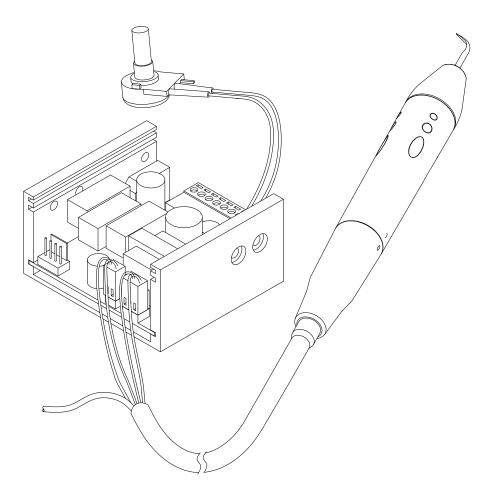
# ULTRASONIC PIEZO SCALER ELITEDENT PS-25B / PS-25B(LED)



Installation and operation instruction

**Rolence Enterprise Inc.** 

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<b>ANESTHE</b>	TIC 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.

# **1.1 Precautions for all systems**

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

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

# 1.2 Precautions for ultrasonic prophylaxis procedures

• Like a toothbrush, ultrasonic tips "wear out" with use. Tips with just 2 mm of wear lose about 50% of their scaling efficiency. In general, it is recommended that ultrasonic tips be discarded and replaced after one year of use to maintain optimal efficiency and avoid breakage.

# Section 2: Glossary of Symbols

Ĩ	Attention, Consult accompanying Documents
$\sim$	Alternating Current
0	Power off
	Power on
	Manufacturer
	Date of manufacture
REF	Catalogue number
A	Type BF Applied Part; Type BF Equipment - Protection against electric shock
	Equipment class: Class II (IEC601-1) - double insulated
<b>C E</b> 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 3: Specification

Power Board:				
Voltage	: 24V AC, 50/60Hz			
Wattage consumption	: Max. 50 W			
Vibration frequency	: 28 - 32 kHz			
Suggested water pressure	: 20 to <mark>6</mark> 0 psi			
Dimension:				
Height	: 36 mm			
Width	: 70 mm			
Depth	: 63.2 mm			
Weight	: 185g			
Handpiece tubing length	: Approx.2.1 M			
Operation Environment:				
Operation Environment: Ambient temperture : $+10^{\circ}C \sim +40^{\circ}C$				
Ambient temperture				
Relative humidity	: 30%~75%			
Atmospheric pressure	: 700 hPa $\sim$ 1060hPa			
Transportation And Storage Environment:				
Ambient temperture	:-10°C $\sim$ +70°C			
Relative humidity	: 10%~90%			
Atmospheric pressure	: 500 hPa $\sim$ 1060hPa			

# Section 4: Introduction

# 4.1 Function:

The Piezo Tech ultrasonic system is designed for use in prophylaxis treatments periodontal, 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 supra gingival and sub gingival, leaving crown and root surfaces clean and smooth.

#### 4.2 How to use:

- During normal operation water should be supplied from the normal water mains. Operating
  without water, or with a tip intended to be used without water, this device can only be
  operated for a maximum time of 4 minutes to be followed by a rest period of 8 minutes.
- The movement of the tip is generated by the piezo transducer in the ps sterilizable handpiece. The tip of the scaler moves back and forth in a straight line. The length of this stroke and the amplitude of the movement can be varied between 0.04 and 0.13 mm. This change is made with the power knob having a setting from minimum to maximum.

# Ultrasonic procedures

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

# Section 6: Contraindications and Warnings

# **6.1 Contraindications**

- Ultrasonic systems should not be used for restorative dental procedures involving the condensation of amalgam.
- Warning Notice :
- To perform daily cleaning for housing surface with mild soap solution or purified water is highly recommended. For further disinfection purpose, 70% ethanol, 70% isopropanol or hydrogen peroxide based disinfectants in appropriate concentration is applicable. Other solution like Acetone, ortho-phthalaldehyde based solution that might cause damage to the housing surface is NOT allowed and the product warranty will be void.
- Do not sterilize the housing with autoclave, gamma-radiation, steam or sterilization method, which result severe damage to device.

# Section 7: Installation Instructions

# 7.1 Checking the package component

Carefully unpack your ultrasonic system kit and verify that all components and accessories are included:

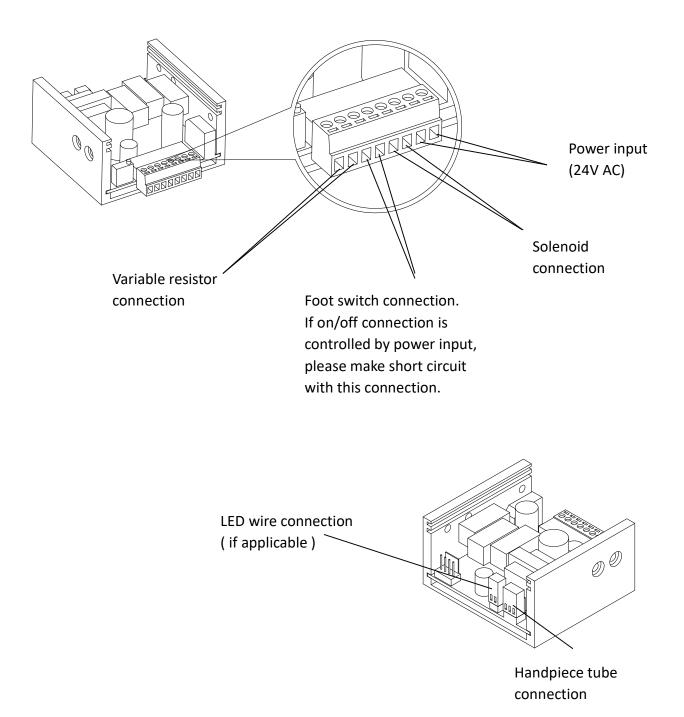
- 1. Power board
- 2. PS Sterilizable Handpiece tube with connector.
- 3. PS Sterilizable handpiece ( with or without LED ).
- 4. Intensity adjustment knob (Variable Resistor 50Kohm)
- 5. Ultrasonic tips (quantity optional)
- 6. Torque wrench.
- 7. Sterilizable accessory box.
- 8. User Manual

# 7.2 Water Line Requirements

- Incoming water supply line pressure to the System must be 1 to 4 bar (14.5 to 58 psi). If your dental water system's supply line pressure is above 58 psi, install a water pressure regulator on the water supply line to your water supply system.
- 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.

# 7.3 Installation of system.

- 1. Remove the contents from the shipping package. Be careful not to drop or impact the components.
- 2. Please ensure the power supplied from dental unit is 24V AC before installation.
- 3. Install the power board in the dental unit where should be free front water.
- 4. Set up power input connection, power control switch, VR intensity adjustment and Handpiece tube by following the figure 6.1.

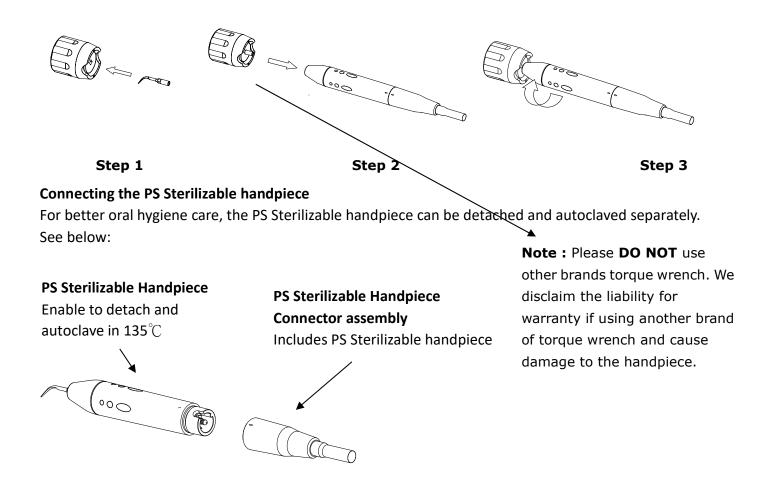


#### **Power Adjustment**

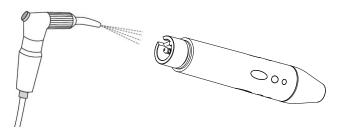
# 7.4 Ultrasonic tip mounting and PS Sterilizable handpiece disassembly

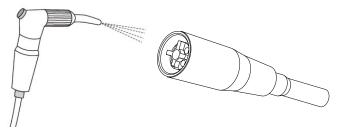
#### Tip mounting :

Use dynamometric wrench to mount and drive ultrasonic Tip onto the appropriate PS Sterilizable handpiece gently. Note: The tip must be screwed and moderately tightened. See below:



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



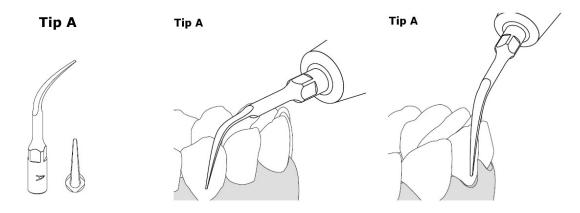


# Section 8: Reorder Number

Part number	Description
PS25B-A150-EL	PS Sterilizable LED Handpiece(EMS Type)
PS25B-A150-SL	PS Sterilizable LED Handpiece(Satelec Type)
PS25B-A150-E	EMS Type PS Sterilizable Handpiece
PS25B-A150-S	Satelec Type PS Sterilizable Handpiece

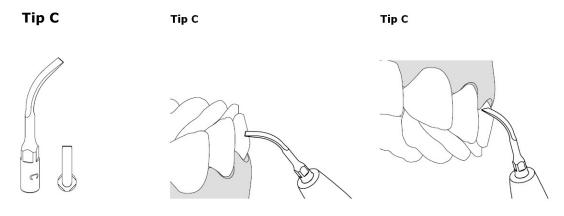
# 9.1 Tip A

Tip A is used for general supragingival deposit removal on all tooth surfaces in all quadrants.



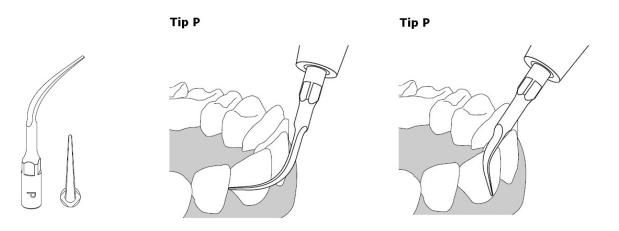
# 9.2 Tip C

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.



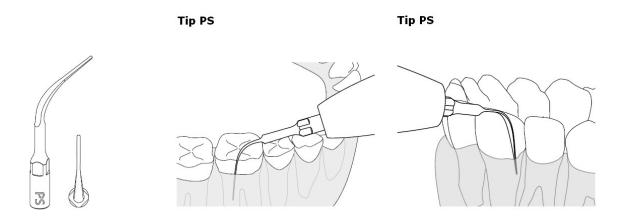
#### 9.3 Tip P

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



# 9.4 Tip PS

Tip PS is for general subgingival deposit 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.



# 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.** 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: Maintenance and Sterilization

#### 10.1 Maintenance:

The outer surfaces of the ultrasonic scaler PS Sterilizable handpiece, PS Sterilizable handpiece cable assembly should be cleaned and disinfected. The detachable PS Sterilizable handpiece and ultrasonic tips require cleaning and sterilization. Preferred methods are discussed. However, alternatives are available. Special steps may be required when following an alternate method.

#### **Recommended daily procedures:**

#### Beginning of the day:

Connect a PS Sterilized handpiece to its mating PS Sterilizable handpiece cable assembly. Hold the PS Sterilizable Handpiece (without tip) over a sink or drain, set power to low, activate the foot pedal and flush the water line at maximum water flow for at least 2 minutes.

Place a freshly sterilized tip into the PS Sterilizable handpiece. The unit is now ready for operation.

# Between patients:

Remove all ultrasonic tips, torque wrench and PS sterilizable handpiece used, clean and sterilize. Clean and disinfect the surfaces of the PS Sterilizable handpiece cord and control knobs by applying an approved non-immersion type disinfectant solution\* carefully following the instructions provided by the disinfectant solution manufacturer. To clean system, generously spray disinfectant solution on a clean towel and wipe all surfaces. Discard used towel. To disinfect system, generously spray disinfectant on a clean towel and wipe all surfaces. Allow disinfectant solution to air dry.

Connect a PS Sterilizable handpiece to its matching PS Sterilizable handpiece cable assembly. Hold the PS Sterilizable handpiece (without tip) over a sink or drain and flush the water line of the unit as above at maximum water flow for 30 seconds.

Place a freshly sterilized tip into the PS Sterilizable handpiece.

# 10.2 Sterilization:

# **Cleanings/Disinfecting**

If necessary, prior to sterilization, rinse tips and PS Sterilizable Handpiece under water to remove any gross debris. The use of cleaning and disinfectant solutions, such as ultrasonic cleaning solutions, is not recommended.

# **Sterilization**

- · Autoclave: compliant with standard EN 13060.
- Place tip in a paper or paper/plastic steam sterilization pouch. Place the paper side up when using a paper/plastic steam sterilization pouch.
- Place the bagged tip into the 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.
- To maintain sterility, the insert should remain in the sealed pouch until it is ready for use.

# **CAUTION**

- DO NOT USE Cold sterilization solution.
- **DO NOT USE** Chemical disinfectant prior to sterilization or rapid deterioration of the materials may occur.
- DO NOT Autoclave PS Sterilizable handpiece cable assembly.
- It is strongly recommended to use the original manufacturer DC24V solenoid valve to optimize the product performance.

# Section 11: Trouble shooting

# 11.1 Trouble shooting

Although service and repair of the ultrasonic system should be performed by authorized 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 connection will often create problems. Check the settings on the system's knobs also.

Error	Cause & solution
1. The ultrasonic tip isn't activated and	<ul> <li>Check if tip is loosen and worn out</li> </ul>

irrigating water still flows.	<ul><li>Check water flow adjustment.</li><li>If not sure what happen, contact dealer for</li></ul>
	service.
2. Water leakage at handpiece connector	<ul> <li>Replace o-ring on the Handpiece connector.</li> </ul>

# Section 12: Warranty

# 12.1 Malfunction

Rolence hereby warrants that for a period of one year for users; 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.

# 12.2 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.

# 12.3 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 those stated 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.)

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# EU authorized representative name and address



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