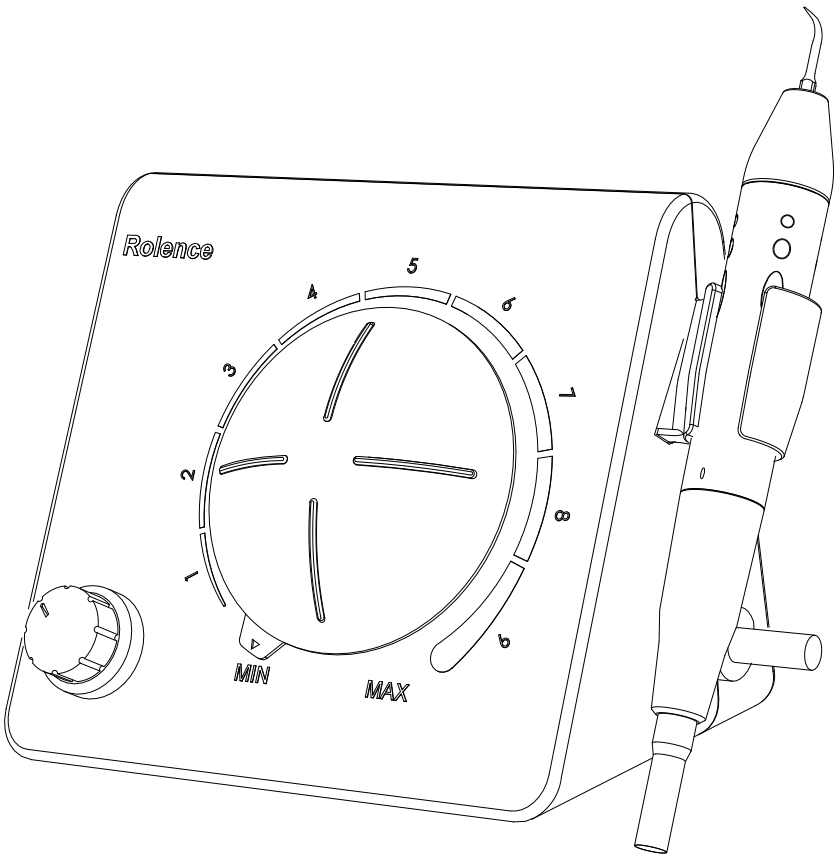
User Manual

ULTRASONIC PIEZO SCALER
ELiTEDENT® PS-30 / PS-30 (LED)



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S-19-01-1209-U0001 V1.6

Table Of Contents

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. Do not cover vents on rear panel.

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

 The ultrasonic scaler is portable, but must be handled with care when moving.

 Equipment and dental water supply system maintenance are strongly recommended. See Section 12: 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 Tips 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 standards (CE Marking).

2.1 Conformance to Standards:

The Rolence® ELiTEDENT® PS-30 / (LED) Ultrasonic Scaler conforms to IEC60601-1-2:2007 and IEC60601-1-1:2006.
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. 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: Glossary of Symbols

	**Attention, Consult accompanying Documents**
	**Alternating Current**
	**Power off**
	Power on
	**Manufacturer**
	**Date of manufacture**
	**Catalogue number**
	**Type BF Applied Part; Type BF Equipment - Protection against electric shock**
	**Equipment class: Class II (IEC601-1) - double insulated**
 **1434**	**The equipment complies with the requirements in the Medical Device Directive 93/42 EEC.（1434 is the ID-number of the Notified body-PCBI）.**

	**Icon to identify electric and electronic devices. The unit must be collected and disposed of separately.**

Section 4: Application

Ultrasonic procedures

·All general supra and subgingival scaling applications.

·Periodontal debridement for all types of periodontal diseases.

Section 5: Specifications

Rolence® ELiTEDENT® PS-30 / (LED) voltage input: 100V, 110V, 230V, 240V optional.

5.1 Electric Voltage:

VOLTAGE:	CURRENT
100VAC 50/60Hz	0.5 A (MAX)
110VAC 50/60Hz	0.42 A (MAX)
230VAC 50/60Hz	0.22 A (MAX)
240VAC 50/60Hz	0.21 A (MAX)
WATTAGE:	MAX. 50 W

Tip vibration frequency: 30±3KHz

Half-excursion force: ≦1N

WATER PRESSURE: 20-60 psi

5.2 Main Unit Dimension:

HEIGHT :	13.5 CM
WIDTH :	20.5 CM
DEPTH :	11.0 CM
WEIGHT :	850g
EXTERNAL POWER WEIGHT	1.2kg

5.3 Operation Environment:

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

5.4 Transportation And Storage Environment:

AMBIENT TEMPERATURE	: －10℃～+70℃
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.

6.2 Warnings

- 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 either 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℃ autoclave logo, while EMS tip compatible Handpiece does not have it. Incorrect tip connection could cause Handpiece thread damaged permanently.

- During using the unit, make sure that water is flowing continuously. Do not continuously operate the ultrasonic system without water spray for more than 2 minutes. If the handpiece overheats please resume the water supply, and stop using the unit for a while.

Section 7: Infection Control

7.1 Function:

The Elitedent® PS-30 / (LED) 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 water spray, requiring little of the physical exertion necessary with hand Tips. It easily and effectively removes stubborn calculus and stains both supragingivally and subgingivally, leaving crown and root surfaces clean and smooth.

7.2 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 20 seconds with highest flow after each treatment.

- Clean and disinfect the torque wrench after unscrewing tip from the PS sterilizable handpiece. The torque wrench can be autoclaved up to 135 ℃ for at least 3 minutes.

Sterilizing:

1. Autoclave: compliant with standard EN 13060.
2. Place the used PS Sterilizable 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 18 minutes, followed by a 20-30 minute drying time.

3. Carefully dry the electrical contact of PS Sterilizable handpiece and cable connector before connecting them.

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

7.3 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 section 12.

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 Water Line Requirements

- The system's water supply line is factory installed. Do not disconnect from the ultrasonic scaler.
- Incoming water supply line pressure to the ultrasonic scaler must be 20 psi (138 kPa) to 60psi(414 kPa)
- If your dental water system's supply line pressure is above 60psi, 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.
- 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 System.
- After flushing system verify there are no leaks.

8.3 Electrical Requirements

Refer to Section 3: Specifications.

8.4 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 water supply line
2. External Power Supply (AC-AC)
3. Foot Pedal.
4. PS Sterilizable Handpiece with PS Handpiece cable
5. Ultrasonic tips (quantity optional)
6. Torque Wrench
7. User Manual.

8.5 System Installation

- Place the ELiTEDENT® PS-30 / (LED) on a level surface.
- Be sure unit is stable and resting on four feet.
- Placing unit in direct sunlight may discolor plastic housing.
- Before powering on the system. Make sure that foot pedal, water supply tube are connected.

8.6 Rear Panel Controls / Power Connection

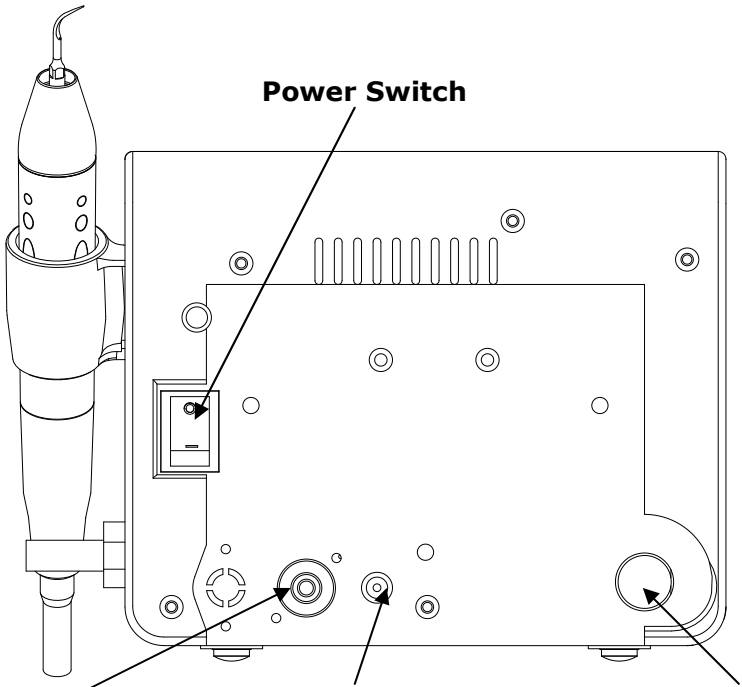
- The ON/OFF Control Pedal and power indicator is located on the Rear Panel of the ELiTEDENT® Ultrasonic Scaler. (See Section 9.1)
- Verify the ON/OFF Control Pedal located on the rear panel of the ELiTEDENT® ultrasonic scaler is in the OFF position before proceeding.
- Plug the foot pedal connector into the receptacle on the back of the ultrasonic system.
- Connect the external power supply into the receptacle on the back of the ultrasonic scaler and into an approved outlet.

8.7 Water Supply Line Connection

Connect the free end of the ultrasonic scaler's water supply line to the dental water supply line. Inspect all connections to make certain there are no leaks.

Section 9: ELiTEDENT® Ultrasonic Scaler Description

9.1 System Controls – Rear Panel



Foot Pedal Connector
Connect foot pedal here, ensure it is firmly seated.

Power Inlet
Connect power cord here, ensure it is firmly seated.

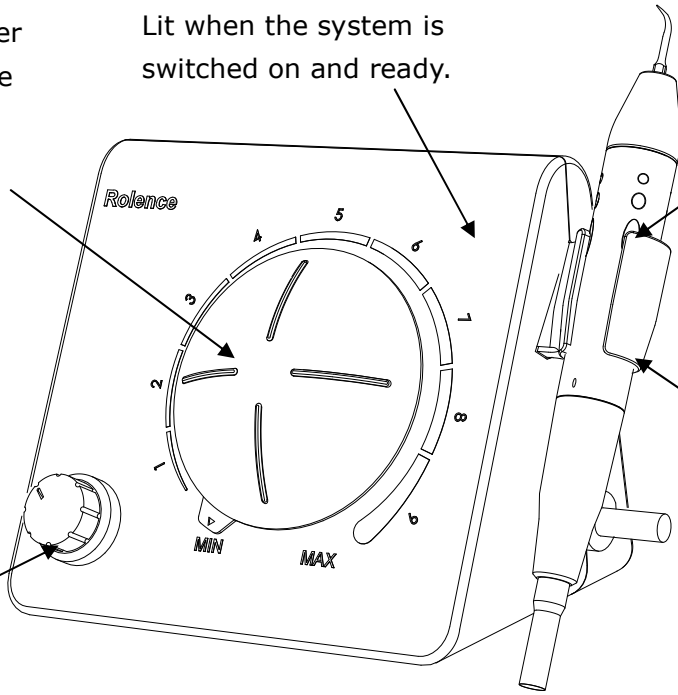
Solenoid Water Inlet
Connect water tube here, ensure there is no leak.

System Controls – Front Panel

Power Intensity Adjustment
Turn the knob to select power level for operation: clockwise increases system power, counterclockwise decreases system power.

AC Power Indicator Light
Lit when the system is switched on and ready.

PS Sterilizable Handpiece
Operates ultrasonic tips and transmits power and water from the system to the tip.

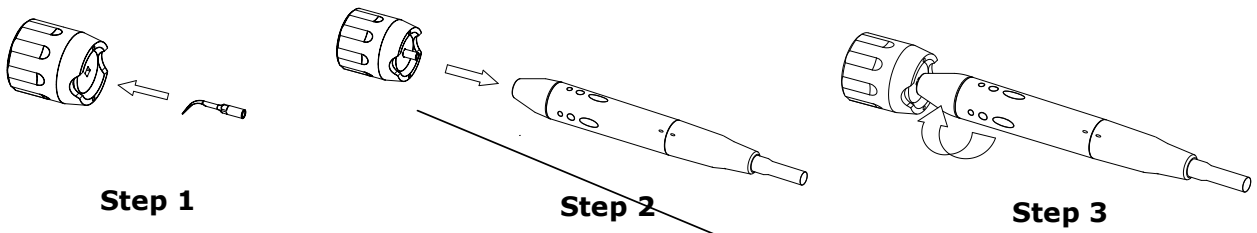


PS Sterilizable Handpiece Holder
Securely holds the Hand piece when system is not being used.

Water flow Adjustment
Turn the knob to select water flow level during system operation. Clockwise decreases flow at ultrasonic tip, counterclockwise increases the flow.

9.2 Installation of PS Sterilizable Handpiece and Tips

This ultrasonic scaler is designed working with 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. Please note you can NOT connect a PS Sterilizable handpiece with LED to a Non-LED Scaler and vise versa. Use Torque Wrench to mount and drive ultrasonic tips to the appropriate PS Sterilizable handpiece gently. Note: The tip must be screwed and moderately tightened. See below:



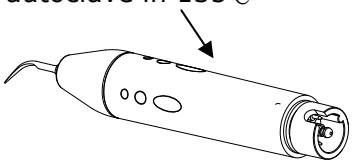
Step 1 **Step 2** **Step 3**

Connecting the handpiece

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

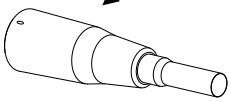
PS Steriliozable Handpiece

Enable to detach and autoclave in 135℃



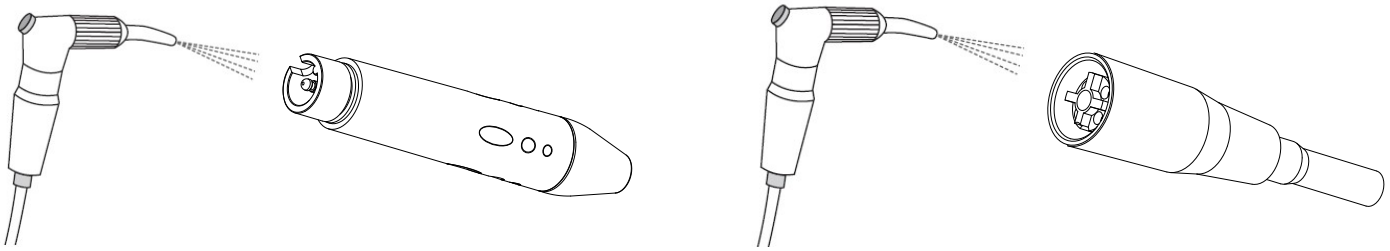
PS Steriliozable Handpiece Connector assembly

Includes handpiece female connector and cable.



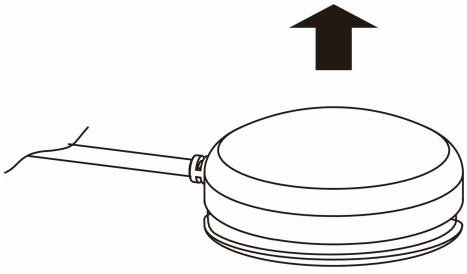
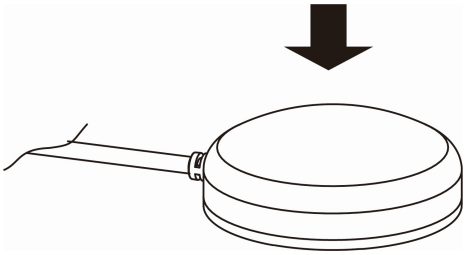
Note : Please **DO NOT** use other brands torque wrench. We disclaim the liability for warranty if using another brand of torque wrench and cause damage to the handpiece.

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



9.3 Foot Pedal Controls and Operation

The Foot Pedal is momentary switch, which activates both ultrasonic energy and water flow at tip.

	
Foot Pedal Released… Both ultrasonic activation and irrigating flow stop.	Foot Pedal Depressed The ultrasonic insert tip is activated and irrigating water flow.

9.4 Use of Tips

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

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

The standard package of ELiTEDENT® PS-30 / (LED) ultrasonic scaler includes very few tips. To afford extra tips, please contact Rolence authorized dealer to order.

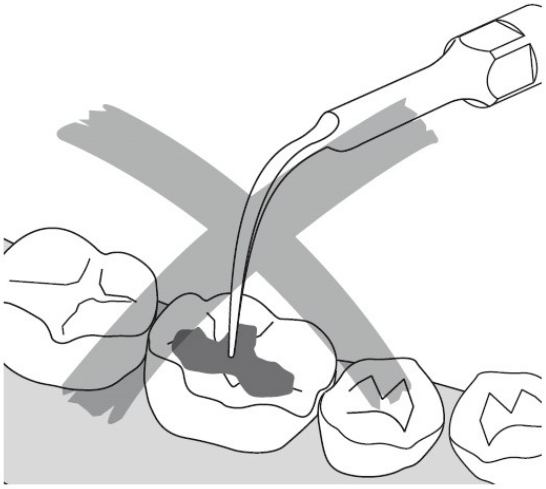
Before use of the ultrasonic Tip, please read following instruction carefully.

⚠ Before use, always disinfect, clean and sterilize PS Sterilizable handpiece and tips. Non-sterile handpieces and Tips may cause bacterial or viral infections.

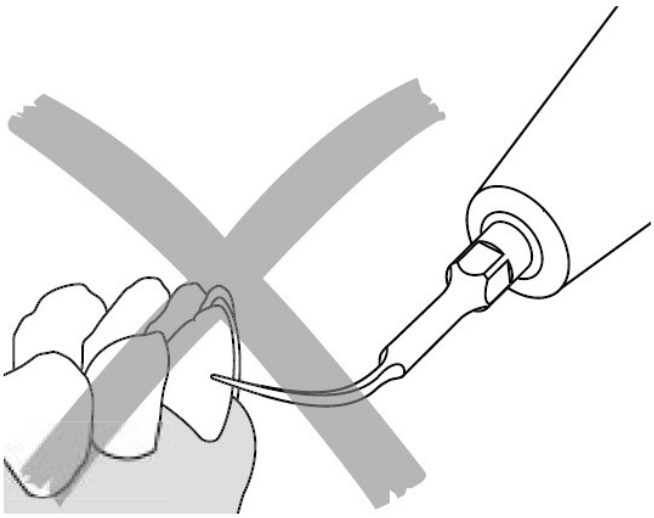
⚠ To avoid heat damage on the tooth or PS Sterilizable handpiece, be careful with working dry. The end of the Tip immediately heats up when used dry.

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

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



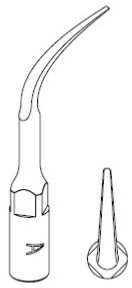
Note: Do not hold the Tip head-on to the enamel. Never direct the end of the Tip vertically or almost vertically to the tooth.



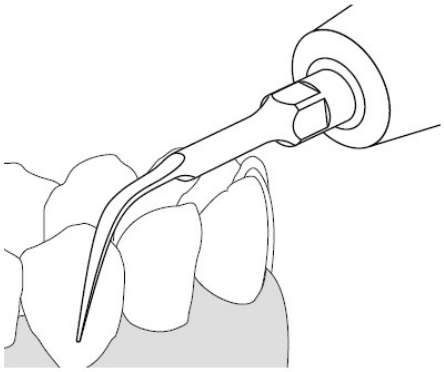
Tip A

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

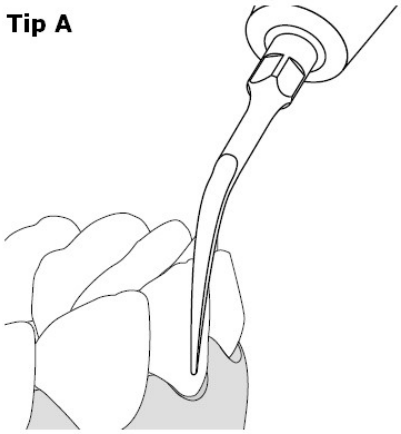
Tip A



Tip A



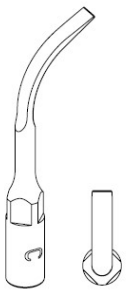
Tip A



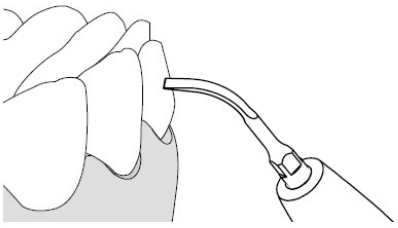
Tip C

Tip 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 tips, tip C may be directed vertically to the tooth surface for optimum efficiency.

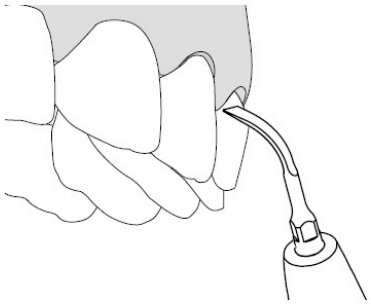
Tip C Tip



Tip C

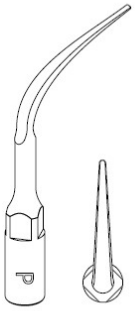


Tip C

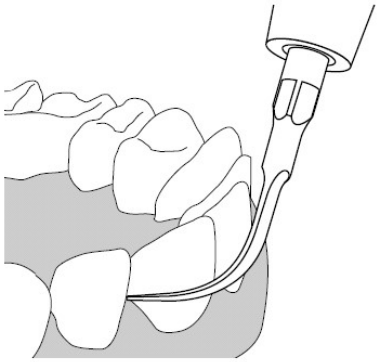


Tip P

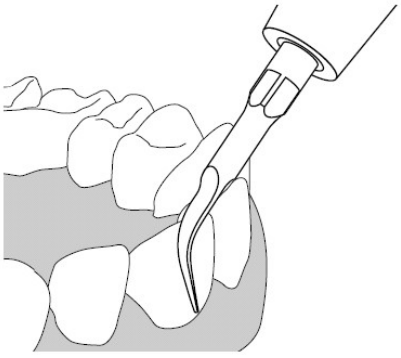
Tip P is designed for general supragingival deposit removal on all tooth surface in all quadrants, including the interproximal and sulcus areas.



Tip P



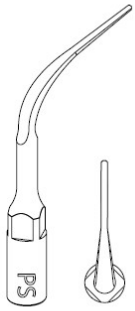
Tip P

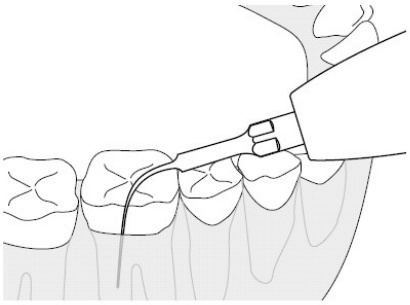


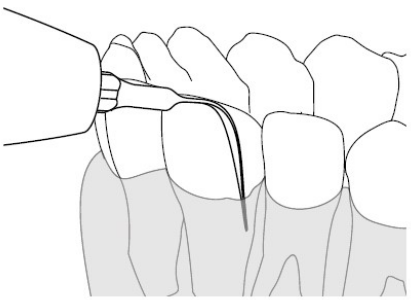
Tip PS

Tip PS is for general subgingival de-posit removal on all root surfaces and can also be used for supragingival maintenance therapy. It is suitable as well for periodontal pocket irrigation with antimicrobial delivery.

Tip PS **Tip PS**







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.

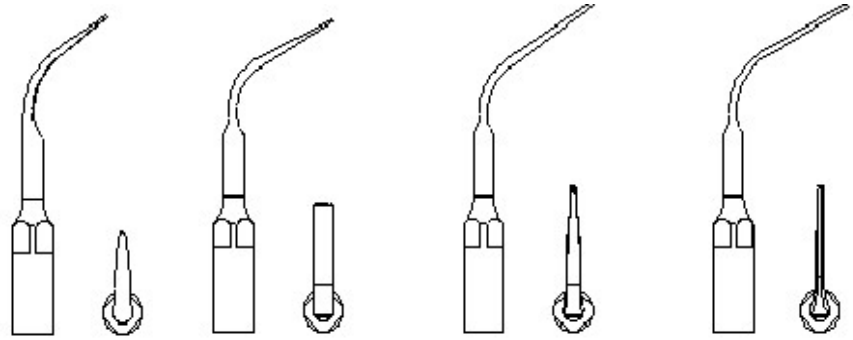
Use the **TIP CARD** coming with tip package to check the wear condition of scaling tips.

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

1. PS Sterilizable Handpiece (LED Optional)
2. External Power Supply (AC-AC)
3. Foot pedal
4. PS Handpiece Cable Set
5. Torque Wrench
6. Ultrasonic tips: tip A, C, P, and PS, or other combination set of the tips.



Tip A **Tip C** **Tip P** **Tip 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 Tips for your practice.
- Autoclave ultrasonic tip and handpiece before use. Fix 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.

Note：If the Power Intensity control is set to minimal, it might get chance you cannot activate the system well, like no water flow or not vibrating. In that case, please set the Power Intensity control up to like level 3, or 4, then activate the Foot Control and then turn the Power Intensity Adjustment Knob to your preferred setting.

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.

Start-Up Procedures at the beginning of a day:

1. Open the manual shut-off valve on the dental office water supply system.
2. Turn the System ON using the Power ON/OFF switch. (see illustration on page 7) Verify the Power Indicator Light is on.
3. Set the Power Control knob to minimum setting.
4. Set the Water Control knob to maximum.
5. Hold the Handpiece (without Tip installed) upright over a sink or drain, activate the Foot Control and flush the water for at least 2 minutes.
6. Install a sterilized tip into the Handpiece and set the water control knob to your preferred operating position.

Between Patients:

1. Remove ultrasonic tip and dismantle handpiece used, clean and sterilize.
2. Clean and disinfect the surfaces of the cabinet, Power Cord, Handpiece cable assembly, control knobs, Foot Control and 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.
3. Install a newly sterilized handpiece. 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 Tip into the handpiece.
5. The handpiece can be autoclaved up to 135℃..

Shut-Down Procedures at the end of a day:

2. Remove ultrasonic Tip and handpiece used, clean and sterilize.
3. Turn the System OFF.
4. 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 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. Close the manual shut-off valve on the dental water supply system.

Sterilizing:

1. Autoclave: compliant with standard EN 13060.
2. 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 18 minutes, followed by a 20-30 minute drying time.
3. 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.

Section 13: Trouble shooting

Although service and repair of the ELiTEDENT® PS-30 / (LED) 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 connector is fully seated in the receptacle on back of the system.
2. Check that the system power 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.
2. Check foot pedal.

System operates:
(No water flow to the tip.)

1. Assure that water control is properly adjusted.
2. Check that water supply control valve(s) (dental office water supply line) are open.

(Tip stops vibrating)

1. Deactivate foot Pedal.
2. Verify ultrasonic Tip is properly installed.
3. Depress foot Pedal to try again

Section 14: Disposal of Unit

- Keep original package 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 15: Disclaimer

ROLENCE 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 16: Warranty

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 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.

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

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

CE

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

EU authorized representative name and address

EC REP

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo n18, C.P 29006, Málaga-Spain

REM: Please contact our authorized dealer if users require user manual in other European language.

ANNEX I

Guidance and manufacturer's declaration-electromagnetic emissions		
The PS-30 / (LED) is intended for use in the electromagnetic environment specified below. The customer or the user of the PS-30 / (LED) should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	The PS-30 / (LED) uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The PS-30 / (LED) is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Compliance	

Guidance and manufacturer's declaration-electromagnetic immunity The PS-30 / (LED) is intended for use in the electromagnetic environment specified below. The customer or the user of the PS-30 / (LED) should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge(ESD) IEC 61000-4-2	+ 6 kV contact + 8 kV air	+ 6 kV contact + 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	+ 2kV for power supply lines	+ 2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	0.5~+ 2kV common mode	0.5~+ 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT(>95% dip in UT) for 0,5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 s	<5% UT(>95% dip in UT) for 0,5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the PS-30 / (LED) requires continued operation during power mains interruptions, it is recommended that the PS-30 / (LED) be powered from an uninterruptible power supply or a battery.
Power frequency(50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The PS-30 / (LED) contains no devices susceptible to magnetic fields.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration-electromagnetic immunity			
The PS-30 / (LED) is intended for use in the electromagnetic environment specified below. The customer or the user of the PS-30 / (LED) should assure that is used in such and environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V/m 150 KHz to 80 MHz 3 V/m 80MHz to 2,5 GHz	3 V/m 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the PS-30 / (LED) including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = 1,2 ˇP d = 1,2ˇP 80MHz to 800 MHz d = 2,3 ˇP 800MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, (a) should be less than the compliance level in each frequency range. (b) Interference may occur in the vicinity of equipment marked with the following symbol: NOTE1 
NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PS-30 / (LED) should be observed to verify normal operation. If abnormal performance is observed, additional measures my be necessary, such as re-orienting or relocating the PS-30 / (LED). b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distance between portable and mobile RF communications equipment and the PS-30 / (LED)

The PS-30 / (LED) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PS-30 / (LED) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PS-30 / (LED) as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.