

成型尺寸: 140×210mm 材质: 80g双胶纸 黑白印刷

粘胶成本

| 物料名称 | RP系列说明书 英文CE | 编制 | 胡卫林 | 日期 | 20190924 |
|------|-----------------|----|-----|----|----------|
| 物料编号 | PA-RX-M-E-9 | 审核 | | 日期 | |
| 版本 | A 1 | 批准 | | 日期 | |



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| 6 | Trademark | | Caution |
|---|-------------------------------|---------------------------------|---|
| | Class II equipment | 8 | Follow instructions for use |
| * | Type B applied part | 30V -↔ | 30VDC input |
| \sim | Alternating current | • ^{H₂O • .} | . Water control switch |
| 2 | Foot switch | H₂O 0.1-0.5 MPa | Water entrance 0.1MPa~0.5MPa(1bar~5bar) |
| 凸 | Use indoor only | X | Appliance compliance with WEEE directive |
| 135°C | Autoclavable | IPX0 | Ordinary equipment |
| $[\begin{tabular}{c} \end{tabular} ta$ | Date of manufacture | IPX1 | Drop-proof |
| Å | Air outlet | | Manufacturer |
| + | Increase power | _ | Decrease power |
| ٢ | ON-OFF button of main unit | 0 - | Pump switch |
| MIN | Minimum power | MAX | Maximum power |
| OPTION Function option button | | S – Scaling function | |
| P – Perio function | | E – Endo function | |
| CE 0197 CE marked product | | EC REP | Authorised representative in the European Community |















3.2 Intended Use

A powered device utilizing a vibrating ultrasonic tip to remove calculus and other accretions from tooth surfaces during dental cleaning, periodontal therapy and root canal treatment.

3.3 Contraindication

3.3.1 The hemophilia disease patients or patients with thrombocytopenia purpura are forbidden to use this equipment.

3.3.2 The patients or doctors with heart pacemaker are forbidden to use this equipment.

3.3.3 The heart disease patients, pregnant women and children should be cautious to use the equipment.

4 Components

| Number | Description | Туре |
|--------|-----------------------|---------------------|
| 01 | Main unit | RP1/RP2/RP3/RP4/RP5 |
| 02 | Adapter model No | DJM-40D30B |
| 03 | Foot switch | F1 |
| 04 | Handpiece | H2/H3/L3/D2/D3 |
| 05 | Scaling tip | T1/S1 |
| 06 | Scaling tip | T2/S2 |
| 07 | Perio tip | T3/S3 |
| 08 | Scaling tip | T4/S4 |
| 09 | Scaling tip | T5/S5 |
| 10 | Endo chuck | E1/ES1 |
| 11 | Endo file | |
| 12 | Torque wrench | TW2/TW3 |
| 13 | Endo wrench | EW1 |
| 14 | "O" circle | |
| 15 | Instruction manual | RP series |
| 16 | Qualified certificate | RP1/RP2/RP3/RP4/RP5 |
| 17 | Warranty card | RP1/RP2/RP3/RP4/RP5 |
| 18 | Packing list | RP1/RP2/RP3/RP4/RP5 |

Product components are subject to the packing list.

| Adapter Input | 100 – 240V~ 50/60Hz 0.7A - 0.4A | | |
|--|---|--|--|
| Main unit input | 30V 1.2A | | |
| Main unit fuse | 250V/T 1.6AL | | |
| Output power | 3W-20W | | |
| Output primary tip vibration excursion | \leq 200 μ m | | |
| Output tip vibration frequency | 28kHz \pm 3kHz | | |
| Output half-excursion force | <2N | | |
| Water pressure | 0.1MPa~0.5MPa(1bar~5bar) | | |
| Weight of main unit | 0.47kg | | |
| Weight of adapter | 0.34kg | | |
| Operating mode | Continuous operation | | |
| Classification 93/42/EEC | Class]]a | | |
| Electric shock protection type | Class [] | | |
| Degree of protection against electric shock | В | | |
| Degree of protection against harmful ingress of water | Ordinary equipment (IPX0), Foot switch(IPX1) | | |
| Degree of safety of application n the presence of a Flammable Anesthetic Mixture with air or with Oxygen or Nitrous Oxide | Equipment not suitable for being used in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. | | |
| 2 The conditions of worl | king environment: | | |
| 2.1 Environmental temper | ature:+10℃ to +40℃ | | |
| 2.2 Environmental humidi | ty: 0 to 80% | | |
| 2.3 Atmospheric pressure | : 700hPa to 1060hPa | | |

6 Usage

6.1 Open the packing, make sure that all the parts and accessories are complete according to the packing list. Take the main unit out of the box and put it on a stable plane.

6.2 Our scaler tip is made of stainless steel. In order to ensure good performance of cleaning teeth, please replace another new scaler tip in time when it wears. Replacement condition refers to the varios tip card.6.3 Turn the water control switch to the max based on symbol as shown

in 9.2.1[Note 1].

6.4 Insert the plug of the foot switch to its socket.

6.5 Connect one end of the water pipe to the water entrance, lock the water pipe tightly with locknut, and connect the other end to the pure water source.

Please refer to Picture 8-3 for the connection of the water supply system.

6.6 Connect the handpiece with the cable(Picture 7-3, 7-4, 7-5, 7-6, 7-7), select a suitable scaler tip as you need and screw it on the handpiece tightly by the torque wrench (Picture 7-9).

6.7 Connect the foot switch and power adapter to the main unit, and then connect to the power socket (Picture 1).

6.8 Push the power switch to start the machine (Picture 1).

6.9 This equipment is intended to be in contact with patient's tooth,10 to 30 seconds every time and 200 to 480 times per day.

 $6.10\,Function$ selection: Press "OPTION" button to switch and select the needed function (Picture 1).

6.10.1 Scaling function.

a) After start the machine, the default initial state is scaling function, and SCALING indicator lights.

b) Vibration intensity: Adjust the vibration according to the requirement. Generally adjust to 3 to 4 grade, but also adjust vibration intensity according to the patient's sensitivity and hardness of dental calculus

at any time during the clinical treatment.

c) Water volume adjustment: Step on the foot switch and the tip vibrates, and then turn the water control switch to form fine spray to cool handpiece and clean teeth.

d) Generally, hold the handpiece in the gesture as a pen in hand.

e) In clinical treatment, don't use the point of tip to contact with the teeth

vertically, so as not to damage teeth and tip.

f) The normal frequency is extremely high. Under the normal working state of scaler tip, a light touch and a certain to-and-fro motion will eliminate the tartar without heating. Overexertion and long-time lingering are forbidden.

6.10.2 Periodontal function

a) Press "OPTION" button, switch to periodontal function, then PERIO mode indicator lights.

b) After switching to periodontal function, select the right tips, and use torque wrench to fix it on the handpiece.

c) Adjust the frequency based on current status, it can be periodontal scaling after adjusting the right frequency.

6.10.3 Endo function (Picture 7-8)

a) Press "OPTION" button, switch to endo function, and ENDO indicator lights.

b) Use endo wrench to fix endo chuck to handpiece (Picture 7-8).

c) Loosen the nut of endo chuck.

d) Insert endo file in the front hole of the endo chuck and use endo wrench to tighten the nut so as to clamp the file.

e) Put the endo file into patient's root canal slowly, start the foot switch can conduct ultrasonic root canal therapy. During clinical treatment, adjust the frequency according to actual situation.

Note: Must put the endo file into root canal before starting the foot switch.

6.11 After finishing operation, keep the machines working for 20-30 seconds on the water supply condition in order to clean the handpiece and tips.

6.12 Uninstall the tip, sterilize handpiece, tips, endo chuck ,endo file and torque wrench.

Note: Please don't pull out the handpiece and tips when the foot switch is stepped on and the machine is producing ultrasonic vibration.

7 Sterilization

7.1 Sterilizing detachable handpiece

7.1.1 Precautions

a) Please pay attention to the handpiece during the process of operation and sterilization to see whether it is externally broken. No protective oil is allowed to be painted on the handpiece.



b) There are two "O" circles in each handpiece which need to be sterilized, plugged and unplugged repeatedly. For the purpose of extending life time, dental lubricant should be used.

The circles should be replaced once they are broken or over abrasive. 7.1.2 Sterilization procedure

| Operation | Operating mode | Warning |
|--------------------------------------|--|---|
| 1 Cleaning and disinfection | Disassemble handpiece from detachable cable. Disassemble tip from handpiece. Wipe handpiece & scaler tip & torque wrench with medical alcohol or with special dental disinfection towel. | Cleaned in the ultrasonic bath is forbidden. Dipped in liquor is forbidden. Torrefied in oven or microwave oven is forbidden. |
| 2 Packing | Pack handpiece & scaler tip & torque wrench in sterilization pouches. | Check the validity period of the pouch given by the manufacturer to determine the shelf life. Use packing which are resistant up to a temperature of 141 °C and in accordance with EN ISO 11607. |
| 3 Sterilization | Steam sterilization at: 135℃ and 0.22MPa during 3 min. | Use fractionated vacuum autoclaves (according to EN 13060, EN 285). Use validated sterilization procedure according to EN ISO 17665-1. Respect maintenance procedure of the autoclave device given by the manufacturer. Use only the listed sterilization procedures. |
| 4 Storage | Keep handpiece & scaler tip & torque wrench in sterilization packing in a dry and clean environment. | Sterility cannot be guaranteed if packing is open, damaged or wet (check the packing before using the instruments). |

8 Precautions

8.1 Please keep the scaler clean.

8.2 Operation must be carried out by professional technician.Please wear a mask and eyepieces to prevent cross infection from splashes during operation.

8.3 The handpiece, scaler tip, endo chuck, endo file, endo wrench and torque wrench must be sterilized before each treatment.

8.4 Don't screw or unscrew handpiece and scaler tip when stepping on the foot switch.

8.5 The scaler tip must be fastened by torque wrench and there must be fine spray coming from the tip when operating.

8.6 Change a new one when the tip is damaged or worn excessively.

8.7 Don't twist the tip or rub it.

8.8 Please use purity water source and be sure not to use normal brine instead of purity water source.

8.9 If use non-pressure water, the water should be one meter higher than the head of the patient.

8.10 When the scaler is operated, please don't pull the handpiece forcibly in case of the handpiece or handpiece cord damage.

8.11 Don't knock or rub the handpiece.

8.12 The equipment should be put in a convenient place, but not near power plug.

8.13 Surface temperature maybe will reach 48 $^{\circ}$ C if water yield is too small, so when too high surface temperature is found, please increase water yield. 8.14 Ontact time for adapter enclosure outside and DC power cord of adapter is 10s~1min.

8.15 Turn off the power switch and cut off the power source after stopping operation.

8.16 We are only responsible for the safety of machine in the following conditions:

I. The maintenance, repair and modification are made by the manufacturer or the authorized dealer.

II. The changed components are original of "RP series" and operated according to instruction manual.

8.17 Please use S series scaler tips on RP4/RP5 scaler, and use T series scaler tip on RP1/RP2/RP3 scaler. If forcibly use other brand tips which may not be compatible with the scaler handpiece, it may result in damaging handpiece beyond repair.

8.18 Please use our power supply or same model power supply.

8.19 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 effected by electromagnetic interference. Avoid using the device in high electromagnetic environment.

| Fault | ng and notes Possible cause | Solutions | |
|--|---|---|--|
| | The power pipe plug is in loose contact. | Make the plug insert to the socket well. | |
| The scaler tip doesn't vibrate and there is no | The foot switch is in loose contact. | Insert the foot switch to its socket tightly. | |
| water flowing out when | The fuse of transformer is broken. | Contact our dealers or us | |
| stepping on the switch. | The fuse in the main unit is broken. | Contact our dealers or us. | |
| The scaler tip | The tip is in loose contact. | Screw the tip on the handpiece tightly (picture 7-9). | |
| doesn't vibrate but there is water flowing out when stepping on the | The connect plug between the handpiece and the circuit board is in loose contact. | Contact our dealers or us. | |
| switch. | Problem of handpiece. | Contact our dealers or us. | |
| | The water control switch is not on. | Turn on the water control switch 【note 1】. | |
| The scaler tip | There is impurity in the solenoid valve. | Contact our dealers or us. | |
| vibrates but there is no spray when | The water system is blocked. | Clean the water pipe by multi-function syringe 【note2】. | |
| stepping on the switch. | There is air in the water pipe. | Disassemble the scaler tip, and turn the water control switch to maximum. Meanwhile, make water pressure higher to 0.5MPa max. | |
| | Water single pass is blocked | Replace water filter (picture 8-1). | |
| There is still water flowing out after he power is off. | There is impurity in the solenoid valve. | Contact our dealers or us. | |
| The handpiece generates heat. | The water control switch is in a low grade | Turn the water control switch to a higher grade 【note 1】. | |
| The amount of | The water pressure is not high enough. | Make the water pressure higher. | |
| spouting water is too little. | The water pipe is blocked. | Clean the water pipe by multi-function syringe【note2】. | |
| | The tip hasn't been screwed on the handpiece tightly. | Screw the tip on the handpiece tightly(picture 7-9). | |
| The vibration of the tip becomes weak. | The tip is loose because of vibration. | Screw the tip tightly (picture 7-9). | |
| | The tip is damaged. | Change a new one. | |
| he joint of the andpiece and cable as water leakage. | "O" shape water-proof rubber circle is broken . | Change a new one. | |

If the problem still can't be solved, please contact with local dealer or manufacturer.

9.2 Notes

9.2.1 [Note 1] Adjust the water control switch according to the direction shown can control the water volume.

9.2.2 [Note 2] Clean the water pipe with the Multi-function syringe of the dental unit (Picture 7-1).

1 Cut the water pipe at a distance of 10cm to 20cm from the water entrance.

⁽²⁾Turn on the electricity and get through the electricity.

③ Connect the multi-function syringe of dental unit to water pipe.

④ Disassemble the tip.

(5) Turn on the power and step on the foot switch to start the scaler.

(6) Turn on the switch of the Multi-function syringe, press the water into

the machine and the impurity blocked in the water pipe can be eliminated.

9.2.3 [Note 3] If the scaler tip has been screwed tightly and there is fine spray too, the following phenomena show that the scaler tip is damaged:

① The vibrating intensity and the water atomization degree become weak obviously.

2 During treatment, it produces the sound like "buzz" from the scaler tip.

9.3 If not use for a long time, please make the machine get through the electricity and water once per month for five to ten minutes.

10 Storage and transportation

10.1 Environmental conditions of storage and transportation:

a) Relative humidity: 0 to 80%

b) Atmospheric pressure: 50kPa to 106kPa

c) Environmental temperature: -10°C to +50°C

10.2 Prevent excessive shock and vibration in transportation, be sure to handle with care and avoid inversion.

10.3 Don't mix with dangerous goods during transportation.

10.4 Avoid the sun, rain or snow during transportation.

10.5 The equipment should be handled carefully and lightly. Be sure that it's far from the vibration, and install or store in a cool, dry and ventilated place.10.6 Don't store the machine with the articles that are combustible, poisonous, caustic and explosive.

11 After-service

11.1 We offer 15 months free repair to the equipment based on warranty card from the date when it is sold to the end user.Lifetime maintenance.11.2 The repair of the equipment should be carried out by our professional technician. Irretrievable damage caused by the nonprofessional technician, and damage accidentally or deliberately caused by operators, are out of the range of warranty.

11.3 If necessary, version information of equipment software can be provided to help technician to repair it.

12 Environmental protections

12.1 You can deal with it based on the local law.

12.2 We reserve the right to change the design of the equipment, product technique, accessories, instruction manual and the content of original packing at any time without notice. If there are some differences between picture and real equipment, take the real equipment as the norm.

13 EMC-Declaration of conformity

The models RP1, RP2, RP3, RP4 and RP5 are intended for use in the electromagnetic environment specified below. The customer or the user of the models RP1, RP2, RP3, RP4 and RP5 should assure that it is used in such an environment.

Guidance and manufacturer's declaration-electromagnetic emissions

| Emissions test | Compliance | Electromagnetic environment - guidance |
|--|------------|---|
| RF emissions CISPR 11 | Group 1 | The models RP1, RP2, RP3, RP4 and RP5 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 | Class B | The models RP1, RP2, RP3, RP4 and RP5 are suitable for use in domestic establishment and in |
| Harmonic emissions IEC 61000-3-2 | Complies | establishment directly Not connected to a low voltage power supply network which supplies buildings used for domestic purposes. |
| Voltage fluctuations / flicker emissions IEC 61000-3-3 | Complies | |

Guidance & Declaration-electromagnetic immunity

The models RP1, RP2, RP3, RP4 and RP5 are intended for use in the electromagnetic environment specified below. The customer or the user of the models RP1, RP2, RP3, RP4 and RP5 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 | \pm 6 kV contact \pm 8 kV air | \pm 6 kV contact \pm 8 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 | ± 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 to line ±2 kV line to earth | \pm 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 % Uτ (>95% dip in Uτ.) for 0.5 cycle 40 % Uτ (60% dip in Uτ) for 5 cycles 70% Uτ (30% dip in Uτ) for 25 cycles <5% Uτ (>95 % dip in Uτ) for 5 sec | <5 % Uτ (>95% dip in Uτ.) for 0.5 cycle 40 % Uτ (60% dip in Uτ) for 5 cycles 70% Uτ (30% dip in Uτ) for 25 cycles <5% Uτ (>95 % dip in Uτ) for 5 sec | Mains power quality should be that of a typical commercial or hospital environment. If the user of the models RP1, RP2, RP3, RP4 and RP5 require continued operation during power mains interruptions, it is recommended that the models RP1, RP2, RP3, RP4 and RP5 be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |

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| | such an environment. | | |
|--|---|---|--|
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - guidance |
| | | | Portable and mobile RF communications equipment should be used no closer to any part of the models RP1, RP2, RP3, RP4 and RP5, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance. |
| Conducted RF | | | d=1.2×P ^{1/2} |
| IEC 61000-4-6 Radiated RF | 150 kHz to 80 MHZ 3 V/m | 3V | d=1.2×P ^{1/2} 80 MHz to 800 MHZ |
| IEC 61000-4-3 | 80 MHz to 2.5 GHz | 3V/m | d=2.3×P ^{1/2} 800 MHz to 2.5 GHz |
| | | | where P is the maximum output power rating of the transmitter In watts (W) according to the transmitter manufacture and d Is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determine 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: $(((\bullet)))$ |
| NOTE 2 These | | apply in all situa | ncy range applies. titions. Electromagnetic propagation is s, objects and people. |
| telephones ar broadcast car environment of considered. If RP3, RP4 and models RP1, abnormal pert reorienting or | nd land mobile radios, not be predicted theo due to fixed RF transr the measured field s d RP5 are used excer RP2, RP3, RP4 and I formance is observed relocating the models | , amateur radio pretically with a nitters, an elec trength in the lo eds the applica RP5 should be l, additional me s RP1, RP2, Rf | ise stations for radio (cellular/cordless) , AM and FM radio broadcast and TV ccuracy. To assess the electromagnetic tromagnetic site survey should be ocation in which the models RP1, RP2, ble RF compliance level above, the observed to verify normal operation. If asures may be necessary, such as P3, RP4 and RP5. d strengths should be less than 3V/m. |

Recommended separation distances between portable and mobile RF communications equipment and the model RP1, RP2, RP3, RP4 and RP5

The models RP1, RP2, RP3, RP4 and RP5 are intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the models RP1, RP2, RP3, RP4 and RP5 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the models RP1, RP2, RP3, RP4 and RP5 as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output power | Separation distance according to frequency of transmitter m | | | | |
|-------------------------------|--|---|--|--|--|
| of transmitter W | 150kHz to 80MHz d=1.2×P ^{1/2} | 80MHz to 800MHz d=1.2×P ^{1/2} | 800MHz to 2,5GHz d=2.3×P ^{1/2} | | |
| 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. NOTE 3 An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 Ghz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

