

iVac™ LED Piezo Ultrasonic Scaler

Read this manual carefully before operating. Keep it in a safe place for further consultation.



Pac-Dent, Inc.

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1. Installation, Components description.

1.1 Introduction

Thanks for purchasing the iVac™ LED Piezo Ultrasonic Scaler.

The Pac-Dent medical device that you are about to install and use in your practice is a medical device designed for professional use. It comprises the chosen tool with which you will provide treatment within the context of your work. To ensure optimum safety for yourself and your patients, comfort in your daily practice and to benefit fully from the technology of your medical device, please read the documentation provided carefully. If you have received this medical device by mistake, please contact Pac-Dent to arrange for it to be collected. This piezoelectric unit is used for different specialties in dentistry, including hygiene, periodontics, endodontics, implant maintenance, restorative and prosthesis.



WARNINGS:

- Read all instructions before operating this unit. The manufacturer accepts no liability for any damage resulting from improper use of this unit and/or for any purpose other than those covered by these instructions.
- US Federal law restricts this unit to sale by or on the order of a dentist.
- As per Endodontic Standards of Care, always use a rubber dam when performing endodontic treatment.
- Do not use dry heat sterilization on any of the device's components.

1.2 Components description

- 1.2.1 The components are listed in the packing list.
- 1.2.2 The iVac™ LED Piezo Ultrasonic Scaler is composed of circuit board, water pump, reservoir (tank and accessory bottles), and ultrasonic transducer handpiece.
- 1.2.3 The iVac™ LED Piezo Ultrasonic Scaler is used for dental procedures such as endodontics, hygiene, periodontics, implant maintenance and cavity preparations.

1.3 Technical specifications 1.3.1

iVac™ LED Piezo Ultrasonic Scaler:

- a) Main unit input: 110V~50Hz/60Hz 2 8 0 mA.
- b) Output primary tip vibration excursion: ≤90μm.
- c) Output half-excursion force: <2N.</p>
- d) Output tip vibration frequency: 28kHz±3kHz.
- e) Output power: 3W to 20W.
- f) Main unit fuse: T0.5AL 250V.
- g) Water pressure: 0.01MPa to 0.5MPa.
- h) Weight of main unit: 3.97 pounds (1.8 Kg).
- i) Operating mode: Continuous operation.
- i) Type of protection against electric shock: class II equipment.
- k) Degree of protection against electric shock: Type BF applied part.
- I) Applied part of the equipment: handpiece and tip. Degree of protection against harmful ingress of water: ordinary equipment. Foot switch is drip-proof equipment (IPX1).
- m) Degree of safety of application in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide: equipment not suitable for being used in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.

1.4.2 Main components

Main unit (front)

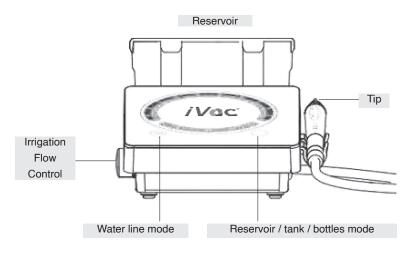
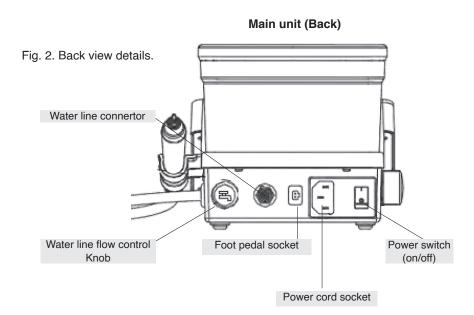


Fig. 1. Front view details.



Handpiece components

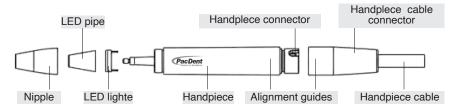
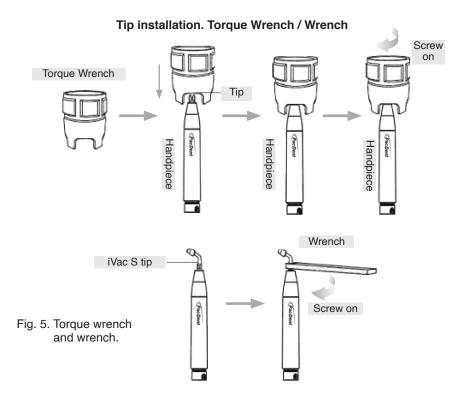


Fig. 3. Handpiece

Handpiece / handpiece cable coupling



Fig. 4. Handpiece and handpiece cable connection alignment guides matching



Touch screen display with water, vibration and power (amplitude) controls.

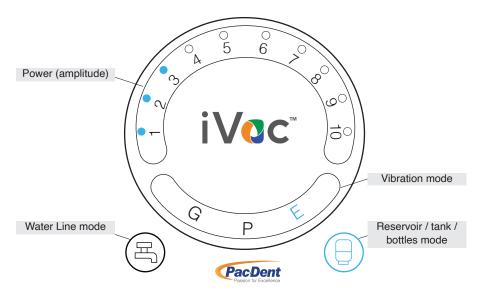


Fig. 6. Touch screen display.

Accessory bottles.

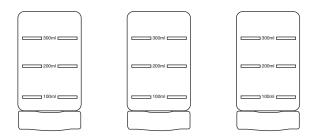


Fig. 7. Accessory bottles (300 ml maximum) for irrigants.

2. Installation/Setup

2.1 Unpacking the device



WARNING:

When you receive your medical device, check for any damage that may have occurred during transportation. If you have received this medical device by mistake, please contact the supplier to arrange for it to be collected.

- 2.1.1 Open the packing box. Make sure that all parts and accessories are complete according to the packing list. Take the main unit out of the box, and place it on a secure and flat surface facing the operator.
- 2.1.2 Installing cords. Ensure the cords do not hinder the movement or free circulation of operators.
- 2.1.3 Never rotate the handpiece connector on its cord as this can damage your medical device.
- 2.1.4 Never wrap the handpiece cord around the medical device.
- 2.1.5 Ensure the unit's cords are not stepped on or rolled over.
- 2.1.6 Set the device to OFF position (power switch, Fig. 2). Check that the power voltage is compatible with that indicated on the device or its power plug.



WARNING:

iVac™ voltage is 110V. 50-60Hz. 280 mA.

- 2.1.7 Next, connect the cord to the wall socket in compliance with the standards in force in the country of use.
- 2.1.8 A different voltage would cause damage to the medical device and could injure the patient and/or user. Any variation in the electrical network voltage or electromagnetic field that is non-compliant with the limits in force, could interfere with the medical device's operation.
- 2.1.9 The medical device's ground must be connected to a supply network equipped with a protective ground.
- 2.1.10 Turn the irrigation flow control knob (Fig. 1) to maximum turning the knob counterclockwise. Turn the water line flow control knob (Fig. 2) to maximum turning the knob counterclockwise. Do not screw it over tight.
- 2.1.11 Insert the foot pedal cord plug to its socket (Fig. 2).

If you are going to use the water line:

2.1.12 Connect one end of the water pipe to the water entrance, and the other end to the clean water source (Fig. 2).

NOTE:

The water line source connector is not included in this device package.



WARNING:

- · The CDC recommends that dental unit water used in nonsurgical procedures contains less than or equal to 500 colony forming units of heterotrophic bacteria per milliliter (≤500 CFU/mL) of water, which is the standard set for drinking water by the Environmental Protection Agency (EPA).
- Use sterile water as a coolant / irrigant when performing surgical procedures (such as prophylaxis, scaling or periodontics treatments).

- Follow dental unit manufacturer's instructions for maintaining and monitoring the quality of dental unit water.
- 2.1.13 With the water connections in place, press the water line mode button on the touch panel (E) (Fig. 6).

If you are going to use the reservoir (tank) or bottles:



WARNING:

The device is equipped with a reservoir (tank) and accessory bottles (Fig. 7) designed to hold the irrigation solution. The irrigation solution reservoir is fitted with a cover. Neither the reservoir, the cover or accessory bottles can be sterilized.

2.1.14 Fill the reservoir up to the line with distilled water. Do not overfill. With the reservoir/bottles in place, press the reservoir mode button (a) on the touch panel (Fig. 6). 2.1.15 The iVac comes with accessories bottles (Fig. 7) to be used during endodontic irrigation. Place the bottle for different solutions.



WARNING:

Do not leave the reservoir (original tank or accessory bottles) with irrigants in place after finishing the procedure. The permanent contact of the reservoir/bottles filled with endodontic irrigants (i.e., sodium hypochlorite, EDTA, chlorhexidine and others) can cause permanent corrosion of the internal parts of the device.

2.1.16 Choose the tip accordingly (see tips Tip Power Table, pg. 40), and install it using the torque wrench (Fig. 5). For installation of endodontic (E) tips, use the wrench (both included).



WARNING:

The screw threads of tips produced by other manufacturers may be coarse, rusty, or damaged, which will irretrievably damage the screw threads of the handpiece. Preferably use iVac brand tips.

2.1.17 Turn on the power switch (Fig. 2).



WARNING:

Every time that the device is turned off and on again, the system will be pre-configured for power (amplitude)1, vibration mode E (for endodontics tips) and reservoir / tank / bottle irrigant mode (Fig. 8).

Fig. 8. Pre-set configuration after turning the device on.



- 2.1.18 Use the touch panel for adjusting the water/irrigant supply mode (water line or reservoir modes), vibration intensity modes (G, P or E) and power (1-10, amplitude).
- 2.1.19 Vibration intensity mode (buttons G. P and E): adjust the vibrating intensity according to the procedure:
- **G** (scaling, hygiene)
- P (periodontics, and cavity preparation)
- **E** (endodontics, including iVac tips irrigation / activation)
- 2.1.20 The iVac uses the S type tips screw thread configuration. iVac tips are identified by letters and numbers. The first letter indicates the vibration intensity model, starting with G (scaling, hygiene), P (periodontics), E (endodontics), and SB (for cavity preparation). The second letter refers to the screw design type (Fig. 9).

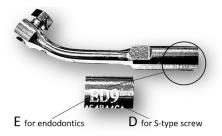


Fig. 9. Example of iVac tip with the number / letters code identification. Letter E stands for endodontic tip; letter **D** stands for **S** type screw design tip.



WARNING:

Always use S type tips for iVac. It is highly recommended to use Pac-Dent ultrasonic tips with the iVac LED Piezo Ultrasonic Scaler. Do not use E type tips (consult tip instructions for use before using ultrasonic tips). The screw threads of tips produced by other manufacturers maybe coarse, rusty, or damaged, which will irretrievably damage the screw threads of the handpiece.

2.1.21 Choose the vibration intensity mode (G, P or E) based on the procedure you will perform (Fig. 6).

IMPORTANT:

Pressing the E button twice will set the system to irrigation mode (E mode at power amplitude 3). This feature allows the 30 seconds timer for iVac irrigation/activation/ suction tips. In this setup the **E** button on the touch panel will blink.

- 2.1.22 Choose the water/irrigant source by pressing the water line (4) mode or reservoir () mode button.
- 2.1.23 Water/irrigant volume adjustment: step on the foot switch (control pedal). The tip will begin to vibrate.
- If you are using the **reservoir mode**: turn the irrigation flow controlknob (Fig. 1) counterclockwise.
- If you are using the water line mode: turn the water line flow control knob (Fig. 2) clockwise

Adjust the knob to achieve a suitable irrigant flow. This adjustment depends on the tip design and procedure. As work habits, feedback and professional training differ from one professional to another, the user must make sure that the irrigation flow is perfectly adapted to the treatment to be carried out to avoid burning the treatment area. Adjust to the minimal irrigant volume for iVac continuous flow endodontic irrigation (consult iVac system instructions).

CAUTION:

· Always use PPE devices such as visor, face mask and high evacuation system to evacuate aerosol from the field of operation.

Thoroughly clean the working area with proper disinfectants.

2.1.24 Operating power adjustment (scale number from 1 to 10): always start the power at a minimal rate (1), adjusting/increasing during the clinical treatment according to procedure needs.



WARNING:

Consult "Tips Power Table" (pg. 40) before starting the procedure. Special attention is needed for endodontic procedures such as activation / irrigation with iVac tips (iVac tip using the iVac S connector). These tips need to be activated (turned on) only when inside the canal, with operating power level from 5 (minimum) to 7 (maximum).

2.1.25 Start the ultrasonic vibration by stepping on the foot switch pedal. Once the tip begins to vibrate, a LED light on the top of the handpiece (Fig. 3) will turn on. Once the foot switch is released, the LED illumination will stay on for 10 seconds.



Fig. 10 Horizontal movements with the tip slightly angled.

2.1.26 After finishing operation, remove the reservoir and dispose () the remaining irrigant. Rinse the tank with water, Fill the tank with distilled water to a quarter of its capacity. Reinstall the tank. Start the cleaning mode by (B) (B) simultaneously pressing the two buttons on the touch screen panel (water line mode and reservoir mode buttons, Fig. 6). A single "beep" alarm will sound and the reservoir mode button will start to blink. Step on the foot switch once to end the cleaning mode (purge) cycle. A continuous flow volume of distilled water will clean the system internally, preventing corrosion or mineral accumulation automatically for 30 seconds. Step on the foot switch to end the cleaning mode cycle before 30 seconds if necessary. After the cleaning cycle, press the two buttons simultaneously to exit cleaning mode.

2.1.27 Unscrew the tip, check for any ware or distortion. Clean and sterilize it.



WARNING:

Do not screw/unscrew tips when the device is on (stepping on the foot switch pedal).

2.2 Cleaning mode (purge cycle) is important to clean internally (purge) the device after use to prevent corrosion or mineral deposits alongside the system.



WARNING:

- Cleaning mode (purge cycle) must be done after every use of reservoir (tank) or accessory bottles.
- · Do not leave irrigants/water inside the reservoir/bottles after use. Discard the irrigants used in a proper way.
- Special attention is needed when using corrosive irrigants like sodium hypochlorite.

Do not use NaOCI concentrations more than 2.0%. Handle sodium hypochlorite with maximum care.

3.Maintenance

3.1 Troubleshooting

Issue	Possible causes	Solutions
	No electrical current.	Contact your electrician.
No operation. The tip doesn't vibrate, and thereis no water flowing out when stepping	Faulty connection between the power cord and the electrical wall socket	Connect the power cord to the electrical wall socket properly.
on the foot switch.	The foot switch is in loose contact.	Insert the foot switch to its socket tightly.
	Internal fuse is not working.	Contact Pac-Dent
The tip doesn't vibrate but there is water flowing out	The tip is in loose contact.	Make sure that the right tip (S type) is being used. Screw the tip on the hand-piece tightly.
when stepping on the switch.	Handpiece and handpiece cord are in loose contact.	Make sure there is no gap between the handpiece and the handpiece cord coupling.
The tip vibrates but there is no spray when stepping on	The water control knob is off or at minimum.	Turn on the water control knob. Adjust the flow turning the knob counterclockwise.
the foot switch.	No irrigation solution at the tank.	Fill the tank with irrigation solution.
The tip does not vibrate at the expected frequency, the treatment is not progressing as normal and is taking longer or is at a standstill.	The tip hasn't been screwed on completely to the handpiece.	Make sure that the right tip (S type) is being used. The E type screw thread is very similar but with a slightly different thread configuration. Replace with a S type (Pac-Dent recommended) and screw the tip on the handpiece tightly.
longer of 10 at a otanicount	The tip is loose.	Screw on the tip tightly.
	The coupling between the hand- piece and the handpiece cord isn't dry.	Thoroughly dry the electrical contacts.
	The tip is damaged.	Replace the tip.
iVac tip is melting at the end part of the tip.	Excessive heat during vibration.	Do not activate (turn on) the tip outside the canal. Use the right vibration (E) mode and the right power (1-7). Make sure there is irrigation.

Issue	Possible causes	Solutions
No irrigation flow or intermittent irrigation flow when using the bottles.	The bottle valve O-ring is damaged.	Replace the O-ring.
The handpiece generates heat.	Low irrigant flow.	Adjust the flow to a higher rate.
	Low irrigant flow.	Turn the knob to a high grade.
No spray. Low spray.	The water pressure is not enough.	Enhance the water pressure.
	The water pipe is jammed.	Clean water pipe with an air/water syringe. [Note2]
The vibrating intensity control is seized up.	The potentiometer is damaged.	Contact Pac-Dent.
LED light in off	Poor contact.	Ensure tight and full contact
LED light is off.	LED worn.	Replace the LED.

If the problem still can't be solved, contact Pac-Dent.

3.2 Corrective maintenance

In the event of faulty operation, the following corrective maintenance actions may be performed by the user.

3.2.1 Clean the water pipe with the air-water syringe (Fig. 11):

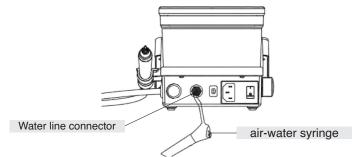


Fig. 11. Water line at the back of the unit.

- a. Snip the water pipe at a distance of 5 to 7 inches from the external water connection.
- b. Turn on the power switch.
- c. Adjust the tip of the air-water syringe to the water pipe.
- d. Screw off the tip or pull out the handpiece.
- e. Step on the foot switch.
- f. Turn on the air-water syringe forcing air or water into the water pipe to unblock the system.

3.3 Cleaning mode

It is important to purge the system after use to prevent corrosion and mineral deposits inside the internal system.

3.3.1 Operation:

- a. After finishing operation, remove the reservoir and dispose the remaining irrigant. Rinse the tank with water. Fill the tank with distilled water to a quarter of its capacity. Reinstall the tank. Start the cleaning mode by simultaneously pressing the two buttons on the touch screen panel (water line mode (a) and reservoir mode (b) buttons, Fig. 6). b. A single "beep" alarm will sound and the reservoir mode button will start to blink.
- Step on the foot switch once to start () the cleaning mode (purge) cycle. A continuous flowvolume of distilled water will clean the system internally, preventing corrosion or mineral accumulation automatically for 30 seconds.
- c. Step on the foot switch to end the cleaning mode cycle before 30 seconds if necessary. After the cleaning cycle, press the two buttons simultaneously to exit cleaning mode.

4. Cleaning, Disinfection and Sterilization

The cleaning, disinfection and sterilization of the handpiece, tip, and wrench (includes torque wrench and wrench) are as followed. Unless otherwise stated, it will be hereinafter referred to as "products".



WARNINGS:

- The use of strong detergent and disinfectant (alkaline pH>9 or acid pH <5) will reduce the life span of products. And in such cases, the manufacturer takes no responsibility.
- Do not clean the handpiece with an ultrasonic cleaning machine. This device must not be exposed to high temperatures above 138°C.
- Processing limit. The products have been designed for a large number of sterilization cycles. The materials used in manufacturing process were selected accordingly to prolong use. However, with every renewed preparation for use, thermal and chemical stresses will result in ageing of the products. The maximum number of sterilizations for handpiece is 600 times. For tips, it is 300 times, and for wrench, it is 1000 times.

4.1 Initial processing

- 4.1.1 Processing principles. It is only possible to carry out effective sterilization after the completion of effective cleaning and disinfection. Please ensure that, as part of your responsibility for the sterility of products during use, only sufficiently validated equipment and product-specific procedures are used for cleaning/disinfection and sterilization, and that the validated parameters are adhered to during every cycle. Also observe the applicable legal requirements in your country as well as the hygiene regulations of the hospital or clinic, especially with regard to the additional requirements for the inactivation of prions.
- 4.1.2 Post-operation treatment. The post-operation treatment must be carried out immediately, no later than 30 minutes after the completion of the operation. The steps are as follows:
- a. Let the device works for 30 seconds under cleaning mode (pg. 14) to flush the sys-

tem internally, the handpiece and the attached tip.

- b. Remove the handpiece from the main unit, and rinse away any debris on the surface of product with water (distilled water/ deionized water).
- c. Dry the product with a clean, soft cloth and place it in a clean tray.



WARNING:

The water to be used to clean must be pure water, distilled water or deionized water.

4.2 Preparation before cleaning

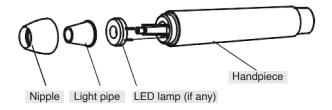
Tools: Torque wrench, tray, soft brush, clean and dry soft cloth.

a.Remove the tip from handpiece with torque wrench (or wrench) provided, and then put the tip and wrench into a clean tray.

b.Unscrew the nipple of product counterclockwise, remove the sealing ring, light pipe, and LED lamp, and put them in the tray.

c.Use a clean, soft brush to carefully brush the joints between product and the connector of cable, front thread, horn, nipple, seal ring, light pipe and LED lamp to remove all visible debris. Then use soft cloth to dry the product and accessories and put them into a clean tray. The cleaning agent can be pure water, distilled water ordeionized water.

Disassembling parts



4.3 Cleaning

The cleaning should be performed no later than 24 hours after the operation. The cleaning can be divided into automated cleaning and manual cleaning. Automated cleaning is preferred if conditions permit.

4.3.1 Automated cleaning

- •The cleaner is proved to be valid by CE certification in accordance with EN ISO 15883.
- •There should be a flushing connector connected to the inner cavity of the product.
- •The cleaning procedure is suitable for the product, and the irrigating period is sufficient.
- •Do not clean the handpiece with an ultrasonic device.

It is recommended to use a washer-disinfector in accordance with EN ISO 15883.

For the specific procedure, refer to the automated disinfection section in the next section "Disinfection".



WARNINGS:

- The cleaning agent can be distilled water, deionized water or multienzyme. Make sure that the selected cleaning agent is compatible with the product.
- In washing stage, the water temperature should not exceed 45°C, otherwise the proteins will solidify and it will be difficult to remove.

• After cleaning, the chemical residue should be less than 10mg/L.

4.4 Disinfection

Disinfection must be performed no later than 2 hours after the cleaning phase. Automated disinfection is preferred if conditions permit.

- 4.4.1 Automated Disinfection. Washer-disinfector:
- •The washer-disinfector is proved to be valid by CE certification in accordance with EN ISO 15883.
- •Use high temperature disinfection function. The temperature cannot exceed 134°C, and the disinfection under the temperature cannot exceed 20 minutes.
- •The disinfection cycle is in accordance with the disinfection cycle in EN ISO 15883.

Cleaning and disinfecting steps by using Washer-disinfector

a.Carefully place the product into the disinfection basket. Fixation of product is needed only when the product is removable in the device. The products are not allowed to contact each other. Use a suitable rinsing adaptor, and connect the internal water lines to the rinsing connection of the washer-disinfector.

b.Start the program.

c.After the program is finished, remove the product from the washer disinfector, inspect (refer to section "Inspection and Maintenance") and packaging (refer to chapter "Packaging"). Dry the product repeatedly if necessary (refer to section "Drying").



WARNINGS:

- · Before use, you must carefully read the operating instructions provided by the equipment manufacturer to familiarize yourself with the disinfection process and precautions.
- With this equipment, cleaning, disinfection and drying will be carried out together.
- Cleaning: (c1) The cleaning procedure should be suitable for the product to be treated. The flushing period should be sufficient (5-10 minutes). Pre-wash for 3 minutes, wash for another 5 minutes, and rinse it for twice with each rinse lasting for 1 minute. (c2) In the washing stage, the water temperature should not exceed 45 °C, otherwise the proteins will solidify and will be difficult to remove. (c3) The solution used can be pure water, distilled water, deionized water or multi-enzyme solution, etc., and only freshly prepared solutions can be used. (c4) During the use of cleaner, the concentration and time provided by manufacturer shall be obeyed.
- Disinfection: (d1) Direct use after disinfection: temperature ≥ 90°C, time ≥ 5 min or A0 ≥ 3000. (d2) Sterilize it after disinfection and use: temperature ≥ 90°C, time ≥ 1 min or A0 \geq 600. (d3) For disinfection, the temperature is 93°C, the time is 2.5 min, and A0>3000.
- Only distilled or deionized water with a small number of microorganisms (<10 cfu/ml) can be used for all rinsing steps. (i.e., pure water that is in accordance with the European Pharmacopoeia or the United States Pharmacopoeia).
- After cleaning, the chemical residue should be less than 10mg / L.
- The air used for drying must be filtered by HEPA.
- Regularly repair and inspect the disinfector.

4.5 Drying

If your cleaning and disinfection process does not have an automatic drying function, dry it after cleaning and disinfection.

4.5.1 Methods

a. Spread a clean white paper (white cloth) on the flat table, point the product against the white paper (white cloth), and then dry the product with filtered dry compressed air (maximum pressure 3 bar). Drving is complete when there is no visible liquid being sprayed on the white paper (white cloth).

b.lt can also be dried directly in a medical drying cabinet (or oven). The recommended drying temperature is 80°C~120°C and the time should be 15~40 minutes.

IMPORTANT:

- The drying of product must be performed in a clean place.
- The drying temperature should not exceed 138°C.
- The equipment used should be inspected and maintained regularly.

4.6 Inspection and maintenance

Check the appearance of the product. After inspection, if there is no problem, the handpiece should be immediately reassembled, installing the sealing ring, LED, light guide, and cone head in sequence to the handpiece, and then tighten the cone head clockwise.

- 4.6.1 Check the product. If there is still visible stain on the product after cleaning/disinfection, the entire cleaning/disinfection process must be repeated.
- 4.6.2 Check the product. If it is obviously damaged, smashed, detached, corroded or bent, it must be scrapped and not allowed to continue to be used.
- 4.6.3 Check the product. If the accessories are found to be damaged, please replace it before use. And the new accessories for replacement must be cleaned, disinfected and dried.
- 4.6.4 If the service time (number of times) of the product reaches the specified service life (number of times), please replace it.

4.7 Packaging

Install the disinfected and dried product and quickly package it in a medical sterilization bag (or special holder, sterile box).

IMPORTANT:

a. The package used conforms to ISO 11607;

b.lt can withstand high temperature of 138 °C and has sufficient steam permeability;



WARNING:

- The packaging environment and related tools must be cleaned regularly to ensure cleanliness and prevent the introduction of contaminants. Avoid contact with parts of different metals when packaging.
- a. The steam sterilizer must comply with EN13060 or be certified according to EN 285 to comply with EN ISO 17665.
- b. The highest sterilization temperature is 138 ° C.
- c. The sterilization time is at least 4 minutes at a temperature of 132°C/134°C and a pressure of 2.0 bar ~ 2.3 bars.
- d. Allow a maximum sterilization time of 20 minutes at 134 °C. Verification of the fundamental suitability of the products for effective steam sterilization was provided by a verified testing laboratory.



WARNINGS:

 Only products that have been effectively cleaned and disinfected are allowed to be sterilized.

- · Before using the sterilizer for sterilization, read the Instruction Manual provided by the equipment manufacturer and follow the instructions.
- Do not use hot air sterilization and radiation sterilization as this may result in damage to the product.
- · Use the recommended sterilization procedures for sterilization. It is not recommended to sterilize with other sterilization procedures such as ethylene oxide, formaldehyde and low temperature plasma sterilization. The manufacturer assumes no responsibility for the procedures that have not been recommended.

If you use the sterilization procedures that have not been recommended, please adhere to related effective standards and verify the suitability and effectiveness.

4.9 Storage

- 4.9.1 Store in a clean, dry, ventilated, non-corrosive atmosphere with a relative humidity of 10% to 93%, an atmospheric pressure of 70KPa to 106KPa, and a temperature of -20°C to +55°C.
- 4.9.2 After sterilization, the product should be packaged in a medical sterilization bag or a clean sealing container, and stored in a special storage cabinet. The storage time should not exceed **7 days**. If it is exceeded, it should be reprocessed before use.



WARNINGS:

- The storage environment should be clean and must be disinfected regularly.
- Product storage must be batched, marked, and recorded.

4.10 Transportation

- 4.10.1 Prevent excessive shock and vibration during transportation, and handle with care.
- 4.10.2 It should not be mixed with dangerous goods during transportation.
- 4.10.3 Avoid exposure to sun, rain or snow during transportation.

4.11 Cleaning and disinfection of main unit

- Before each use, wipe the surface of the connector of cable and cable with a soft cloth or paper towel soaked in 75% medical alcohol. Repeat the wipe for at least 3 times.
- Before each use, proceed cleaning mode (pg. 18) mode for 30 seconds.
- · After each use, proceed with the cleaning mode for 30 seconds, then remove the handpiece.
- · After each use, wipe the surface of the connector of cable and cable with a soft cloth soaked in clean water (distilled or deionized water) or a clean disposable wipe. Repeat the wipe for at least 3 times.

5. Precautions

5.1 Usage notice

- 5.1.1 Keep the scaler clean before and after operation.
- 5.1.2 The tip, torque wrench, wrench, and handpiece must be sterilized before each treat-
- 5.1.3 Don't screw the tip when stepping on the foot switch.
- 5.1.4 The tip must be fastened. There must be fine spray coming out from the tip when operating.
- 5.1.5 Replace the tip if it is damaged or worn excessively.



WARNINGS:

- · A piezo ultrasonic scaler tip is a medical device to which a mechanical force is applied to perform dental treatments. The mechanical force of the user is combined with the ultrasonic force generated by the dental handpiece.
- The tips have been developed to ensure safe use in association with handpieces in accordance with the power levels defined.
- However, tips may break depending on frequency of use, force exerted or by being dropped.
- To reduce all risk (however minimal) it is recommended the use of a high suction device such as a saliva suction cannula. You should also encourage your patient to breathe through the nose.
- 5.1.6 Don't twist or rub the tip.
- 5.1.7 While working, the heat of the tip will become higher if there is no water (irrigant) flowing out, please keep the water (irrigant) flow smoothly.
- 5.1.8 Don't use an impure water source.
- 5.1.9 If use the water source without hydraulic pressure, the water surface should be one meter higher than the head of the patient.
- 5.1.10 Don't knock or rub the handpiece.
- 5.1.11 After each clinical operation with different irrigants, fill the reservoir with distilled water, proceed the cleaning mode for 30 seconds in order to keep the water way and spare parts clean and durable.
- 5.1.12 Ensure the power plug in the socket is accessible to make sure it can be pulled out in an emergency.



WARNINGS:

- · For devices connected to the water line, shut off the dental office's water inlet. In the event of non-use, storage or prolonged absence, unplug the power plug from the electrical supply system.
- Before unplugging the power cord, switch the medical device to off position.
- To unplug the power cord, take hold of it and hold the wall socket.
- 5.1.13 When using the equipment, keep the water (irrigant) flowing smoothly, otherwise patient's tooth surface can be injured by the handpiece overheating.
- 5.1.14 After operating, turn off electrical source, and then pull out the plug.
- 5.1.15 As a professional manufacturer of medical devices, we are only responsible for the safety on the following conditions:
- I.The maintenance, repair and modification are made by the manufacturer.
- II. The changed components are original of Pac-Dent and operated correctly according to instruction manual.
- 5.1.16 The screw threads of tips produced by other manufacturers maybe coarse, rusty, or damaged, which will irretrievably damage the screw threads of the handpiece. It is highly recommended to use iVac Pac-Dent brand tips.
- 5.1.17 Select a suitable power setting when using different type of tips (refer to "Tips Power Table", pg. 27).



WARNINGS:

- The shape and weight of the tips are determined to obtain maximum performance of the ultrasonic generator. The medical device will perform best if the user pays attention to these two characteristics. Therefore, we strongly advise against the modification of the structure of the tips by filing, twisting or by performing other types of modification.
- In addition, tip ageing from normal wear can modify the tip characteristics. Immedi-

ately replace a tip that is damaged due to wear or accidental impact (drop. distortion, etc.). · As it is not possible to establish a maximum number of uses (that may be determined by many parameters such as duration of use, hardness of enamel, the force applied. wear, etc.), we recommend that tips being used are replaced at least every 6 months.

5.2 Contraindication

- 5.2.1 This equipment must not be used with any patient with homephillia. Special attention is needed during scaling/periodontal procedures with patients undergoing anticoagulation treatments.
- 5.2.2 This equipment must not be used with patients or operators who are fitted with a cardiovascular pacemaker device.



WARNING:

Interferences may occur when the system is used on patients fitted with a pacemaker. The medical device presents potential risks due to the emission of electromagnetic fields. It may in particular cases cause malfunction of implanted devices such as a pacemaker or implantable defibrillator and, generally, of any type of active implant. Before using this product, check whether patients or practitioners are fitted with a device of this type:

- explain the situation.
- weigh up the benefits versus the risks and contact your patient's cardiologist or another qualified health professional prior to starting treatment.
- keep this system away from implantable devices.
- apply suitable emergency measures and act fast if the patient shows signs of being unwell.
- · symptoms such as an increased heartbeat, irregular pulse or dizziness may indicate a malfunction of a pacemaker or an implantable defibrillator. The medical device is not designed to withstand electrical defibrillation shocks.
- 5.2.3 Patients with heart disease, pregnant woman, or children should be cautious with this equipment.
- 5.2.4 The medical device was designed and developed with its accessories to guarantee maximum safety and performance. The use of accessories from another source could put you and your patients at risk and could damage your medical device.
- 5.2.5 Do not try to connect accessories not provided by to your medical device connector(s) or to the handpiece. Even if the manufacturer or dealer of your accessory claim's full compatibility with equipment, it is advisable to exercise caution with regards to the origin and safety of the product offered. Look out in particular for lack of information, information in a foreign language, very attractive prices, suspect appearance, mediocre quality or premature wear. If necessary, contact Pac-Dent.
- 5.2.6 Never cover the medical device and/or obstruct the air inlets.
- 5.2.7 Do not immerse or use outside.
- 5.2.8 Do not place the medical device next to a source of heat or in direct sunlight.
- 5.2.9 Do not expose the medical device to water spray or mist.
- 5.2.10 Never fill an irrigation solution tank or bottle when they are installed on the medical device.
- 5.2.11 Always remove the irrigation tanks or bottles from the medical device before
- 5.2.12 Never fill an irrigation solution tank or bottle over the maximum level mark.
- 5.2.13 Irrigation tank covers must always be closed when the medical device is in use.
- 5.2.14 Use the medical device with bottles that do not exceed the maximum levels recommended for the medical device (depending on options).

5.2.15 To prevent any interaction such as crystallization or precipitate between the different irrigation solutions used, rinse through the irrigation circuit and clean the tank in accordance with the instructions provided in the medical device User Operating Manual (cleaning mode, Page 14).

5.3 Storage and maintenance

- 5.3.1 The medical device should be handled carefully and lightly. Be sure that it is far from excessive vibration, and is installed or kept in a cool, dry and ventilated place.
- 5.3.2 Don't store the medical device together with items that are combustible poisonous, caustic, or explosive.
- 5.3.3 This medical device should be stored in a room where the relative humidity is 10% 93%, atmospheric pressure is 70kPa to 106kPa, and the temperature is -20°C $\sim +55$ °C.
- 5.3.4 Turn off the power switch and pull out the power plug when the equipment is not in use. If the medical device has not been used for a long time, ensure it is powered on and off, and is used with water once per month for five minutes.

5.4 Transportation

- 5.4.1 Excessive impact and shaking should be prevented in transportation. Lay it carefully and lightly and don't invert it.
- 5.4.2 Don't put it together with dangerous goods during transportation.
- 5.4.3 Avoid solarization and getting wet in rain or snow during transportation.

5.5 Working condition

- 5.5.1 Environment temperature: +5°C to +40°C
- 5.5.2 Relative humidity: 30%~75%
- 5.5.3 Atmosphere pressure: 70kPa to 106kPa
- 5.5.4 Temperature of the water (irrigant) at the inlet is not higher than +25°C
- 5.5.5 An accessory that has reached the end of its service life must be disposed of in infectious clinical waste containers.

6. After service

Pac-Dent offers one year of free repair to the equipment after purchase according to the warranty card. The repair of the equipment should be carried out by Pac-Dent's professional technical support/maintenance department. We are not responsible for any irretrievable damage caused by any third party.

7. Symbols instructions

iVac™	Trademark	<u></u>	Earth ground
	Alternating current	IPX0	Ordinary equipment
سا	Date of manufacture	(6 0197	CE market product
፟	Type B applied part		Use indoor only
	Class II equipment	H ₂ O 0.01Mps-0.5MPs	Water entrance pressure
	Manufacturer for	134°C 555	Sterilizable up to the temperature
H ₂ O	Water line (irrigant) flow adjustment	(3)	Follow instructions for use
ح	Water line mode	102kPa	Atmospheric pressure for storage
H ₂ O	Adjustment to reservoir mode water (irrigant) flow	-20°C 131°F	Temperature limitation for storage
0	Reservoir/bottle water (irrigant) mode	110V	Voltage to be used
WARNING	Warning and precautions	i	Important Notes
FDA	F.D.A. Food and Drug Administration (U.S.) marked the product		

8. Environmental protection

8.1.1 Please dispose according to the local laws. An accessory that has reached the end of its service life must be disposed of in infectious clinical waste containers.

9. Manufacturer's liability

We reserve the rights to change the design of the equipment, the technique, fittings, the instruction manual and the content of the original packing list at any time without notice. If there are some differences between blueprint and real equipment, take the real equipment as the norm.

10. European authorized representative



EC REP

Llins Service&Consulting GmbH Obere Seegasse 34/2, 69124, Heidelberg, Germany

11. EMC - Declaration of conformity

The device has been tested and homologated in accordance with EN 60601-1-2 for EMC. This does not guarantee in any way that this device will not be affected by electromagnetic interference Avoid using the device in high electromagnetic environment.

Guidance and manufacturer's declaration - Electromagnetic emissions

The models iVac, D600, D600 LED are intended for use in the electromagnetic environment specified below. The customer or the user of the models D600, D600 LED should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The models iVac, D600, D600 LED use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Group B	The models iVac, D600, D600 LED
Harmonic emissions IEC 61000-3-2	Group A	are suitable for used in domestic establishment and in establishment directly connected to a low voltage power supply network which supplies
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	buildings used for domestic purposes.

Guidance & Declaration — Electromagnetic immunity

The models iVac, D600, D600 LED are intended for use in the electromagnetic environment specified below. The customer or the user of the models iVac, D600, D600 LED should assure that It is used in such an environment.

Immun ity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic dicharge(ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1 kV for Input/ output lines	±2kV for power supply lines ±1kV for interconnecting cable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earh	±1 kV line to line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips short interruptions and voltage variations on power supply input lines IEC 61000-4-11.	<5 % UT (>95% dip in UT.) for 0.5 cycle 40 % UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 5 sec	<5 % UT (>95% dip in UT.) for 0.5 cycle 40 % UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the models iVac, D600,D600 LED require continued operation during power mains interruptions, it is recommended that the models iVac, D600, D600 LED be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE UT is the a.c. mains voltage prior to application of the test level.

Guidance & Declaration - Electromagnetic immunity

The models iVac, D600, D600 LED are intended for use in the electromagnetic environment specified below. The customer or the user of the models D600, D600 LED should assure that it is used in such an environment.

Immun ity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms150kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms	Port able and mobile RF communications equipment should be used no closer to any part of the models iVac, D600, D600 LED, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=[3,5/V1]×P1/2 d=1.2×P1/2 80 MHz to 800 MHz d=2.3×P1/2 800 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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range.b Interference may occur In the vicinity of equipment marked with the following symbol: (((*)))
			_

NOTE I At 80 MHz end 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.

Recommended separation distances between portable and mobile RF communications equipment and the models iVac, D600, D600 LED

The models iVac, D600, D600 LED are intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the models iVac, D600, D600LED can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the models iVac, D600, D600 LED are recommended below, according to the maximum output power of the communications equipment.

Rated maximum	Separation distance according to frequency of transmitt		
output power of transmitter W	150kHz to 80MHz d=1.2×P1/2	80MHz to 800MHz d=1.2×P1/2	800MHz to 2,5GHz d=2.3×P1/2
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 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) accordable to the transmitter manufacturer.

NOTE I 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.

^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 models IVac, D600, D600 LED are used exceeds the applicable RF compliance level above, the model IVac, D600, D600 LED should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the models D600, D600 LED.

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

12. Statement

All rights of modifying the product are reserved to the manufacturer without further notice. The pictures are only for reference. The final interpretation rights belong to **Pac-Dent**.

The industrial design, inner structure, etc., are claimed by several patents by the primary manufacturer, any copy or fake product must take legal responsibilities.

TIPS POWER TABLE (OPERATING POWER

Scaling		
Tip Model	Power	
GD3	1-10(G)	
GD4	1-10(G)	
GD4D	1-10(G)	
GD5	1-10(G)	
GD6	1-10(G)	
GD7	1-10(G)	
GD8	1-10(G)	
GD9	1-10(G)	
GD10	1-10(G)	
GD11	1-10(G)	
GD12	1-10(G)	
GD30	1-10(G)	

Periodontics		
Tip Model	Power	
PD1	1-10(P)	
PD2L	1-3(P)	
PD2LD	1-2(P)	
PD2R	1-3(P)	
PD2RD	1-2(P)	
PD3	1-6(P)	
PD3D	1-6(P)	
PD4	1-6(P)	
PD4D	1-6(P)	
PD7	1-10(P)	
PD12	1-10(P)	

Endodontics		
Tip Model	Power	
ED70	1-3(E)	
ED73	1-3(E)	
ED74	1-6(E)	
ED28	1(E)	
ED27	1-3(E)	
ED14	1-8(E)	
ED15	1-3(E)	
ED8	1-10(E)	
ED9	1-10(E)	
ED10	1-6(E)	
ED10D	1-6(E)	
ED11	1-6(E)	
ED11D	1-6(E)	
ED12	1-6(E)	
ED12D	1-6(E)	
iVac S	1-7(E)	
(with iVac tip)		

Cavity Preparation		
Tip Model	Power	
SBD1	1-10(P)	
SBD2	1-10(P)	
SBD3	1-10(P)	
SBDL	1-10(P)	



Scan QR Code for more information.



Manufactured For: Pac-Dent, Inc. 670 Endeavor Circle Brea, CA 92821 www.pac-dent.com info@ pac-dent.com

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