*U.S Federal law restricts this device to use by or on the order of a dentist*

XPEDENT ULTRASONIC SCALING DEVICES

CE 0120

# SHEL-Y

## Users' Operating Instructions

IMPORTANT: Read instructions fully before operating this device


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West Chiltington, West Sussex RH20 2JY England.


THIS XPEDENT SHEL ULTRASONIC SCALER UNIT HAS BEEN DESIGNED FOR USE ONLY BY QUALIFIED OPERATORS SUCH AS DENTISTS AND DENTAL HYGIENISTS IN DENTAL PRACTICES. PLEASE FAMILIARISE YOURSELF WITH THE INFORMATION IN THE USERS OPERATING INSTRUCTIONS BEFORE OPERATING THIS EQUIPMENT.

U.S. Federal law restricts this device to sale by or on the order of a dentist


Shel-Y version 6

**OPERATING INSTRUCTIONS**

Features:

The XPEDENT SHEL range of ultrasonic scaling devices offers a scaling system that is designed for use with industry standard 25K to 31k scaling inserts in the same handpiece. The advanced electronics ensures smooth effortless calculus removal, even at low power settings, and compensates for the degree of tenacity of the deposits to ensure maximum patient comfort, and reduced operator fatigue.

The Xpedent Shel Spaces can operate from a mains water supply or via an independent pressurized fluid supply (see accessories)

Intended use:

a）Removing supra and sub gingival calculus deposits and stains from the teeth.

b）Periodontal pocket lavage with simultaneous ultrasonic tip movement.

⚠ Warning:

The ultrasonic scaler is intended use to:

The water supply must be of drinking water quality.

The handpieces, tips and control knobs have been designed for easy removal for autoclaving between patients to reduce cross infection.

Intended patient population:

Adults and children who need to be treated.

⚠ Warning:

The heart disease patient, pregnant women and children should be cautious to use the device.

Indication:

This device is to use by dentist or under the supervision of dentist.

INSTALLATION

1.Connect the water supply tube provided (1A) to the water inlet connector (1) on the rear of the unit (Fig.1). Push well home before tightening the locking collar, connect a suitable connector to the water supply tube and connect to the water supply source or to an independent fluid source if available – (See accessories) and check for leaks.

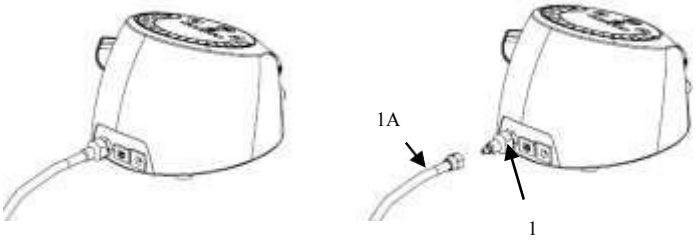



Fig.1

2.Ensure that the mains electrical supply is compatible with the power supply unit, and connect the power supply lead (2A) to the socket (2) on the scaler unit (Fig.2)

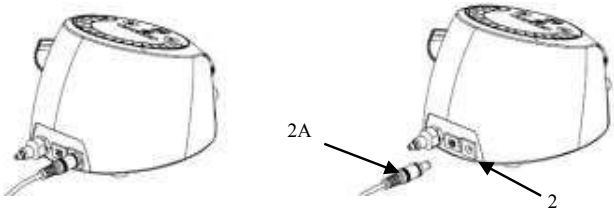



Fig.2

3.The foot switch plug (3A) is to be connected to the foot switch socket (3) . (Fig.3)

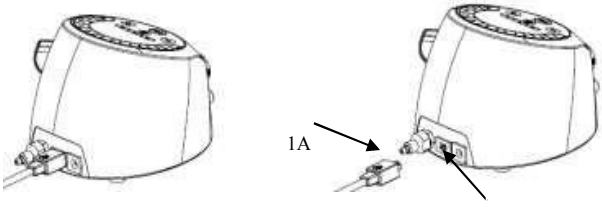



Fig.3

4.Attach the scaling handpiece (Fig.4) to the lead and place into the hand piece holder.

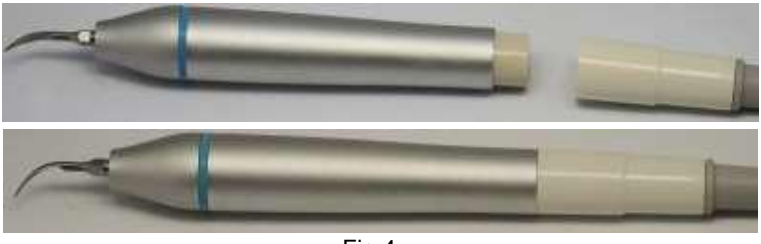
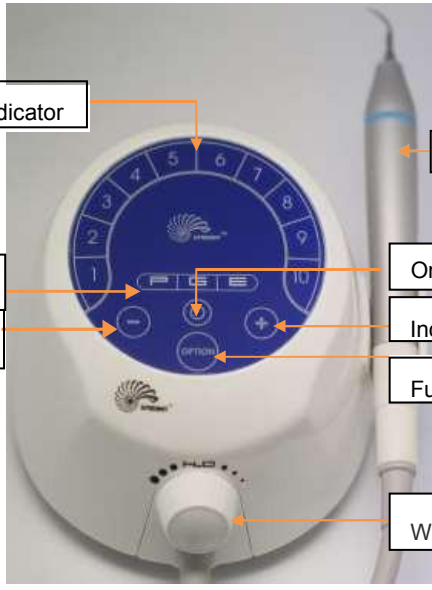


Fig.4

**SHEL-Y Scaler Machine**



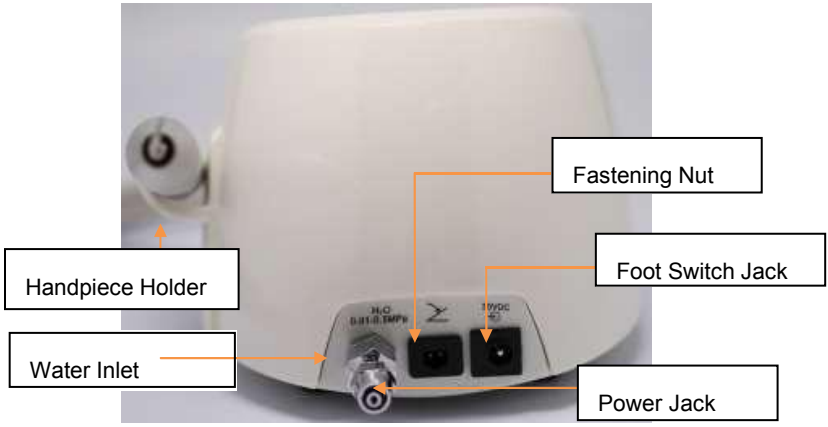



Fig.6 External Connections

1.Scaler Machine Operating Instructions.

a）The touch screen design aids hygiene and precise operation. The scaler machine will start to work when the ON/OFF key is pressed for 3 seconds. Its start-up setting is for periodontal treatment, with the same power as was last used.

**Note**: Please check power intensity when used each time.

a） Perio (P) Scaling (G), and Endo (E) functions are available for SHEL-Y scaler machine.

b）Pressing the "OPTION" button for 3 seconds will put the instrument into the LED brightness adjustment mode; the three function indicator light goes out and the user can then press the "+" & "-" keys to adjust the power of the LED. Once the light is set, the foot pedal can be depressed to come out of the LED brightness adjustment mode. The instrument will remember the last LED setting; if the LED brightness needs further adjustment, carry out the same procedure as specified previously.

⚠ If the unit is moved from one workstation to another, always ensure that the connections are correct.

⚠ Warning:

Do not place the Xpedent Ultrasonic Scaling device close to any RF transmitter. A low power transmitter such as a cordless or mobile phone should be at least 2M from the Xpedent Shel, and a powerful transmitter such as a commercial TV or radio broadcast antenna should be at least 25M distant.

**ULTRASONIC SCALING**

**SCALING INSERT CONNECTION**

Always sterilize scaling inserts prior to each use (autoclave 134°C for 18 minutes). Tip Selection:

The primary factor in selection of an insert is the type of deposit that is to be removed (biofilm, light, medium or heavy calculus) and the location of these deposits.

Fine tips are designed for the removal of light sub-gingival calculus in pockets > 4mm and for disrupting sub-gingival biofilm.

⚠ Warning:

Finely designed inserts are more likely to fracture if used with a high power setting, and therefore thin scaling tips should always be operated on LOW -POWER setting only.

Select the insert for the procedure at hand, and always select the lowest power setting when beginning a procedure. Increase power incrementally to achieve efficient deposit removal and patient comfort.

Standard-diameter tips should be used for heavy or medium calculus deposits. Straight or Universal tips are designed to be used in pockets < 4mm.

⚠ Warning:

If any change in power is experienced during use, which may indicate a micro-fracture of the tip, or if the tip and handpiece is dropped accidentally, the insert should be discarded and replaced. If for any reason the insert has become bent or deformed, do not attempt to bend it – discard and replace with a new insert.

Use the comparison table for tips

| Tips model | Recommend to select function and power | Recommended amount of water |
|---|---|---|
| eA | S model 2-5 | small |
| eP | S model 2-5 | small |
| ePS | P model 2-5 | small |
| ePL3 | P model 2-5 | small |
| eICP | S model 2-5 | big |

Some wear of the tip occurs with time and use and is normal. When approximately 2mm of length of the tip is worn, the tip has outworn its usefulness (approximately 50% of scaling power has been lost) and should be replaced (See insert XPEDENT Tips template)

⚠ Warning:

Micro-fractures can occur in tips if they are dropped. This is not always immediately visible. This can sometimes result in a reduction of power during usage and further use can lead to fractures of the tip during function and subsequent soft tissue trauma, or inhalation or swallowing of the fractured portion. Always discard tips that have been dropped or where a change of power is experienced during use.

⚠ Remember:

Do not leave tips in the handpiece at the end of the working session.
Scaling tips should always be positioned in the tip –holder or autoclavable torque wrench, such that they will not cause damage to patients or staff.
The thread of scaling tip needs to be compatible with EMS.

**WATER FLOW**

Operators must learn to manage water production and visibility. Adequate water spray is needed (approximately 30-35ml/min.) to cool the vibrating insert and to provide lavage of the work area to improve visibility and flushing of debris. Turn the Scaler power control knob to low or medium output (Fig.5). Hold the handpiece over a bowl and depress the foot switch to activate the scaler. The scaler water control knob is then rotated to achieve a satisfactory ‘halo’ spray or rapid drip

around the instrument tip.
The patient should be positioned in a supine position with head turned to the side and chin pointing down. This will enable the water to collect in the corner of the mouth where it can easily be suctioned.
⚠ Warning:
Reduction of the amount of water may result in overheating of the insert in function and can cause patient discomfort or trauma to soft tissues.
The water supply must be of drinking water quality.
Remember: Disconnect the XPEDENT SHEL from the water supply at the end of a working session.
⚠ Warning:
Use of power-driven scalers is contra -indicated with patients who are at risk of aspiration into the respiratory tract because of breathing or swallowing difficulties or for patients with strong gag reflexes.

**POWER CONTROL**
The power control ranges on a scale from 1-10.
Always select the minimum power setting when beginning to scale and increase incrementally according to the power needed to achieve efficient calculus removal and patient comfort.
⚠ Excessive power can result in early fracture of the tips, without increasing the scaling efficiency.
N.B. There is no advantage to using more power than is necessary to remove the calculus gently and efficiently.

**SCALING TECHNIQUE**
Aerosol production:
Power scaling units can generate high levels of contaminated aerosols. This can be reduced in the following ways.
- Having a patient rinse with a pre -procedural antibacterial mouthwash containing chlorhexidine can reduce bacterial counts by over 90%.
- Reduction of the power setting and modifying the water flow rate to a drip rather than mist.
- Cup the patient's lips and cheeks to contain the spray, rather than to retract them.

⚠ Warning:
Patients with communicable diseases or at high risk for infection should not be treated with power scaling devices, because of the potentially

highly infective aerosol production.
Although modern cardiac pacemakers are shielded, care must be taken when using the Xpedent Shel scaling unit with patients with cardiac pacemakers. Consult the patient's cardiologist if in doubt. Magnetic field generation may interfere with certain types of pacemakers.
Proper use of personal protective equipment, including eye protection for the operator and patient, and effective surface disinfection and barriers should be employed.
The Xpedent Shel enables efficient calculus removal to be achieved in less time and with less operator fatigue than with hand instrumentation, but adequate training is needed. In contrast to hand scaling, where heavy lateral pressure is applied to engage the lower edge of the deposit, power scaling requires light pressure of multiple strokes and light taps, to pulverize and detach the deposits. It is important to keep the tip moving in short strokes with light pressure. If blanching of the fingertips is observed during the scaling procedure, too heavy pressure is probably being applied.

De-plaquing can be effectively accomplished using a series of gentle sweeping movements that overlap to cover the entire surface in a multidirectional pattern.

N.B. With adequate water flow and low power settings, it has been reported that there is little concern for damage to teeth with large pulp chambers, because the amount of heat generated will not be sufficient to harm the pulp.

Although tip changing is simple, it is normally more efficient to perform as much work as possible with a tip before changing. Only the minimum power needed to perform the work required should be selected and light finger pressure only should be used.

Use less angulation than with hand instruments. Angulation should be close to 0 degrees and should never exceed 15 degrees. Firm pressure should be avoided as this can cause overheating and damping of the tip vibration which decreases scaling efficiency.
⚠ Warning: Contra-indications.
The Xpedent Shel scaling unit should not be used on patients with dental hypersensitivity, demineralised areas, or on porcelain or composite restorations. It is contra-indicated for use on titanium implant

surfaces unless specially designed tips for this purpose are used. Care should be used when considering the use of the Xpedent Shel scaling unit on patients with cardiac pacemakers.

⚠ Warning:

Continuous function without adequate water coolant can cause overheating and may cause damage to tooth and soft tissues.

⚠ Warning:

This unit is not designed for use in operating theaters. This equipment should not be used in the presence of a flammable anaesthetic mixture with air oxygen or nitrous oxide.

⚠ Warning:

Sub-gingival scaling should be regarded as a surgical procedure for patients with cardiac conditions and implants. Systemic antibiotics and other relevant medication should be used appropriately and with the advice of a medical doctor. Patients that have undergone organ transplants should be treated with caution, and only with the advice of a medical doctor.

⚠ Warning

Always disconnect the water and electrical supply to the scaler at the end of each working day. When reconnecting at the beginning of a treatment session ensure that all connections are made correctly.

**CLEANING AND STERILIZATION**

Ultrasonic tips, handpieces and wrenches must be sterilized before first use and after each use (they are not delivered sterile).

**Cleaning:**

The removal of organic deposits is very important and will achieve best results by putting them immediately after use into 70% Isopropyl alcohol (Isopropanol) or a low-alcohol cleaning solution. After that use an ultrasonic bath with a low-foaming detergent. Alternatively, you can clean them in warm water with a low-foaming detergent and an autoclavable brush.

**Attention:**

Do not use chemical disinfectants as these can damage the ultrasonic tips and wrenches

**After the cleaning:**

Rinse the cleaned tips thoroughly in warm water to remove all chemicals and let them dry completely. Xpedent ultrasonic tips are made out of stainless steel of the highest quality. Therefore, the use of

an antirust agent before steam sterilization is acceptable, although it is not required. Pack them in suitable packaging, bags, trays or cassettes. Check them with spore test sets. Biological monitoring devices should be used at least once a week. In addition, every time if new packaging, new staff, new procedures, new equipment or repaired equipment is used, a biological monitoring should be added to check if these changes are still effective.

**Attention:**

Do not use closed containers during sterilization with steam or ethylene oxide. The cleaning and Disinfecting device must be approved by its manufacturer for cleaning and disinfection be released by dental instruments and EN ISO 15883-1

**Sterilize with ethylene oxide:**

Put the dried packaged materials in the unit and work according to the manufacturer's instructions.

**Sterilize with steam:**

Place the dried wrapped tip in an autoclave. Recommended settings are 134 degrees for 18 minutes.

**Regarding sterilization:**

Ethylene oxide is the preferred method for sterilization. Steam autoclaving is the preferred method of dentistry. Dry heat should NOT be used for materials which can be sterilized by steam. Chemical agents are not recommended since their effectiveness cannot be monitored biologically, their cycle times are longer (6-10 hours), and all rinsing and handling must be aseptic. Dry Heat and chemical steam sterilization are considered ineffective methods, with the risk of damaging materials. DO NOT use chemiclaves or drying ovens for sterilizing Xpedent ultrasonic tips and wrenches.

The scaling tip has no sterilization cycle limit, but after the tip is worn exceeding 2mm, the scaling tip needs to be replaced. The minimum sterilization cycle for handpiece and torque wrench is 250 cycles.

The tip can be autoclaved inside the torque wrench, this is recommended as it protects the dentist from risk of contaminated sharps injury.

The handpiece and torque wrench must not be soaked in solution. It should be wiped clean with a gauze or soft sponge using 70% isopropanol and detergent or appropriate disinfection equivalent. Autoclaving is recommended to avoid cross patient infection.

The cover can be wiped off with a soft cloth. Use 70% isopropanol and detergent or appropriate disinfection equivalent.

**MAINTANENCE**

There are two aspects of maintenance that should be carried out by the user. They are:

Hand piece O-rings. The hand piece O-rings will require changing when warn; a spare set of O-rings is included with the scaler machine. The life of the O-rings will vary from dentist to dentist and depends upon how the hand piece is used, but the life of the O-rings should be several months, at least.

Scale-tip replacement. Scaler tips are subject to wear, and will need periodic replacement.

**TRANSPORTATION**

Care must be taken during transportation to prevent damage to Xpedent SHEL Ultrasonic Scaling Devices.

⚠ Warning:

Do not transport with dangerous goods.

⚠ Warning:

Avoid excessive vibration and impact during transportation ⚠ Warning:

**Xpedent Shel Ultrasonic Scaling Devices should only be transported in the manufacturer's original packaging**.

⚠ Warning:

**Avoid exposure to strong direct sunlight or excessive humidity or precipitation**. **ACCESSORIES**

**Scaling Inserts:** A variety of Xpedent scaling inserts are available. It is the manufacturer's policy to constantly improve and expand the range of available tips. Check with your distributor.

**Torque Wrench**: A torque wrench is provided with the scaling machine. The torque wrench is autoclavable, and can be autoclaved with the tip inside. It has the same autoclaving requirements as the tip.

**Pressurised Water Bottle**: A pressurized water bottle (Autobott) is available for those dentists that do not want to connect the Scaler to a chair or mains potable water supply. The Autobott contains a pump that uses the scaler's power supply to provide water to cool the scaler tip.

**AUTOBOTT**

The AutoBott is used in conjunction with ultrasonic scaler machines to provide an integral water supply. It is particularly useful in the following

circumstances:
1) The dentist wants to add medication to the water.
2) The dentist wants to use distilled or sterile water.
3) The local water supply is of poor or unknown quality.
4) Mobile dentists.
5) The dentist or hygienist does not have a convenient water supply.

**Box Contents**.

1 x AutoBott Base
1 x Bottle complete with lid and internal silicone tube. 1 x Power Lead with twin plugs
1 x double silicone tube.

**Operating Principle**. The AutoBott works by slightly pressurising the water bottle to ensure a smooth flow of water into the scaler machine.

**Assembly**. Take the double silicon tube and attach to the bottle top at the two nipples labelled air and water ($H_2O$). The air-line is then attached to bottle stand, and the water line to the scaler machine water inlet.

**NOTE**. It is important that the two lines are connected the correct ports. The power lead is connected to the scaler power supply jack, the two split jacks are used one for the AutoBott base and the other for the scaler machine.

**Filling the Bottle**. Prior to filling, the bottle should be clean and free from any solid residues. The bottle is filled with the water or medicated solution that the dentist wants to use for scaler treatment. Any solid medication should be mixed before filling the bottle and, if there are solid particles, these should be filtered out. **It is important that the water is of suitable quality and has no solid particles in it as this may affect the function of the scaler machine**. If the water may have suspended solids in it (such as un-dissolved medication), the bottle should be filled through a filter.

**Note**. For maximum patient comfort, the dentist should use slightly warm water (around 30°C).

**Trouble shooting guide**. If water is not flowing from the bottle to the scaler, please check the following:

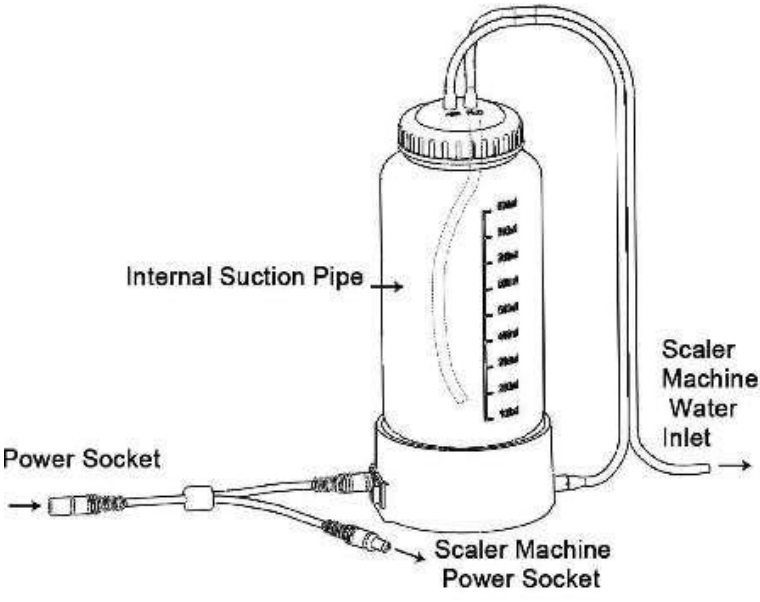
| Symptom | Possible cause | Solution |
|---|---|---|
| AutoBott not working | Power line not connected or not turned on. | Connect power and turn on. |
| | Internal circuit failure | Contact supplier for repair. |
| Autobot working, but no water flow | Double silicone tube connection error. | Check connections and ensure they are correct (ie port marked Air connected to Autobott Base and port marked H20 connected to scaler machine). |
| | Insufficient water in bottle | Ensure bottle is at least ¼ full |
| | Blocked water line or kinked air line. | Remove blockage or kink. |
| | Internal water tube missing, detached or end not in water. | Replace internal water tube. |
| | Damaged air or water line | Contact supplier for replacement. |
| | Bottle not sealing. | Check lid is screwed on fully and not cross-threaded. Check 'O' ring is present. If both of these do not solve the problem, contact supplier for new bottle. |
| Pump working constantly | Bottle not sealing. | |
| | Leak in silicone air line | Contact supplier to replace air-line. |

**Spare Parts**.

Power supply lead with twin plugs. Bottle with cap.
AutoBott Base. Double silicone tube. Internal Silicone Tube
DC power supply(optional).

⚠ Warning:

Use only potable quality water; treatment enhancers such as antibacterial solutions may also be used. Water containing solid residues or undissolved crystals should be avoided.


Internal Suction Pipe
Scaler
Machine
Water
Inlet
Power Socket
Scaler Machine
Power Socket

**TROUBLE SHOOTING GUIDE**:

General

The scope of this guide is for operatory management of simple problems. Any more complicated problems may require dismantling, testing, servicing and re-assembly of components. These procedures require access to the inside of the unit and can be dangerous. Only a qualified person must undertake this otherwise it will invalidate the warranty.

| | |
|---|---|
| 1. Tip will not oscillate & mains switch fails to illuminate. | Check electrical supply. Check fuse (2 4) (Fig.1) and replace with correct fuse rating,if necessary. When tip is oscillating, light contact with a glass bowl will produce a squeaking noise. |
| 2. Tip does not oscillate,but mains lamp is on. | Remove tip and replace with Torque wrench. Try with another hand piece. Check electrical connections. Replace foot switch if a spare is available. If this fails to produce results, the fault condition is in the electronic unit (or foot switch). Call service technician. |
| 3. Water failure. | a. Check electrical connections.<br>b. Check water mains supply, or bottles if fitted.<br>c. Check that the water regulator is set at the full open position.<br>d. Check operation of the solenoid valve by listening for a clicking noise from the electronic unit when the foot switch is operated. If there is no noise, call service technician.<br>e. Verify that the scaling insert is not the source of the blockage. Remove the scaling insert; application of the foot pedal should cause water to flow out of the hand piece. Using a thin wire along the insert water channel may on occasion unblock the tip.<br>f. Check the water filter (if fitted) for signs of clogging. Unplug the electrical mains cable and disconnect the water supply cable from the water supply. Keep the apparatus horizontal to prevent residual water leaking into the electronic unit. Disconnect the filter, and clean the filter if clogged. If this fails to restore the fault condition, call the service technician . |

**WARRANTY**

This Xpedent SHEL Ultrsonic scaler unit is manufactured to the highest standards. It is guaranteed for a period of 12 months from the date of purchase against defects arising from faulty materials or workmanship. Normal wear and tear, willful, accidental or consequential damage, however caused, is specifically excluded from this guarantee.

The manufacturer is responsible for the effects on safety, reliability and performance of the equipment only if:

1. Repairs and service are carried out by persons authorised by the manufacturer.
2. The electrical installation of the relevant room in which the equipment is being operated complies with appropriate requirements.
3. The equipment is used in accordance with the instructions for use.

The manufacture or his representative undertakes to replace or repair free of charge any defective parts within 12 months of purchase. The warranty does not cover the ultrasonic scaling tips, which are only warranted for a period of 3 months.

⚠ Warning:

The Xpedent hand piece can have its O-rings replaced by the end user. All other repairs need to be carried out by the manufacturer.

⚠ Warning:

The hand piece must be cleaned daily and inspected for any visual damage to the connection point or the body. Ensure that no water is allowed to contact the connection point and the hand piece is kept away from water at all times during storage or when out of use.

If the hand piece is not used for an extended period of time ensure that it is clean and stored in a dry environment away from water and heat sources.

⚠ WARNING:

If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

**TECHNICAL SPECI FICATIONS**

Height: 170 mm
Width: 140 mm
Depth: 108 mm
Weight: 0.55 Kgs. Power Weight: 0.35 Kgs Fuse: T 2 AL 250V
Water supply: 0.2-0.6 Mpa, 29-87 PSI Scaler working frequency： 25-31KHz Input power：100~240V 50Hz/60Hz 1.2A Output power ： 30V DC 1.3A
Output power ： 3W to 20W
Output primary tip Vibration amplitude: ≤200 μm Output force at ½ amplitude: < 2N
Operating mode: Continuous operation
Type of protection against electric shock: Class II equipment Degree of protection against electric shock: Type B applied part ()
Degree of protection against harmful ingress of water: Ordinary Equipment (IPX0)
Operation Environment
a) Operation Temperature: 5℃ to 40℃
b) Humidity: ≤80%
c) Air Pressure: 70kPa-106kPa Storage and transport Environment
d) Storage Temperature: -10℃-+55℃
e) Humidity: ≤80%

**Safety Classification of Medical Electrical (ME) Equipment.**

| | |
|---|---|
| Type of protection against electric shock | According to the dental unit<br>(The dental unit transformer which has output of DC 30 V for the Ultrasonic Piezo Scaler shall have two means of patient protection. The built-in part of Ultrasonic Piezo Scaler shall be covered by the dental unit enclosure with two means of protection.) |
| Degree of protection against electric shock | Type B applied part<br>(Type B applied part: Hand piece and tip, Type B Symbol shall be marked adjacent to the connector between scaler and dental unit ) |
| Degree of protection against ingress of water | IPX0 |
| Mode of operation | Continuous operation |
| Degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide | Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide |

## Logo Descriptions

| SIgns | Notes on the signs | Signs | Notes on the signs |
|---|---|---|---|
|  | Type B Applied Part |   | Trade mark |
|  | Follow instructions for use | SN | SERIAL NUMBER |
| CE 0120 | CE mark | EC REP | European Representative |
|  | DATE OF MANUFACTURE |  | Dispose of through designated collection facility (DCF) |
|  | MANUFACTURER |   | 134℃ Maximum autoclave temperature |
|   | ROHS | | |

**EMC declaration**

This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided. This unit can be affected by portable and mobile RF communications equipment.

* Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.

* Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.

Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!

* Caution: this machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

⚠ Warning:

The use of accessories and cables other than those specified, with the exception of items sold by the manufacturer as replacement parts for internal components, may result in increased emissions or decreased immunity of the ME

EQUIPMENT.

<table>
<tr><th colspan="3">Guidance and manufacture’s declaration – electromagnetic emission</th></tr>
<tr><td colspan="3">The Xpedent SHEL Ultrasonic scaler is intended for use in the electromagnetic environment specified below. The user of the Xpedent SHEL Ultrasonic scaler should assure that it is used in such an environment.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The Xpedent SHEL Ultrasonic scaler use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.</td></tr>
<tr><td>RF emission CISPR 11</td><td>Class B</td><td rowspan="3">The Xpedent SHEL Ultrasonic scaler 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.</td></tr>
<tr><td>Harmonic emissions IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions IEC 61000-3-3</td><td>Complies</td></tr>
</table>

| **Guidance and manufacture's declaration – electromagnetic immunity** | | | |
|---|---|---|---|
| The Xpedent SHEL Ultrasonic scaler is intended for use in the electromagnetic environment specified below. The customer or the user of Xpedent SHEL Ultrasonic scaler 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<br>±8 kV air | ±6 kV contact<br>±8 kV air | Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst IEC 61000-4-4 | ±2 kV 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 | ± 1 kV line(s) to line(s) | ±1 kV differential 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% $U_T$ (>95% dip in $U_T$) for 0.5 cycle<br>40% $U_T$ (60% dip in $U_T$) for 5 cycles<br>70% $U_T$ (30% dip in $U_T$) for 25 cycles<br><5% $U_T$ (>95% dip in $U_T$) for 5 sec | <5% $U_T$ (>95% dip in $U_T$) for 0.5 cycle<br>40% $U_T$ (60% dip in $U_T$) for 5 cycles<br>70% $U_T$ (30% dip in $U_T$) for 25 cycles<br><5% $U_T$ (>95% dip in $U_T$) for 5 sec | Mains power quality should be that of a typical commercial or hospital environment. If the user of the Xpedent SHEL Ultrasonic scaler requires continued operation during power mains interruptions, it is recommended that the Xpedent SHEL Ultrasonic scaler be powered from an uninterruptible power supply or a battery. |

| | | | |
|---|---|---|---|
| Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8 | 3A/m | 3A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE $U_T$ is the a.c. mains voltage prior to application of the test level. | | | |

| **Guidance and manufacture's declaration – electromagnetic immunity** | | | |
|---|---|---|---|
| The Xpedent SHEL Ultrasonic scaler is intended for use in the electromagnetic environment specified below. The customer or the user of Xpedent SHEL Ultrasonic scaler should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment - guidance** |
| Conducted RF IEC 61000-4-6<br><br>Radiated RF IEC 61000-4-3 | 3 $V_{rms}$<br>150 kHz to 80 MHz<br><br>3 V/m<br>80 MHz to 2.5 GHz | 3 Vrms<br><br>3 V/m | Portable and mobile RF communications equipment should be used no closer to any part of the Xpedent SHEL Ultrasonic scaler, including cables, than recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** 80 MHz to 800 MHz<br>800 MHz to 2.5 GHz<br>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).<br>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: |

NOTE 1 At 80 MHz and 800 MHz, 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.

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 SHEL-B is used exceeds the applicable RF compliance level above, the Xpedent SHEL Ultrasonic scaler should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Xpedent SHEL Ultrasonic scaler.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**Recommended separation distances between portable and mobile RF communications equipment and the XPEDENT SHEL ULTRASONIC SCALER .**

The Xpedent SHEL Ultrasonic scaler is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the X Xpedent SHEL Ultrasonic scaler can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Xpedent SHEL Ultrasonic scaler 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** | **80 MHz to 800 MHz** | **800 MHz to 2.5 GHz** |
| 0.01 | **0.117** | **0.117** | **0.233** |
| 0.1 | **0.369** | **0.369** | **0.738** |
| 1 | **1.167** | **1.167** | **2.333** |
| 10 | **3.689** | **3.689** | **7.379** |
| 100 | **11.667** | **11.667** | **23.333** |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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.