

SHEL-P

OPERATING INSTRUCTIONS

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

XPEDENT ULTRASONIC SCALING DEVICES



SHEL-P

Users' Operating Instructions

SHEL-P version 3 Jan 2019

IMPORTANT: Read instructions fully before operating this device

OPERATING INSTRUCTIONS

1.Features:

The XPEDENT SHEL range of ultrasonic scaling devices offers a scaling system that is designed for use with industry standard 23K to 33k scaling inserts in the same hand-piece. The advanced electronics ensure 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 Shel-P can operate from a mains water supply or by using the built-in reservoir.

Intended use:

The ultrasonic scaler is used for:

- a) Remove supra and sub gingival calculus deposits and stains from teeth.
- b) Periodontal pocket lavage with simultaneous ultrasonic tip movement.
- c) Preparing, cleaning and irrigating root canals.

Warning:

The water supply must be of drinking water quality.

The hand-pieces, insets, reservoir 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.

Indication:

This device is used by, or under the supervision of, a dentist.

2. Contra-Indications.

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.

Patients with infectious disease should not be treated with ultrasonic scalers; hand instruments should be used instead.

Warning:

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 insert for this purpose is 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 theatres. This equipment should not be used in the presence of a flammable anaesthetic mixture with air oxygen or nitrous oxide.

 Warning:

Subgingival 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:

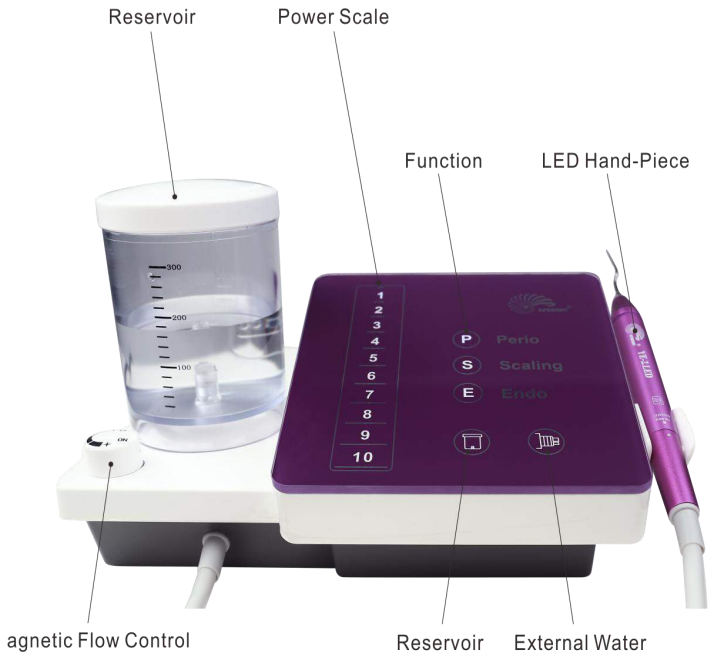
Although modern cardiac pacemakers are shielded, care must be taken when using the Shel-P scaling unit with patients with cardiac pacemakers. Consult the patient's cardiologist if in doubt. Magnetic field generation may interfere with certain types of pacemakers.

 Warning:

Care should be taken if the patient has heart disease, is pregnant, or is a child.

3. Installation Instructions

a) Front Schematics



Note: The Magnetic water controller can be removed for cleaning; when replaced, turn fully anticlockwise to the off position.

b) Back Schematics



c) Water Use

The External Water and Reservoir keys select the water supply (Reservoir is selected by default):

Reservoir Supply Mode: Fill the reservoir with clean water or saline solution.

External Water Supply Mode: Ensure the external water supply is connected. For both options, control is via the foot pedal.

d) Power Supply and Foot Pedal Switch Set Up

The power supply and foot pedal are to be plugged in to the back of the machine. The power supply is to be connected to a standard power socket.

e) Hand Piece Set up



Select the correct insert for the operation. Sharp inserts are best for subgingival scaling, and flat for supragingival applications. Always sterilise scaling inserts prior to each use (wash then autoclave 134°C for 18 minutes). The insert can be autoclaved inside the torque wrench. The insert is screwed in to the hand-piece using the torque wrench provided.

 **Warning:**

Use of the correct torque wrench is critical as it controls the applied torque. Over torqueing may damage the hand-piece and under torqueing will impair function and could lead to the insert detaching from the hand-piece.

4. Scaler Instructions.

a)Controls.

The SHEL-P has touch panel controls for function, power level and selection of water source.

Water flow control is by the Magnetic Flow Control (front left] and Water Flow

Control (rear) knobs.

The Power Switch is at the rear.

b)Start-Up.

Turn the power switch to the on position.

By default, the machine is set to Perio.

The power setting is remembered from last use.

The Water Control is set to Reservoir.

c)Setting Water Flow.

Use the Magnetic Flow Controller (MFC) to adjust liquid discharge when using the reservoir. The MFC is OFF in the fully anticlockwise position, and ON when turned fully clockwise. When the foot-pedal is depressed, the water flow increases incrementally from the OFF position to the ON position. When the foot-pedal is not depressed, the water flow is off, except when the MFC is turned to fully ON. Use the Water Flow Control (WFC) to adjust water discharge when using the external water supply.

Depress the foot pedal to start water flow, adjust the relevant control knob until the required flow is achieved (see 6. below for details). Water is then turned on and off using the foot pedal.

Prior to first use, and after long periods without use, the pump will need to be run in: use clean water in the Reservoir and run until water comes through. This could take several minutes.

Note: For cleaning purposes, set to maximum. This should be done after using anything other than pure water in the Reservoir.

d) Setting the Power.

Select the function most suitable for the scaling to be undertaken.

The **E (Endo)** setting is a low power mode suitable for long thin inserts.

The **P (Perio)** setting is medium power suitable for subgingival work.

The **S (Scaling)** setting is a higher power for general work.

The power is then selected using the touch scale, with 10 being maximum power for the function.

5. Machine Operation.

Once the power and water have been correctly set for the operation:

Depress the foot-pedal to commence scaling, water flow and LED illumination.

Operator confirms correct function; water flow and light are observed and vibration can be felt by touching the insert to a sterile surface or finger.

Scaling can now commence.

Always select the lowest power setting when beginning a procedure.


Increase power incrementally to achieve efficient deposit removal and patient comfort.

The hand piece is held like a pen. Gently move the insert to break dental calculus.

Once the procedure is complete, release the foot pedal. Scaling and water flow cease immediately and the light is turned off 5 seconds later.

Do not leave inserts in the hand piece at the end of the working session.

Scaling Inserts should always be positioned in the insert holder or autoclavable torque wrench, such that they will not cause damage to patients or staff.

 **Warning:**

The Shel-P must only be operated by, or under the supervision of, a qualified dental practitioner.

Power is to be OFF prior to changing insert or hand-piece.

Water supply is required when scaling as the inserts will otherwise heat-up and may burn the patient.

Avoid excessive pressure when scaling to avoid patient discomfort or insert breakage. Always use a Torque wrench (supplied) for insert installation.

Liquids in the Reservoir and external water supplies must be potable. Do not shine LED to patient's eye.

⚠ 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.

6. Scaling Insert Connection.

Always sterilise scaling inserts prior to each use (autoclave 134°C for 18 minutes). Use torque wrench provided to ensure the correct torque is applied to the insert to Hand-piece connection.

When using the inserts with an endo file, ensure inserts are tightened to the hand-piece and files are tightened to the Endo insert.

a) 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 inserts 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 inserts should always be operated on LOW-POWER setting only.

Standard-diameter inserts should be used for heavy or medium calculus deposits. Straight or Universal inserts 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 insert, or if the insert and hand piece 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 |
|------------|--|-----------------------------|
| A | S model 2-5 | small |
| P | P model 2-5 | small |
| PS | P model 2-5 | small |
| ICP | S model 2-5 | big |

b)Wear and Replacement.

Inserts wear with use and from time to time need to be replaced. For scaling inserts, when approximately 2mm of length of the insert is worn, the insert has outworn its usefulness (approximately 50% of scaling power has been lost) and should be replaced.

Perio inserts need to be replace more frequently as they need to retain their sharper profile.

Endo inserts require the most frequent replacement.

Warning:

Micro-fractures can occur in inserts 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 insert during function and subsequent soft tissue trauma, or inhalation or swallowing of the fractured portion. Always discard inserts that have been dropped or where a change of power is experienced during use.

Over-worn inserts will reduce the efficiency of the scaling operation, cause patient discomfort and may damage the equipment.

Remember:

Do not leave inserts in the hand piece at the end of the working session. Scaling inserts should always be positioned in the insert 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.

7. 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 hand piece 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 insert. 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 SHEL-P from the water supply at the end of a working session.

8. Power.

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.

Warning

Excessive power can result in early fracture of the insert, without increasing the scaling efficiency.

There is no advantage to using more power than is necessary to remove the calculus gently and efficiently.

9. Scaling Technique.

a) Scaling.

The Shel-P 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 gentle strokes and light taps, to pulverize and detach the deposits. It is important to keep the insert 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. Plaque removal can be effectively accomplished using a series of gentle sweeping movements that overlap to cover the entire surface in a multidirectional pattern.

With adequate water flow and low power settings, there is little concern for damage to teeth with large pulp chambers; the amount of heat generated will not be sufficient to harm the pulp.

Although insert changing is simple, it is normally more efficient to perform as much work as possible with an insert 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 insert vibration which decreases scaling efficiency.

b) 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

Excessive power can result in early fracture of the insert, without increasing the scaling efficiency.

c) PPE:

Proper use of PPE, including eye protection for the operator and patient, and effective surface disinfection and barriers should be employed.

⚠ 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.

10. Cleaning and Sterilisation

- Ultrasonic tips, handpieces and wrenches must be sterilised 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, they can be cleaned in warm water with a low-foaming detergent and an autoclavable brush.

⚠ Warning

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 sterilisation 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.

⚠ Warning

Do not use closed containers during sterilisation 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

- Sterilise with ethylene oxide

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

- Sterilise with steam

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

- Regarding sterilisation

Ethylene oxide is the preferred method for sterilisation. Steam autoclaving is the preferred method of dentistry. Dry heat should NOT be used for materials which can be sterilised 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 sterilisation are considered ineffective methods, with the risk of damaging materials. DO NOT use chemiclaves or drying ovens for sterilising Xpedent ultrasonic tips and wrenches.

- The scaling tip has no sterilisation cycle limit, but after the tip is worn exceeding 2mm, the scaling tip needs to be replaced. The minimum sterilisation 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.

11.Maintenance.

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 worn; 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.

Insert replacement. Scaler Inserts are subject to wear, and will need periodic replacement.

Transportation.

Care must be taken during transportation to prevent damage to Shel-P Ultrasonic Scaling Devices.

⚠ Warning:

Do not transport with dangerous goods.

⚠ Warning:

Avoid excessive vibration and impact during transportation.

⚠ Warning:

Shel-P should only be transported in the manufacturer's original packaging.

⚠ Warning:

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

13. Accessories

a) 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 inserts.

Check with your distributor, or visit www.xpedent.com

b) Torque Wrench

A torque wrench is provided with the scaling machine. The torque wrench is autoclavable, and can be autoclaved with the insert inside. It has the same autoclaving requirements as the insert. Torque wrenches do need replacing from time to time. The replacement frequency is, to some extent, dependent upon the cleaning system used. They are sensitive to hypochlorite solutions (bleach for example), and should not be cleaned with or left to soak in them.

WARRANTY

This Shel-P Ultrasonic scaler unit is manufactured to the highest standards. It is warrantied for a period of 12 months from the date of purchase against defects arising from faulty materials or workmanship. Normal wear and tear, wilful, accidental or

consequential damage, however caused, is specifically excluded from this warranty.

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

Repairs and service are carried out by persons authorised by the manufacturer.

The electrical installation of the relevant room in which the equipment is being operated complies with appropriate requirements.

The equipment is used in accordance with the instructions for use.

The manufacturer or his representative warrants to replace or repair free of charge any defective parts within 12 months of purchase. The warranty does not cover the ultrasonic scaling inserts, 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 can contact the connection point and the hand piece is always kept away from water during storage or when out of use.

If the hand piece is not used for an extended period, 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 Specifications:

Height: 155 mm

Width: 290 mm

Depth: 168 mm

Weight: 1.55 Kgs.

Fuse: T 5 AL 250V

Water supply: 0.2-0.6 Mpa, 29-87 PSI

Scaler working frequency: 23-33KHz
Input power: 100-240V 50Hz±1Hz
Output power: ≤20W
Output primary insert Vibration amplitude: ≤200um
Output force at 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: Temperature 5°C to 40°C, Humidity: ≤80% Air Pressure: 70kPa-106kPa
Storage and transport Environment: Temperature: -10°C -+55°C, Humidity: ≤80%

Safety Classification of Medical Electrical (ME) Equipment.











| | |
|---|--|
| Type of protection against electric shock | According to the dental unit (The dental unit transformer, DC 30 V has two means of patient protection. The built-in part of it will be covered by the dental unit enclosure with two means of protection.) |
| Degree of protection against electric shock | Type B applied part |
| 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 anaesthetic mixture with air or with oxygen or nitrous oxide |

Trouble Shooting Guide:

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.

| | |
|---|--|
| Insert will not oscillate & Touch screen fails to illuminate. | Check electrical supply. Check fuse (2 4) (Fig.I) and replace if necessary. When insert is oscillating, light contact with a glass bowl will produce a squeaking noise. |
| Insert does not oscillate, but touch screen is on. | Remove and replace insert 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. |
| Water failure. | Check electrical connections. Change between Reservoir and external supply. Check that the water control is fully open. 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. Verify that the insert is not the source of the blockage. Remove the scaling insert; depressing 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 insert. If these actions fail to restore the fault condition, call the service technician. |

Logo Description:

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

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. 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.

 Warning:

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

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, apart from items sold by the manufacturer as replacement parts for internal components, may result in increased emissions or decreased immunity of the ME

EQUIPMENT.

| Guidance and manufacture's declaration – electromagnetic emission | | |
|---|------------|---|
| 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. | | |
| Emission test | Compliance | Electromagnetic environment – guidance |
| RF emissions CISPR 11 | Group 1 | 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. |
| RF emission CISPR 11 | Class B | 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. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies | |

| Guidance and Manufacture's Declaration - Electromagnetic Immunity | | | |
|---|---|---|--|
| The Shel-P is intended for use in the electromagnetic environment specified below. The user of Shel-P 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 floor is 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 | ±2 kV 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 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec | <5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <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 SHEL-P requires continued operation during power mains interruptions, it is recommended that the SHEL-P 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 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 SHEL-P is intended for use in the electromagnetic environment specified below. The user of SHEL-P should assure that it is used in such an environment.

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - guidance |
|---|---|-------------------------|--|
| <p>Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3</p> | <p>3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz</p> | <p>3 Vrms 3 V/m</p> | <p>Portable and mobile RF communications equipment should be used no closer to any part of the SHEL-P, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance 80 MHz to 800 MHz 800 MHz 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, should be less than the compliance level in each frequency range. Interference may occur near equipment marked with the following symbol</p> |

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

For the applicable RF compliance level above, the Shel-P should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Shel-P.

Recommended separation distances between portable and mobile RF communications equipment and the SHEL-P

The Shel-P is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the X Shel-P can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Shel-P 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 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.

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



Guilin Yikeshi Medical Instrument Co., Ltd
D08 High Tech Park, Chaoyang Road
Guilin, 541000 PRC



The Old Granary, East Street 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