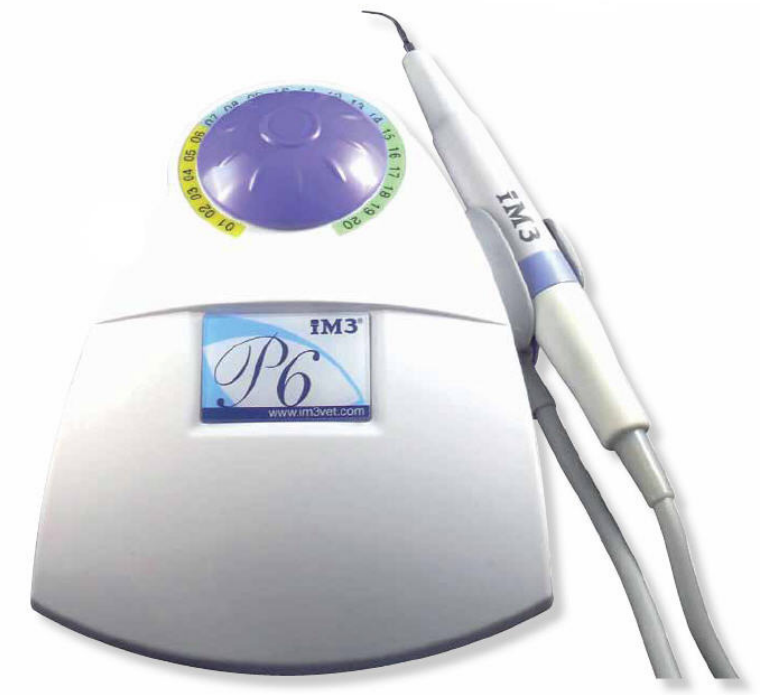
iM3® P6/P6 LED Ultrasonic Scaler

INSTRUCTIONS FOR USE AND TECHNICAL MANUAL



ENGLISH **FRANCAIS** **DEUTSCH**

FOR VETERINARY USE ONLY

iM3 P6/P6 LED Piezo Ultrasonic Scaler

Directions for Use

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Operator Safety

PLEASE READ THIS MANUAL BEFORE OPERATING. THE iM3 P6 PIEZOELECTRIC ULTRASONIC SCALER SHOULD BE OPERATED, MAINTAINED AND REPAIRED BY QUALFIED AND TRAINED PERSONNEL ONLY.

- ***NOTE, CAUTION AND WARNING STATEMENTS***

  NOTE: Provides tips and advice.

  CAUTION: Provides correct operating or maintenance procedures

  WARNING: Alerts user of danger of injury or damage.

- ***About the iM3 P6 Piezoelectric Ultrasonic Scaler***

  How it works

  The iM3 P6 Piezoelectric Ultrasonic Scaler generates ultrasonic waves in the hand piece to vibrate the tip, which allows the iM3 P6 to remove calculus and tartar easily. These ultrasonic waves are created by 4 ceramic piezoelectric plates subjected to high frequency alternating currents.

  The piezoelectric transducer operates at a frequency of 29khz with minimal noise and heat, and efficiently reduces the amount of cooling water required during treatment. This electric-mechanical feature provides greater efficiency than traditional magnetostrictive systems.

Table of Contents

Section I: Indications for Use

Ultrasonic procedures:

- Removal of calculus and plaque during dental prophylaxis.
- General supra and sub-gingival scaling applications.
- Periodontal debridement for all types of periodontal diseases.
- Endodontic procedures.

Section II: Contraindications and Warnings

- Do not use the iM3 P6 for restorative dental procedures.
- Do not use the iM3 P6 if the patient or operator is wearing a pacemaker.
- Do not immerse the iM3 P6 in water or liquid. If the iM3 P6 has water damage, return the machine to iM3 for servicing.
- Do not modify the iM3 P6. Modifications will invalidate the warranty on the machine and may endanger the patient and operator.
- Do not attempt service or maintenance while the iM3 P6 is in use.

Section III: Precautions

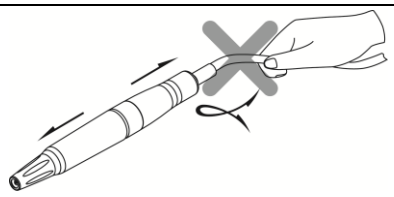
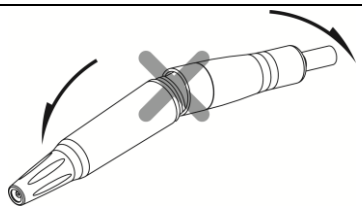
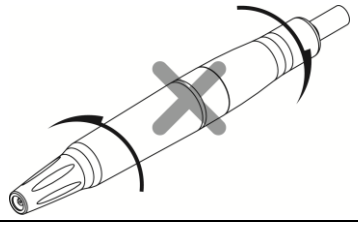
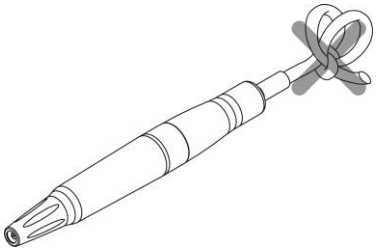
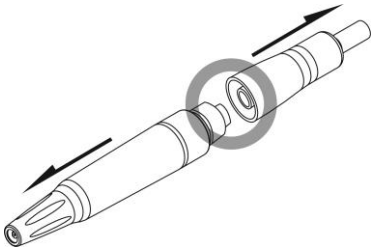
3-A: Precautions for all Ultrasonic Scaler Units and Systems

- Ensure sufficient water flow to the scaler tip during use to cool the hand piece and tips.
- Take precaution as all ultrasonic scalers produce aerosols that may transmit contagious diseases.
- Use tips manufactured by iM3 for optimal performance and results.
- Keep the unit away from intense heat. Excessive heat may damage the electronic components.
- Switch the water valve off when the iM3 P6 is not in use.
- Do not treat patients who have a pacemaker.

3-B: Precautions for Ultrasonic Prophylaxis Procedures

- Scaler tips (piezo tips) will wear with use. Tips with 2mm of wear will lose approximately 50% of their scaling efficiency. In general, it is recommended that tips be discarded and replaced every 4-6 months to maintain optimal efficiency and avoid breakage.
- Avoid direct contact of tips with the patient's lips, cheeks and tongue.
- Do not reuse scaling tips (piezo tips) that are damaged, bent, or reshaped. Discard immediately.
- Use the long axis of the scaler tip (piezo tip) to wipe accretions from the tooth. Do not gouge the tooth with the tip.

3-C: Precautions for Hand piece

Do Not Twist and Pull Cable	
Do Not Bend	
Do Not Twist	
Do Not Bundle	
Pull To Disconnect	

<u>WARNING</u>: Do NOT reinsert the hand piece into the cable until the contacts have fully dried. Wet sockets or plugs will result in an electrical short and non-warranty damage!

3-D: Precautions for Tips

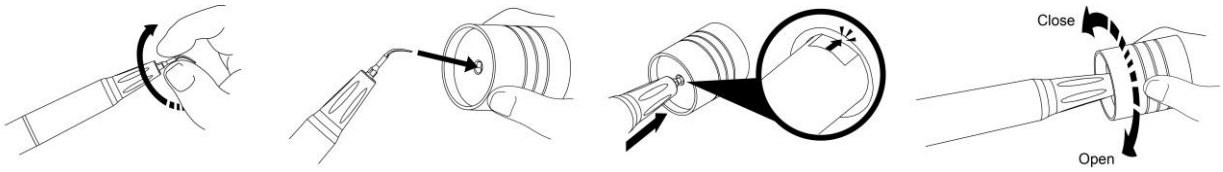
For proper installation of the tips, please follow the instructions below.

A. Screw and secure the tip clockwise on the hand piece with your fingers.

B. Insert the attached tip into the torque wrench opening.

C. Ensure that the root of the tip is in the opening of the torque wrench.

D. Rotate the torque wrench clockwise until it is tight; proceed to rotate the wrench clockwise for 3 more turns. The tip is now secured.



<u>CAUTION</u>: Do not 'rock' the torque wrench while installing the tip! Lateral movement can result in a broken tip and hand piece, which is not covered under warranty. Always be sure to thread the tip carefully prior to using the wrench to avoid cross-threading.

Section IV: Infection Control

4-A: General Infection Control Recommendations:

As with all dental procedures, use standard protective equipment such as face masks, eyewear, face shields, gloves and protective gowns.

To ensure safety to the operator and patient, carefully follow the Infection Control Procedures detailed in Section IV.

4-B: Water Supply Recommendations

All dental water supply systems should conform to applicable Centers for Disease Control and Prevention (CDC) and American Dental Association (ADA) standards. These standards should apply to flushing, chemical flushing and general infection control procedures.

4-C: Cleaning and Sterilization:

All sterilization procedures must be followed in accordance with the EN ISO17665 standards.

- **Autoclave sterilization conditions:**

In order to avoid bacterial or viral infections, always clean and sterilize the following components after each treatment:

1. Hand piece
2. Tips
3. Torque Wrenches

The components above are composed of materials that can withstand a maximum temperature of 135℃ or (275℉) for ***3 minutes***. Items should take at least 16 minutes to dry before using it.

WARNING: The components should be steam autoclaved for sterilization. Do not use any other method of sterilization (dry heat, radiation, ethylene oxide, gas, low-temperature plasma, etc.)

CAUTION: Prior to cleaning and sterilizing your iM3 P6 unit, always remember to turn off the device by using the power switch and disconnect the power plug from the outlet.

CAUTION: Please make sure that the components are completely dry before starting the sterilization cycle. This will prevent stains and patches from appearing on the surface of the accessories.

NOTE: The Sterilization Assurance Level (SAL) of steam autoclave should be 10^{-6}. (The sterilization must be performed in compliance to the standard EN/ISO 17665 or ANSI/AAMI ST79)

NOTE: Please refer to the manufacturer's guidelines of the disinfectant solution /detergent in question to determine if is appropriate for disinfecting instruments and/or for use in ultrasonic cleaning applications.

WARNING: Do not use any other method of sterilization (dry heat, radiation, ethylene oxide, gas, low-temperature plasma, etc.)

- **Preparations for sterilization**

1. Carefully remove the tip from the hand piece using the torque wrench.
2. Clean and disinfect the surface of the outer casing, cords and connectors with a cloth and mild detergent or disinfectant solution with a neutral pH (pH7).
3. Allow the disinfectant solution to air dry.

- **Preparations for autoclave sterilization of the hand piece**

1. Take special care not to break the threading pin of the hand piece. The threading pin is where the tips are installed.

NOTE: Breakage of this treading pin is not covered under warranty.

2. Disinfect the hand piece with a cloth and mild disinfectant containing a neutral pH.
3. Dry the electric contacts by blowing air onto them with the syringe.

WARNING: Do NOT reinsert the hand piece into the cable until the contacts have fully dried!

4. Seal the hand piece in a sterilization pouch (without any tips).
5. Follow the instructions of your autoclave machine to sterilize the hand piece in the autoclave machine. The components are composed of materials that can withstand a maximum temperature of 135℃ or (275℉) for **3 *minutes***. Items should take approximately at least 16 minutes to dry.

- **Preparations for Autoclave sterilization of the tip(s)**

1. Clean the tip(s) preferably in an ultrasonic tank with mild disinfectant containing a neutral pH.
2. Rinse the tip(s) in distilled water.
3. Dry the tip(s).

NOTE: Before starting the sterilization cycle, make sure that the inside of the tip is completely dry by blowing air through the internal hole with the syringe. This will prevent stains and patches from appearing on the surface of the tip.

4. Seal the tip inside a sterilization pouch. If you are autoclaving more than 1 tip, place each tip in an individual bag.
5. Autoclave the tip.

- **Preparations for Autoclave sterilization of the torque wrench**

1. Clean the wrench.
2. Disinfect the wrench with a cloth and mild disinfectant containing a neutral pH.
3. Seal the wrench in a sterilization pouch.
4. Autoclave the wrench.

Section V: Installation

5-A: General Information

If the installation of your iM3 P6 system is performed by non-iM3 distributor personnel, check to see that requirements below are followed.

5-B: Water Line Requirements

- Incoming water supply line pressure to the iM3 P6 must be 25 psi (172 kPa minimum) to 60 psi (414Kpa maximum). If your dental water supply line pressure is above 60 psi, install a water regulator on the water supply line to your iM3 P6 unit.
- After the above installation requirement is fulfilled, thoroughly flush the water prior to connecting to the scaler.

- Please use the manual shut-off valve on the dental water system supply line when the office will be unoccupied.

5-C: Electrical Requirements

Refer to Section XII: Specifications

5-D: Unpacking the Unit

Carefully unpack your iM3 P6 unit and verify that all components and accessories are included:

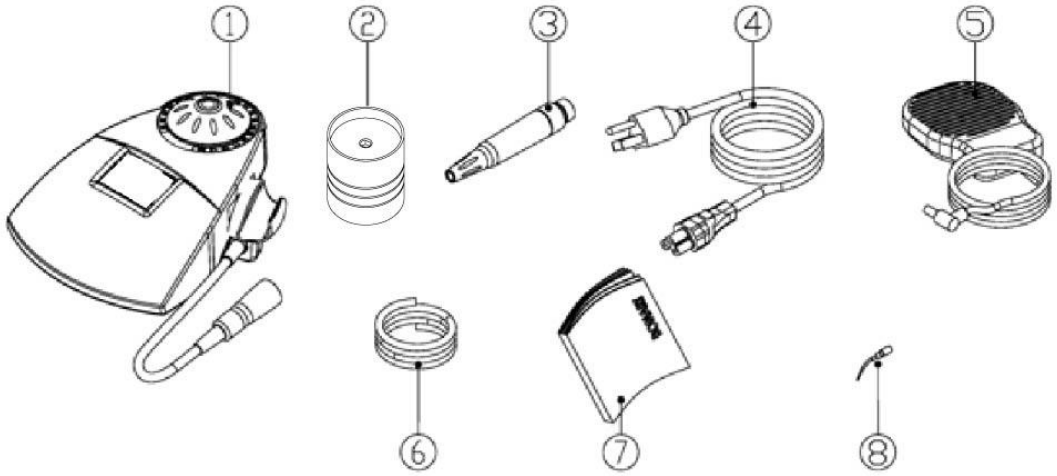


Fig.1, All components and accessories

Item	Quantity	Item	Quantity
(1) Main Unit	1	(2) Torque Wrench	1
(3) Piezo Hand Piece (LED or Standard)	1	(4) AC Power Cord	1
(5) Foot Switch	1	(6) PU Water Tube	1
(7) User Manual & Literature Packet	1	(8) BS1 Universal Pointed Tip BS2 Chisel Head Flat Tip BS3 Round Flat Tip	Optional

<u>NOTE</u>: Other piezo tips are available and can be purchased separately through distributors. Included items are subject to change depending on location.

<u>NOTE</u>: Upon receipt of your iM3 P6, check your iM3 P6 unit for any damages. If any damages are found, please contact your dealer immediately.

5-E: Power Cord / Power Connection

Always make sure that the power switch is set to the OFF position before performing the following tasks:

- Plug the detachable AC cord into the back of the unit.
- Plug the 3-prong plug into a grounded outlet.

Safety Instructions

A. Grounding:

Prior to connecting accessories to the unit, check that the main unit is plugged into a grounded wall outlet.

B. Main voltage range and fuse:

Prior to plugging the AC adapter into the power outlet, check that the voltage is supported.

5-F: Foot Control Cable Assembly Connection

Align the pins of the foot control plug with the receptacle on the back of the device and push in until the plug is firmly seated.

5-G: Water Supply Line Connection

Push the blue water tube into the stainless steel receptacle until the water tube cannot be pushed any further. Then tighten the screw.

Connect the quick connect to the water supply line. The iM3 P6 should be prepackaged with a male quick connect. If a female quick connect is necessary, please contact the iM3 representative to purchase the part.

Inspect all connections for leaks.

To remove the water line from the iM3 P6 scaler, first turn off the water supply or disconnect the water supply line. Then loosen nut on the water tube from the receptacle of the unit and gently pull the water tube out.

5-H: Hand piece connection and tip compatibility

The iM3 P6 hand piece is not only compatible with iM3's tips, but also with tips designed for Satelec Acteon piezoelectric scalers. The hand piece is also detachable from the hand piece cable. During use, the operating frequency of the tip is measured to be approximately 29khz.

5-I: Assembling the Scaler Unit

1. Ensure that the power switch is set to off. If plugged in, the power indicator light should not be lit.
2. Plug the power cord of the main unit into a grounded AC power outlet.
3. Insert the tip into the hand piece and lock it into place by using the torque wrench. Be careful not to cross-thread or overturn the tip as it may cause the tip and hand piece to break. NOTE: breakage of this type is not covered under any warranty.
4. Plug the free end of the blue water tube into the back of the unit by firmly pushing it over the water nozzle, and then fastening it down via the provided nut until secure.
5. Attach the male quick connect to your water supply (or use a saddle valve if connecting directly to a water line. Please contact a licensed plumber if you require direct installation of this manner).

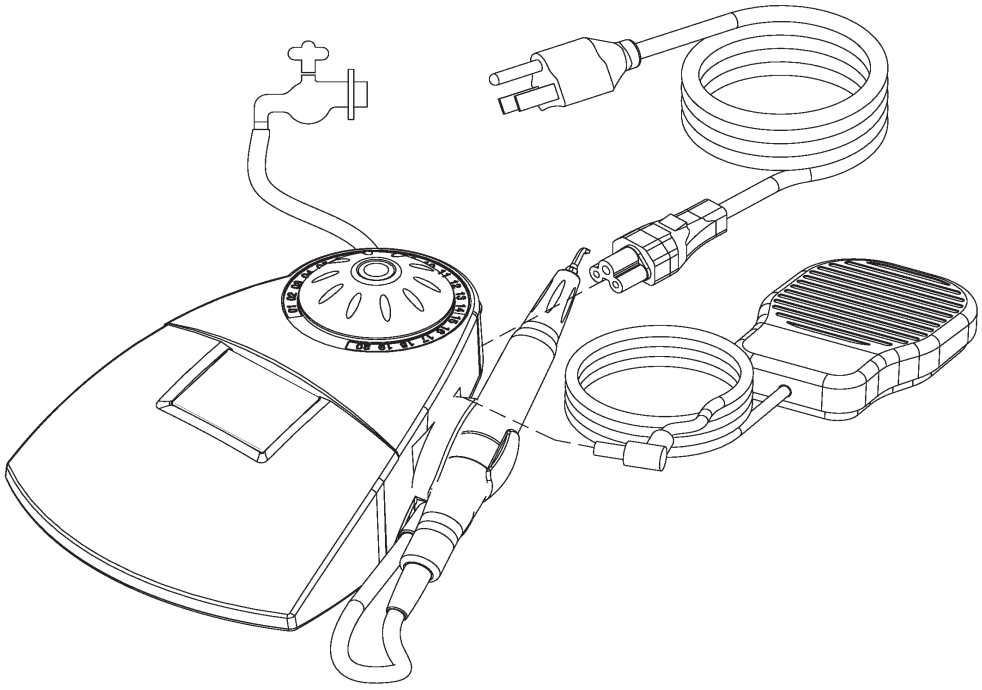


Fig.2, System Installation Diagram

Section VI: General Information and Parts Description

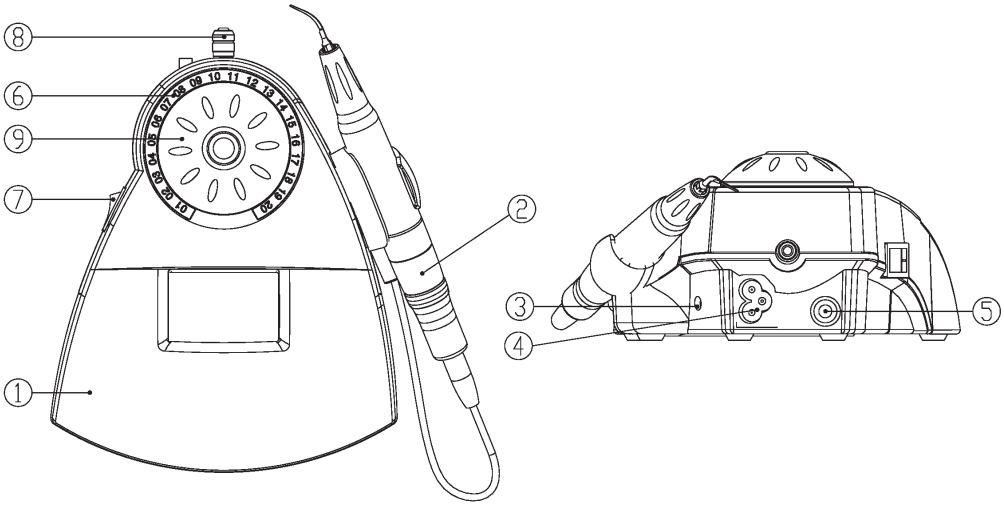


Fig.3, Outlook diagram

1. **Main Unit**

   The main unit generates power and produces a signal that is passed to the hand piece. The hand piece is then powered up and vibrates the installed tip.

2. **Hand piece (LED* or Standard)**

   **LED version not available in some regions. Please check dealers for availability.*

3. **Footswitch**
4. **Power Cord**
5. **Water-In Nozzle**
6. **Power Panel**

   The power panel displays power levels from 1 to 20. The selected power level will be indicated by a lit number.

7. **Main Power Switch**
8. **Water-Adjustment Knob**
9. **Power-Adjustment Dial**

Section VII: Techniques

7-A: Performing Ultrasonic Scaling Procedures

1. Use purified or distilled water to prevent infection when patients experience tissue laceration during treatment.
2. Keep the power cord tidy to avoid tripping and other accidents.
3. Position the footswitch in an easily-accessible spot for the user. Keep the footswitch cord tidy to avoid tripping and other accidents.
4. Lock the tip in the hand piece securely using the enclosed torque wrench.

<u>CAUTION</u>: DO NOT FORCE OR OVERTURN THE TIP INTO PLACE! Doing so will damage the tip, hand piece, and wrench.

<u>NOTE</u>: The scaler will not operate if the tip is either removed from the hand piece or improperly installed.

5. Hold the hand piece over a sink or drain with a tip installed. Verify that water is reaching the tip.
6. Check your iM3 piezo tip for wear and replace as needed. Tips should be disposed of and replaced every 4-6 months.
7. Use the foot control to regulate water flow to the hand piece. Hold down the foot control to allow water to flow through. Release the foot control to stop.
8. Adjust the water flow to the desired level using the water-adjustment knob. Increase the water flow by turning the water-adjust knob clockwise. Decrease the water flow by turning the water-adjustment knob counter-clockwise.

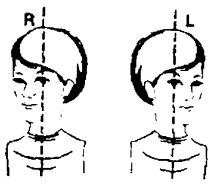
<u>NOTE</u>: Increased water flow results in a cooler hand piece temperature.

<u>CAUTION</u>: During operation, a continuous flow of water is required to keep the hand piece cool.

9. The LED in the hand piece lights up when the foot switch is activated. It will remain lit for 20 seconds after the foot switch is released (*on LED model hand pieces only).*

7-B: Patient Comfort Considerations

1. Position the patient comfortably in the patient chair. Adjust the chair angle and position to access the patient's oral cavity with ease and comfort.
2. Remove excess saliva and debris in the patient’s mouth with a saliva ejector.
3. Rotate the patient's head gently so that the oral cavity can be easily reached without causing discomfort to the patient (see figure below).



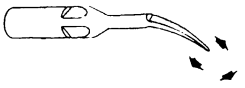
4. During treatment, try to keep the angle between the surface of the tooth and scaling insert at 15 degrees. If the patient experiences any discomfort during treatment, follow the suggestions below:

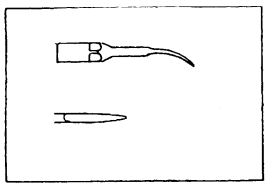
- Increase your manual movement speed of the hand piece on the surface when treating sensitive areas.
- Treat less sensitive areas first, and then return to sensitive areas.
- If the problem persists, reduce the power output intensity of the hand piece.

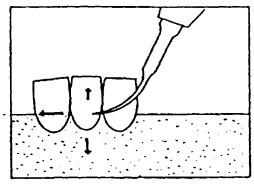
7-C: Applications of the TIP

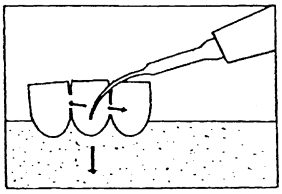
A. Tangential application (BS1 TIP)

Do not apply the BS1 tip directly to the tooth. Doing so may damage the enamel. Control the hand piece with a slow and steady motion.



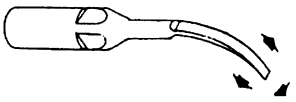


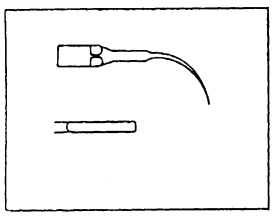


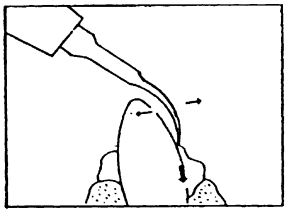


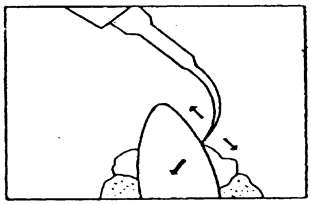
B. Frontal application (BS2 TIP)

Apply the BS2 tip directly against the tartar, but not directly against the tooth. Use a slight amount of pressure.



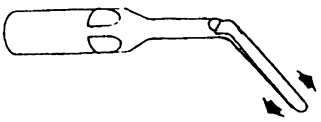


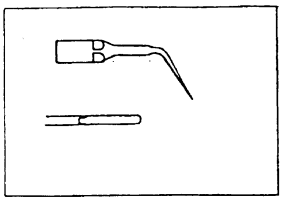


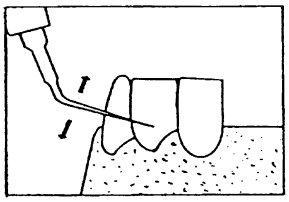


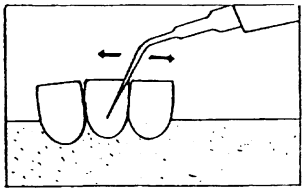
C. Tangential application (BS3 TIP)

Do not apply pressure when applying the BS3 tip to the enamel.









Section VIII: System Maintenance

8-A. Hand piece maintenance

1. After each use, the hand piece and tip should be rinsed with clean water for about 20 to 30 seconds.
2. Inspect the hand piece cable daily to ensure it is in good condition.
3. For sterilization of the hand piece, please refer to Section IV.

8-B. TIP maintenance

Worn out tips can adversely affect performance, resulting in insufficient power and vibration. Check tips regularly for wear and tear and replace as necessary. Tips should be disposed of and replaced every 4-6 months.

8-C. Main Unit Maintenance

The housing of the iM3 P6, as well as the hand piece cord, should be cleaned and disinfected (using alcohol or soap and warm water) on a daily basis.

Section IX: Electromagnetic Compatibility

The use of accessories or replacement parts other than those specified or sold by iM3 may have the consequence of increasing the electromagnetic emissions or decreasing the immunity of the device.

The device must not be used near other equipment or placed on top of it. If this cannot be avoided, correct operation of the device in operating conditions must be checked prior to use.

- **Electromagnetic Emissions**

The device is intended for use in the electromagnetic environment specified below. The user must assure that the device is used in such an environment.

<table>
<tr><th colspan="3">Emission</th></tr>
<tr><th>Test Item</th><th>Compliance</th><th>Electromagnetic Environment - Guidance</th></tr>
<tr><td>Conducted Disturbance CISPR 11</td><td>Class B, Group 1</td><td>The device 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.</td></tr>
<tr><td>Radiated Disturbance CISPR 11</td><td>Class B, Group 1</td><td rowspan="3">The device 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 Current Emissions IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage Fluctuations & Flicker IEC 61000-3-3</td><td>Section 5</td></tr>
</table>

- **Electromagnetic Immunity**

The device is intended for use in the electromagnetic environment specified below. The user must assure that the device is used in such an environment.

Immunity			
Test Item	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2.	± 8KV for contact; ± 2KV, ±4 KV, ±8 KV, ± 15KV for air	± 8KV for contact; ± 2KV, ± 4KV, ± 8KV, ±15 KV for air	Floors must be wood, concrete, cement or tiled. If floors are covered with synthetic material (carpet, etc.), the relative humidity must be at least 30%.
Electrical fast transients IEC 61000-4-4.	±2KV for power supply lines; ±1 KV for interconnect lines	±2KV for power supply lines; ±1 KV for interconnect lines	Mains power quality should be that of a typical commercial or hospital environment (hospital, clinic).
Surges IEC 61000-4-5.	±0.5KV, ±1KV (line to line); ±0.5KV, ±1KV, ±2KV (line to earth)	±0.5KV, ±1KV (line to line); ±0.5KV, ±1KV, ±2KV (line to earth)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations IEC 61000-4-11.	• 0% residual voltage for 0.5 cycle. • 0% residual voltage for 1 cycle. • 70% residual voltage for 25 cycles. • 0% residual voltage for 250 cycles.	• 0% residual voltage for 0.5 cycle. • 0% residual voltage for 1 cycle. • 70% residual voltage for 25 cycles. • 0% residual voltage for 250 cycles.	Mains power quality should be that of a typical commercial or hospital environment. If the use of the device requires continued operation during power mains interruption, it is recommended that the product be powered from a separate power supply (UPS, etc.).

- **Electromagnetic Immunity, Handheld Radiofrequency Equipment**

The device is designed for use in the magnetic and electromagnetic environment described in the table below. The user must ensure conformity of the electromagnetic environment.

Immunity test	**Test level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Portable and mobile radiofrequency communication devices must not be used near the medical device (including cables) at a distance below that recommended and calculated according to the frequency and power of the transmitter.			
Radiated radio frequency electromagnetic field (IEC61000-4-3)	3 V/m 80 MHz to 2.7 GHz	3 V/m	d = 2.3 √P 800 MHz to 2.5 GHz Where (P) is the maximum nominal power of the transmitter in Watts (W) according to the manufacturer specifications and (d) is the minimum recommended separation distance in meters (m).
Radio frequency conducted disturbance (IEC61000-4-6)	3 V/m 150KHz to 80MHz	3 V/m	d = 1.2 √P 80 MHz to 800 MHz Recommended separation distance: d = 1.2 √P
The electromagnetic field intensity of fixed radiofrequency transmitters, as determined by an electromagnetic environment measurement (a), must be less than the conformity level for each frequency range (b). Interference may occur near equipment marked with the following symbol:			

Note 1: At 80 MHz and 800 MHz, the highest frequency range applies.

Note 2: These specifications may not be applicable in all situations. The electromagnetic propagation is affected by the absorption and reflection of structures, objects and people.

(a) The electromagnetic field strengths of fixed radiofrequency emitters, such as base stations for mobile telephones (cellular / cordless), mobile radios, amateur radio, AM/FM radio broadcasts and TV broadcasts cannot be determined exactly by theory. To assess the electromagnetic environment due to fixed radiofrequency emitters, an electromagnetic environment measurement must be made. If the measured radiofrequency field strength in the immediate environment where the product is used exceeds the compliance level specified above, the performance of the product must be tested to verify whether it conforms to the specification. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the product.

(b) In the 150 kHz to 80 MHz frequency range, the electromagnetic field strengths must be less than 3 V/m.

- **Recommended Separation Distances**

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

Rated maximum output power of transmitter'W'	**Separation distance according to the frequency of transmitter 'm'**		
	from 150 kHz to 80 MHz $d = 1,2 \sqrt{P}$	**from 80 MHz to 800 MHz** $d = 1,2 \sqrt{P}$	**from 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 meters (m) can be calculated 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 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.			

Section X: Troubleshooting

Although service and repair of the iM3 P6 system should be performed by iM3 personnel, the following are some basic trouble shooting procedures that will help save you time and avoid making service calls. Generally, check all lines and connections to and from the system. A loose plug or connection will often create problems.

10-A Troubleshooting Guide

PROBLEM	POSSIBLE CAUSE	SOLUTION
The device does not turn on when the switch is in the "ON" position.	The power cord is not plugged in.	Check your connection to the outlet and the unit.
The device is turned on but does not vibrate when you press the foot switch.	Tip is worn out/ not screwed in properly. Tip is wrong style (not Satelec-compatible).	Check the style and quality of the tip and ensure that it is screwed in properly by using the enclosed torque wrench. Replace tip if old or damaged.

PROBLEM	POSSIBLE CAUSE	SOLUTION
The device is turned on but does not produce water when you press the foot switch.	The water supply is not connected to the unit properly.	Check your water supply for sufficient flow, and ensure that the water tube is properly secured to the back of the unit.
	The tip may not be installed properly.	Check your tip installation, quality and type.
	Foot switch may be broken/defective [NOTE: only applies if there is no vibration as well]	Reposition the foot switch and cable to see if there might be a 'short' in the wire. Replace footswitch if necessary.
Insufficient vibration/oscillation.	The tip is old/ worn out/ wrong style/not inserted properly.	Check the style and quality of the tip and ensure that it is screwed in properly by using the enclosed torque wrench. Replace tip if old or damaged.
	The dial is set too low.	Turn the power dial to a higher setting.
Insufficient Water pressure.	Water source is set below the optimal 25-60 PSI setting.	Check the pressure of your water source.
	Water dial is set too low.	Check the dial setting.

10-B Service and Support

For technical support and assistance, please refer to the information below.

iM3 Dental Ltd
IRELAND
Tel: +353 (0) 1 6911277
sales@im3dental.com

iM3 Pty Ltd
Sydney, AUSTRALIA
Tel: +612 9420 5766
sales@im3vet.com

iM3 Inc
Vancouver, WA USA
Tel: (800) 664-6348
info@im3usa.com

www.im3vet.com

Section XI: Symbols

	CE marking of conformity		Fragile; handle with care
	Manufacturer		Keep dry
	Date of manufacture		This side up
	Authorized representative in the European Community		Requires immediate attention
	Type BF equipment	SN	Serial number
	Consult instructions for use		Illumination, LED
	Autoclavable up to 135 ℃		

Section XII: Specifications

- **Classifications**
  - Type of protection against electric shock：Class I
  - Degree of protection against electric shock：Type BF
  - Mode of operation：Intermittent (5 min on/10 min off)
  - According to medical device directive：IIa

- **Complies to following Directive/Standards**

EN/ISO13485:	Medical Devices, Quality Management Systems, Requirements for regulatory purposes
EN/IEC 60601-1:	Medical Electrical Equipment, General Requirement for Safety
EN/IEC 60601-1-2:	Medical Electrical Equipment, Electromagnetic Compatibility, Requirements and Tests

- Specifications
  - Power supply: 115V ±5% ～50/60Hz 28VA
    230V ±5% ～50/60Hz 28VA
  - Working frequency: 26KHz ~ 32KHz
  - Water supply: 25～60 PSIG (172~414KPa)
  - Dimension: 19.5 cm(L) x 16 cm(W) x 8.5 cm(H)
  - Weight: 1.3 Kg
  - Hand piece Cable: 260 cm
  - Light color(LED): White LED
  - Luminous Intensity: Min. 30,000 lux
  - Footswitch Cable: 250 cm

  Operation environment
  - Temperature: 10℃~40℃
  - Relative Humidity: 15% ~ 85%
  - Atmospheric pressure: 860~1060 hPa

  Transport and storage conditions
  - Temperature: 10℃~60℃
  - Relative Humidity: 15% ~ 85%

Section XIII: Disposal

Please follow county and state regulations for disposal of the iM3 P6.

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EC REP

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