CM
WIDTH:	21.5 CM
DEPTH:	22.0 CM
WEIGHT (with bottle):	3.4 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. The high frequency ultrasonic oscillations may loosen the restoration.
- This device is designed to work with ultrasonic tips compatible with EMS or Satelec system. For optimal performance please use only qualified ultrasonic tips supplied by EMS, Satelec and Rolence.
- Please check prints on your Handpiece to identify your Handpiece fits EMS or Satelec (S) tips. Satelec tip compatible Handpiece comes with (S) mark following the 135°C autoclave logo, while EMS tip compatible Handpiece does not have it. Incorrect tip connection could cause Handpiece thread damaged permanently.

Remark: EMS® is the registered trademark of the Electro Medical Systems.

# 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 detailed in the operating instruction accompanying your ultrasonic scaler.
- 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 at least for 30 seconds with highest flow after treatment.**
- Clean and disinfect wrench after unscrewing tip from the handpiece. The Dynamometric Wrench can be autoclaved in 135°C for at least 3 minutes.


### 7.2 Sterilizing:

1. Place handpiece and pouched ultrasonic tips 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 tips should remain in the sealed pouch until it is ready for use.

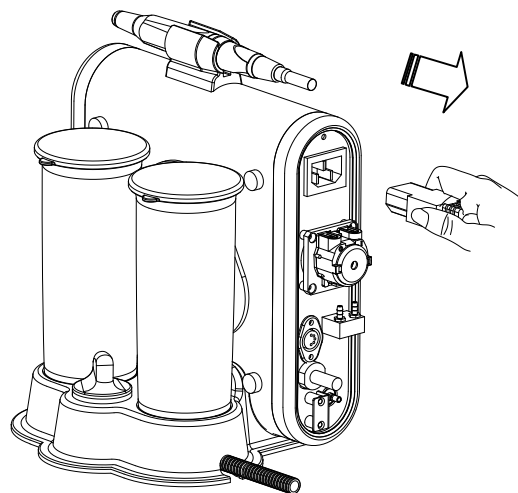
**DO NOT USE Cold sterilization solution.**

**Please note liquid tank can not be sterilized.**

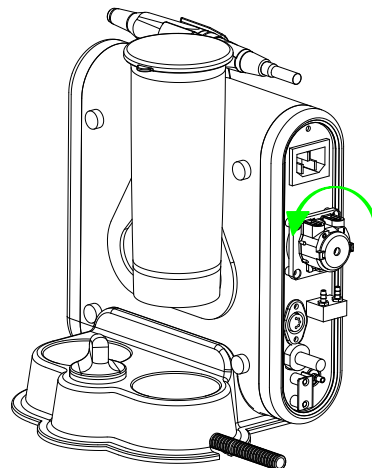
### 7.3 Replacement of tubing pump set

 **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.

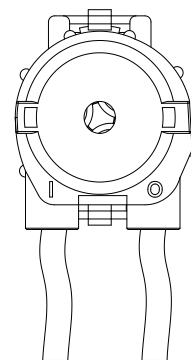
1. Switch off the system. Disconnect power cord on the back of the system.



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.

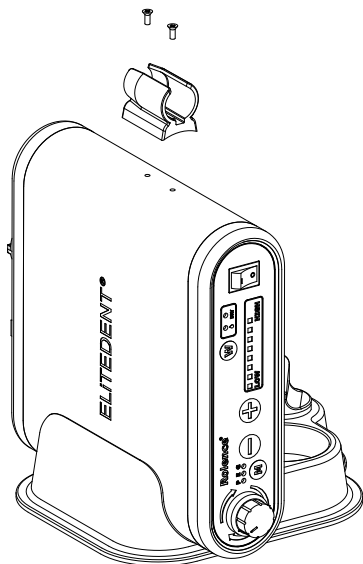
### 8.2 Unpacking the System

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

1. ELITEDENT® Ultrasonic scaler main unit with factory installed handpiece tubing.
2. Detachable AC Power Cord.
3. Foot Control Pedal.
4. 2 Liquid bottles with cap
5. Autoclavable Handpiece Set
6. Handpiece Holder with screws
7. Ultrasonic Tips and Dynamometric Wrench.
8. Spare tubing pump for replacement
9. User Direction Manual.

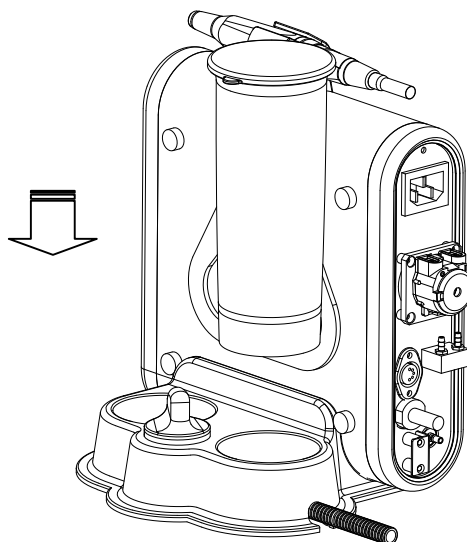
### 8.3 System Installation

- 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.



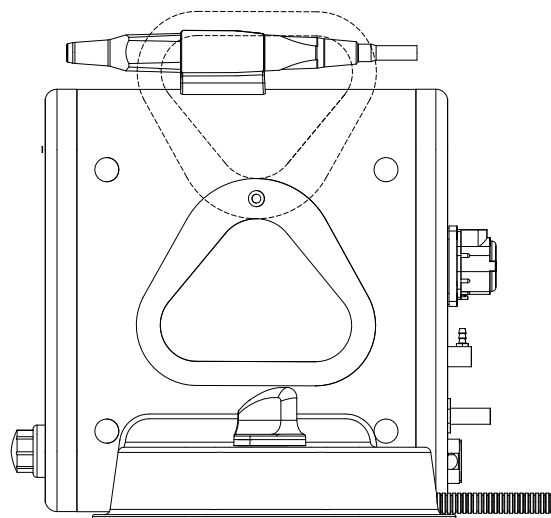
### 8.4 Install liquid tanks

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



### 8.5 Use Of Handle

Rotate the handle making it ready for hand carry.



### 8.6 Electrical Requirements

Refer to Section 3: Specifications.

### 8.7 Rear Panel Controls / 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 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

### Handpiece Holder

Securely holds the Handpiece when system is not being used.

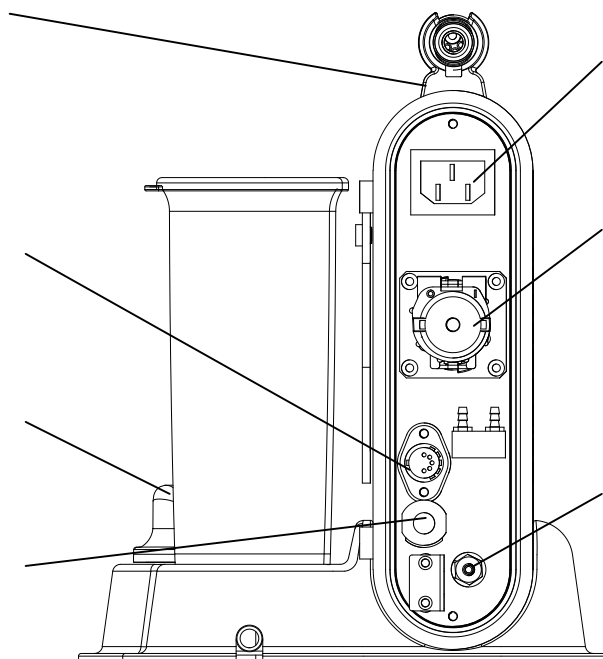
### Foot Switch Connector

Connect foot switch here, ensure it is firmly seated.

### Liquid tank switch

Choose liquid source from the tanks.

### Handpiece cord outlet



### Power Socket

Connect AC power cord here, ensure it is firmly seated.

### Tubing pump

Drive liquid from the water tank into ultrasonic scaling system.

### Solenoid Water Inlet

## Front Panel

### Water Supply Mode & Auto Cleaning

. Choose "DRY" mode with no water spray for some special tips or procedures.  
 . Press the KEY for 3 seconds to activate Auto Cleaning process. (Refer to Section 14)

### 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.

### Handpiece

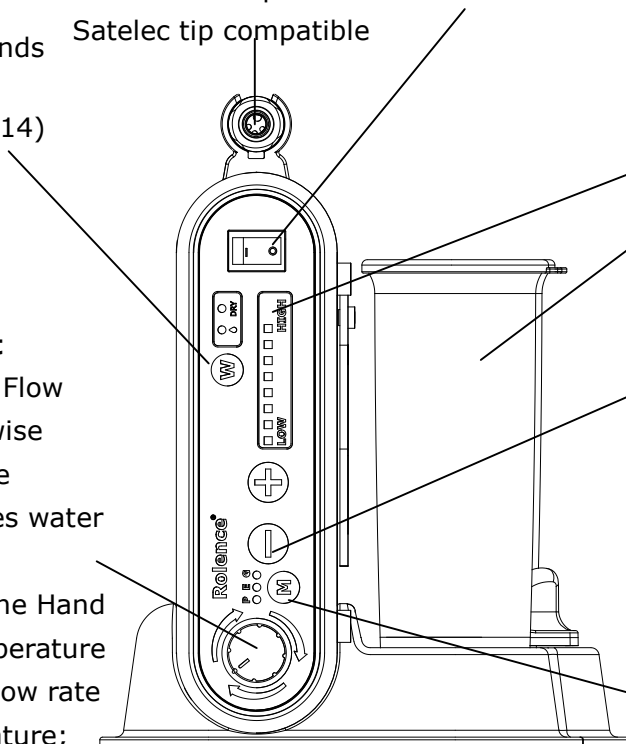
Operates ultrasonic tips and transmits power and water flow from the scaler to the tip. EMS or Satelec tip compatible

### Power Switch / AC Power Indicator Light

Illuminates when POWER ON/OFF control switch is on.

### Intensity Display

Indicates the power level,



### Liquid Tanks

Allow to fill in medicament for treatments.

### Intensity Control

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

### Mode Selection and Indicator

**G:** General scaling, Indicator flickers when "Turbo" mode is activated.

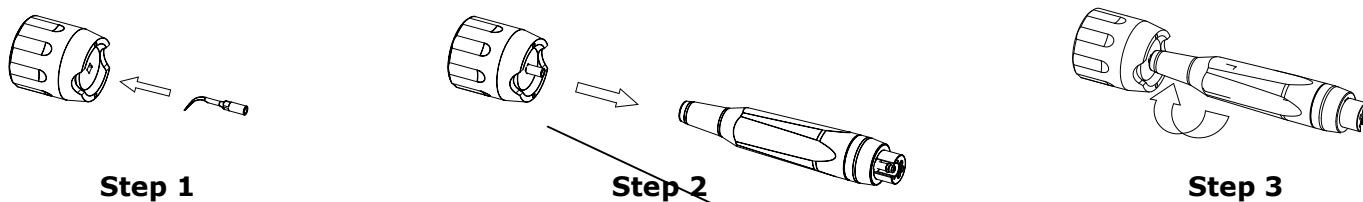
**E:** Endodontic procedures

**P:** Periodontal procedures



## 9.2 Installation of ultrasonic instrument and Handpiece

The ultrasonic scaler is designed working with all EMS® or Satelec (S) tips. Please check prints on handpiece to identify which tip spec. is required. Incorrect tip connection can cause handpiece thread damaged. Use Dynamometric Wrench to mount and drive ultrasonic instrument onto the appropriate handpiece gently. Note: The tip must be screwed and moderately tightened. See below:



### Connecting the handpiece

For better oral hygiene care, the handpiece can be dismantled and autoclaved separately. See below:

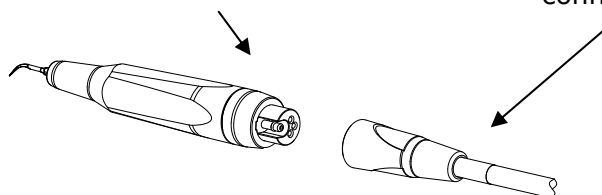
#### Handpiece

Enable to dismantle and autoclave in 135°C

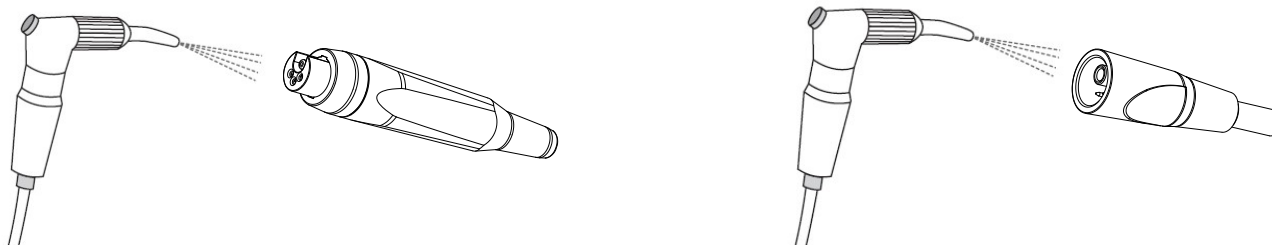
#### Handpiece Connector assembly

Includes handpiece female connector and tubing.

**Note :** Please **DO NOT** use other brands torque wrench. We disclaim the liability for warranty if using another brand of torque wrench and cause damage to the handpiece.



Before connecting the handpiece, blow dry the connections to remove eventual presence of liquid to ensure a proper electrical contact.



## 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 tip. Turbo function is only available in "G" mode.

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


## 9.4 Use of Instrument


The ultrasonic instrument is for use in dentistry with Rolence® ELiTEDENT® Ultrasonic scaler.


Rolence offers 5 different kinds of ultrasonic instruments. The longer and thinner an instrument is, the better becomes its access to periodontal pockets and inter-proximal areas. Also, at a constant power setting on the unit, a longer and thinner instrument delivers less clinical power. This means slower concretment removal and less pain for the patient. For gentle treatment, choose a very long and very thin instrument. Only switch to a shorter instrument if a particular treatment situation requires more power than the longer instrument can deliver.

The standard package of ELiTEDENT® ultrasonic scaler includes few tips only. To afford extra tips, please contact Rolence authorized dealer to order.

Before use of the ultrasonic instrument, please read following instruction carefully.

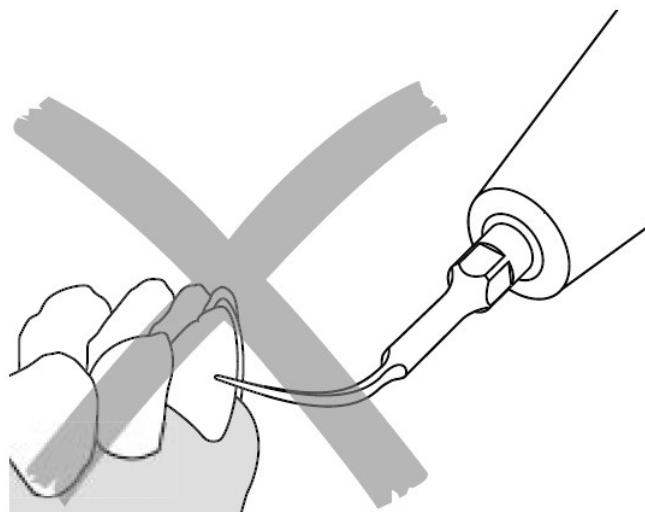
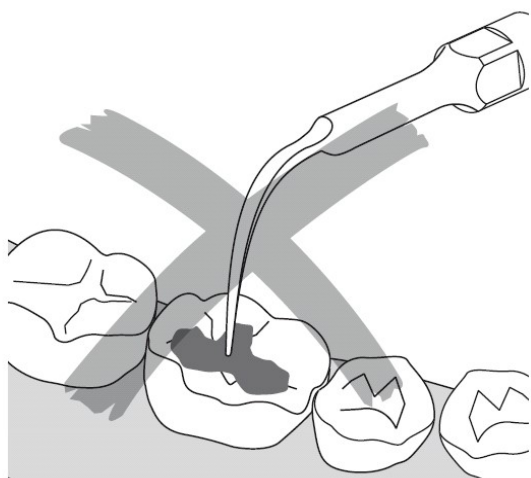
 Before use, always disinfect, clean and sterilize handpieces and instruments. Non-sterile handpieces and instruments may cause bacterial or viral infections.

 To avoid heat damage on the tooth or handpiece, be careful with working dry. The end of the instrument immediately heats up when used dry.

 Always examine your ultrasonic system and instrument for damage before commencing treatment. Damaged accessories or a damaged product must not be used and must be replaced.

**Note: Never use the instruments of this system on metal or porcelain restorations. The high frequency ultrasonic oscillations may loosen the restoration.**

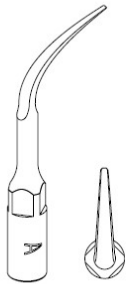
**Note: Do not hold the instrument head-on to the enamel. Never direct the end of the instrument vertically or almost vertically to the tooth.**



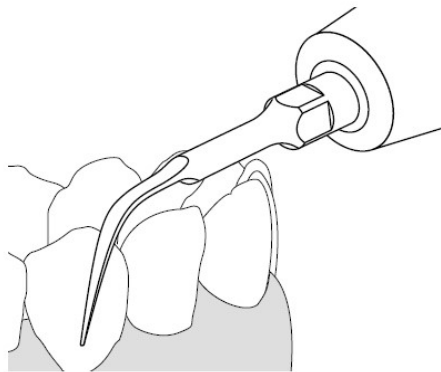
### Instrument A

Instrument A is used for general supra-gingival deposit removal on all tooth surfaces in all quadrants.

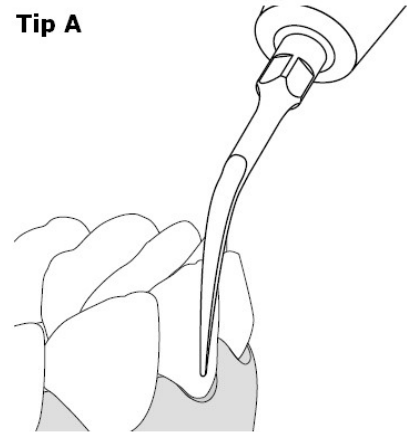
Tip A



Tip A



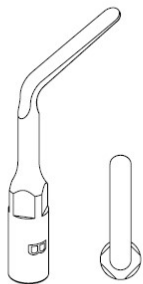
Tip A



### Instrument B

Instrument B is designed for gross supra-gingival deposit removal on all tooth surfaces in all quadrants. It can also be used for the removal of orthodontic cements. Unlike other instruments, instrument B may be directed vertically to the tooth surface for optimum efficiency.

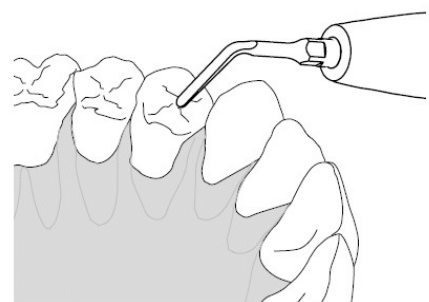
Tip B



Tip B



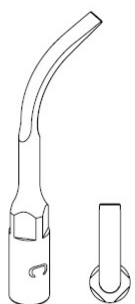
Tip B



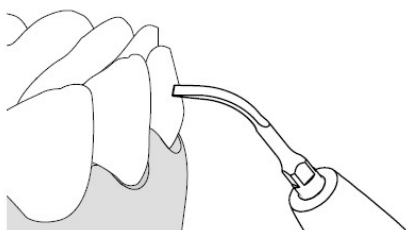
### Instrument C

Instrument C is designed for the removal of heavy deposits on anterior teeth. It can also be used for the removal of orthodontic cements. Unlike other instruments, instrument C may be directed vertically to the tooth surface for optimum efficiency.

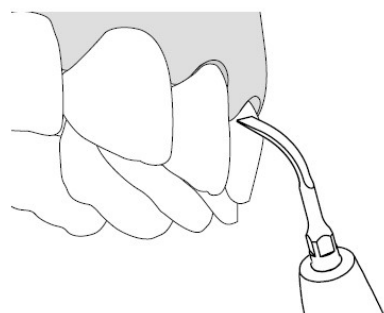
Tip C



Tip C

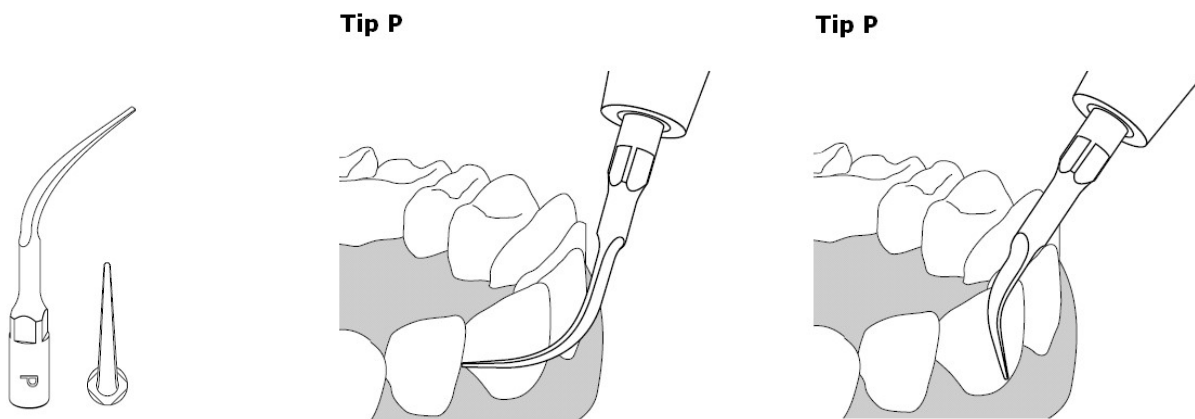


Tip C



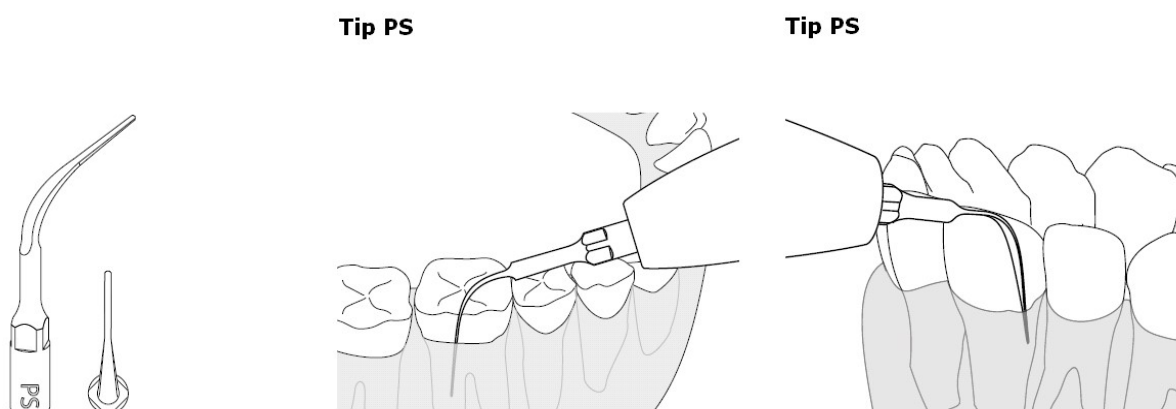
### Instrument P

Instrument P is designed for general supra-gingival deposit removal on all tooth surface in all quadrants, including the inter-proximal and sulcus areas.



### Instrument PS

Instrument PS is for general sub-gingival deposit removal on all root surfaces and can also be used for supra-gingival maintenance therapy. It is suitable as well for periodontal pocket irrigation with antimicrobial delivery.



## 9.5 Scaling tip worn out

### When is a scaling tip worn out?

The shape and mass of the individual tips are determining characteristics for achieving maximum ultrasonic generator efficiency. Both characteristics should be monitored in order to maintain the best possible performance of the unit.

**Therefore, it is strongly advised not to alter the structure of a scaling tip by filing or bending.**

Use the **TIP CARD** coming with tip package to check the wear condition of scaling tips.

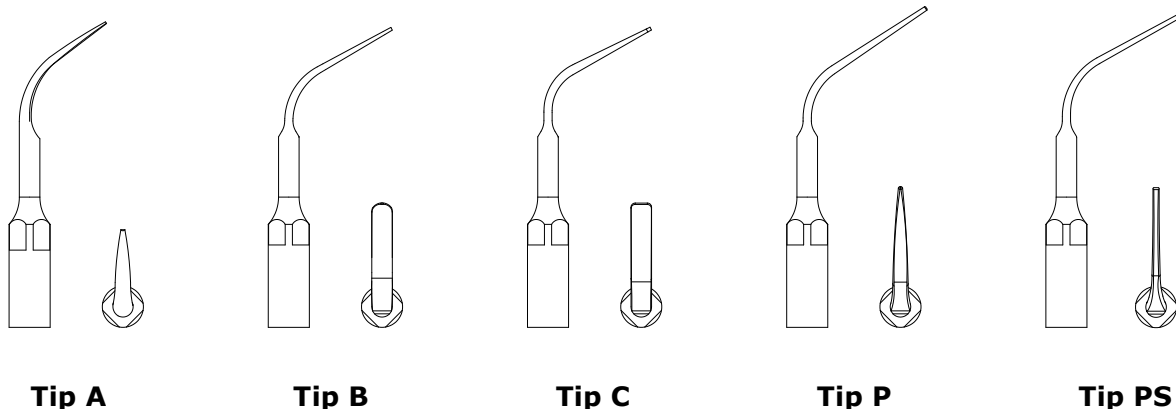
Similarly, the ageing of tips due to normal wear results in a change in their characteristics.

Tips damaged as a consequence of wear or accidental impacts (fall, etc.) must be systematically replaced.

## Section 10: Accessories

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1. Autoclaveable Handpiece Set
2. Liquid Tank with cap (250ml)
3. AC Power Cord Set
4. Foot control switch
5. Replacement Tubing Pump Set(optional)
6. Dynamometric Wrench
7. Autoclaveable accessory box.
8. Ultrasonic tips: Tip A, B, C, P, and PS.



## 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, check and tongue should be retracted to prevent accidental prolonged contact with the activated tip.
- Choose your preferred mode setting and prepare relevant ultrasonic instruments for your practice.
- Autoclave ultrasonic tip and handpiece before use. Install ultrasonic tip onto handpiece gently. DO

NOT FORCE IT INTO PLACE.

- 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 the tip card coming in tip package.
- The use of a saliva ejector or High Volume Evacuator (HVE) is recommended during all procedures.
- If water leakage found in handpiece, check the handpiece and handpiece connector 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 tips, and scaling performance.

#### **Preparation prior to the treatment:**

1. Clean and fill up the liquid bottle.
2. Turn the system ON using the Power ON/OFF switch. (see illustration on page 8) Verify the Power Indicator Light is on.
3. Install a sterilized instrument onto the handpiece and insert handpiece into the handpiece connector. Select mode and set the water control knob to your preferred operating position.

#### **Between Patients:**

1. Remove ultrasonic tip and disconnect handpiece used, clean and sterilize.
2. Set power to minimum. Hold the handpiece tubing (without handpiece) over a sink or drain and flush the water line at maximum water flow for 30 seconds.
3. When ready, install a sterilized instrument into the handpiece and then insert the handpiece to the connector of handpiece tubing.
4. The unit is ready for use.
5. The handpiece can be autoclaved in 135°C.

#### **Shut-down procedures at the end of day:**

2. Remove ultrasonic instrument and handpiece used, clean and sterilize.
3. Set power to minimum. Hold the handpiece tubing over a sink or drain and flush the water line at maximum water flow for 30 seconds.
4. Turn the system OFF.
5. Clean and disinfect the surfaces of the cabinet, Power Cord, Handpiece cable assembly, control knobs, Foot Control 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 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.

6. Clean and disinfect the liquid bottle. The bottle can be washed in a dishwasher and disinfected at up to 95 °C in a washer disinfectant.

#### **7. Please note the bottle cannot be sterilized.**

#### **Sterilizing:**

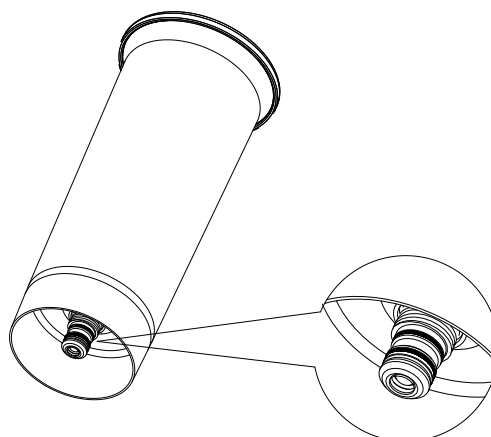
1. Place the handpiece and pouched ultrasonic tips into steam autoclave. After warm-up is completed, operate at a sterilizing temperature and pressure of 273° F/31 psi (134°C/216 kPa) for 12 minutes, followed by a 20-30 minute drying time.
2. Carefully dry the electrical contact of handpiece and cable connector before connecting them.

#### **DO NOT USE Cold sterilization solution.**

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

#### **Replacement of O-rings**

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



## ***Section 13: Trouble shooting***

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Although service and repair of the ELITEDENT® PS-1 Dual / PS-1(LED) Dual 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.

### **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.)**

3. Check that the Foot Control Connector is fully seated in the Foot Control Receptacle on the back of the System.

#### **System operates:**

##### **(No water flow to the tip.)**

1. Assure that water control is properly adjusted.
2. Check that water supply indicator on front panel is properly chosen. If a "Dry" mode is selected, there won't be any water spray coming out.
3. Check that liquid bottle is filled and fully mounted on its base.
4. Check if tubing pump on the back of the ultrasonic scaler is broken. Replace pump set to eliminate.

##### **(Instrument stops vibrating)**


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


##### **Water Leakage at the bottom of bottle base**

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

## ***Section 14: Auto-Cleaning Function***

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 After each use, remove all the disinfectant solution and perform Auto-Cleaning procedure to keep the tubing system clean. If you do not clean the tubing system, the disinfectant dirt might be stuck in the tubing and cause some metal parts rusted.

 Prior to conducting the Auto-Cleaning procedure, be sure to remove the tips from the handpiece, turn the water flow adjustment dial to maximum, and put the handpiece into a cup or over a sink because the water will come out from the handpiece.

- 1) Remove the 2 Bottles from the Main Unit.
- 2) Clean inside of the Bottles.
- 3) Half fill the bottle with distilled water (DO NOT USE SALINE)
- 4) Install the cap on the Bottle. Install the bottles on the Main Unit.
- 5) To activate the Auto-Cleaning procedure, keep pressing the "Water Supply Mode & Auto-Cleaning" KEY for

more than 3 seconds. The LED above the "Water Supply Mode & Auto-Cleaning" KEY will start to blink and the water will flush through the bottle to the handpiece. The flushing continues 30 seconds. After cleaning one bottle and tubing, you can switch to the other bottle and conduct the Auto-Cleaning again to clean the other bottle and tubing.

6) When the Auto-Cleaning is finished, the Main Unit returns to the settings prior to cleaning.

7) For emergency cancellation of Auto-Cleaning procedure, you can keep pressing the "Water Supply Mode & Auto-Cleaning" KEY for 3 seconds. The LED blinking and water flushing will stop and return to the setting prior to Auto-Cleaning.



Use only distilled water for Auto-Cleaning.



Activate Auto-Cleaning without tips and make sure the handpiece and cord are firmly attached.



The LED above the "Water Supply Mode & Auto-Cleaning" KEY will keep blinking during the flushing procedure.



For Manual Cleaning, kindly check Section 12

## ***Section 15: Disposal of Unit***

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- Keep original packaging until the 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 ELITEDENT® Ultrasonic Scaler in accordance with local and national laws.

## ***Section 16: Disclaimer***

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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 17: Warranty**

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### **16.1 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.

### **16.2 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.

### **16.3 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 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.**



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#### **EU authorized representative name and address**



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