TEL 0553-2673688

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Registrant's Residence/ Production Address: 33rd , East Wanchun Road, Wuhu Economic and Technological Development Zone, Wuhu , Anhui Province, P.R.C.
After-sales service unit: Wuhu Ruijin Medical Instrument & Device Co., Ltd
TEL: 0553-2673688 FAX: 0553-2672513 Zip Code: 241000
Production License: W.X.Z.Z.XU NO.: 20160013
Medical Device Registration Certificate: W.X.Z.Z. No.: 20172040005

Revised date：Jul.2022
Version/Times：B/1

Medical electric shaver system

Operating Manual RJ-PX-I

RJ-050001-Rev:01

Please read this manual carefully before use and keep it properly

Dear user

Thank you for using this product! This manual contains important contents that must be understood for safe and proper use of the product.

The instruction manual is a part of the product. Therefore, this manual should be placed in a proper position for easy reference at any time for the whole lifetime.The product must be operated by trained personnel with relevant knowledge and experience. All personnel must read this instruction carefully before using this product.

This manual shall be transmitted to subsequent owners or users of the product.Any duplication, photogrammetry, digital post-processing or duplication is prohibited without consent of Wuhu Ruijin Medical Instrument & Device Co.,ltd.

This product is safe and reliable to use, except for the risk s arising from special factors like operated by non-professionals or used for other purposes,etc.Therefore, please follow strictly the following rules to avoid accidental use. The product must be operated by professionals.

Product maintenance must be carried out by professional technicians or skilled users of Wuhu Ruijin Medical Instrument & Device Co.,ltd and the authorized person.

If there are any operation problems not mentioned, please contact WuhuRuijin Medical Instrument & Device Co.,ltd.

Instructions are subject to change without prior notice.Please put the manual in a proper position for reference.

I.Product information

Product name : Medical electric shaver system

Product Model No.: RJ-PX-I

Product technical requirement no.:W.X.Z.Z.NO.:20222010105

II.Corporate information

Registrant/manufacturer name：Wuhu Ruijin Medical Instrument & Device Co., Ltd.
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III.Main performance parameters

Sequence	Model No.:	Performance parameters
1	RJ-PX-I	i. Handpiece power input : alternate current : 110-220V 300VA 50/60HZ Output : direct current : 24V ii. Speed of Medical shaver system : forward or reverse : 0-6000r/min Reciprocation : 0-5000r/min iii. Non-load noise : ≦ 65db

IV.The structural composition

RJ-PX-I Medical electric shaver system mainly consists of handpiece , foot switch , shaver motor , shaver cutting head, among them cutting head is an outsourced product with medical device registration certificate.

V.The scope of application

For the shaving ,cutting , and grinding of bone tissue or soft tissue in surgical operation.

VI.Contraindications, precautions, warnings and explanatory notes

i.Contraindications

NO

ii.Precautions

(i). Handpiece and switch foot can not be placed in high temperature and high pressure environment;

(ii). After the instrument is cleaned , it can be used only once it has been sterilized and sterilization according to the hospital's specifications. The shaver motor can be gauze soaked in water or wipe clean and put them away.

(iii). This is product is a dedicated medical device. The user of this product must be a medical staff with appropriate skills or appropriate training.

iii.Graphics and Symbols description

Supplementary external mark: ⚠ Working schedule：Short time operation
Each starup time shall not exceed 5min;
⧈ Class II equipment;

Marking pattern description: B-type equipment;

Description of the connection part of Power console：

C Shaving handpiece interface Pedal switch connection

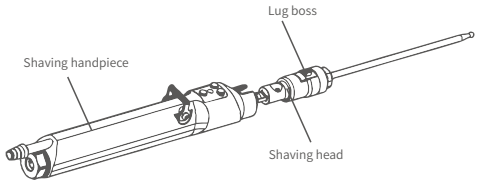
VII.Installation and dis-assembly

This product is professional medical device, the installation and dis-assembly must be performed by medical personnel with appropriate technology or with appropriate professional training.

I.Shaving cutting head assemble

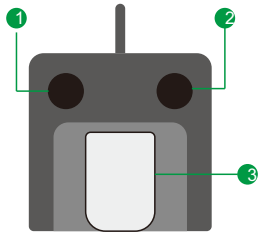
(i).Align the protruding head of the shaving head with the notch in the front of the main unit, insert the shaving head to complete the installation

(ii). When dis-assembly the shaving head, pull out the shaving head' lug boss with the pressure.



VIII.Operating instructions

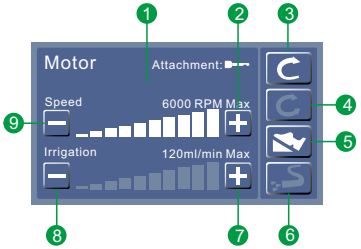
I.Foot switch function



1 Accelerate button
2 Decelerate button
3 Stepless speed control pedel

ii.Handpiece operation

(i).Liquid crystal display and buttons

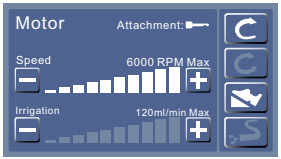


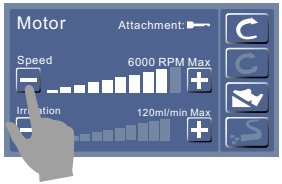
1. Display area
2. Rotating speed and button
3. Forward and reverse switch button
4. Reciprocating switch buttom
5. Hand and foot switch buttom
6. Peristaltic pump start and stop button
7. Flow plus buttom
8. Flow reduce buttom
9. Speed reduce buttom

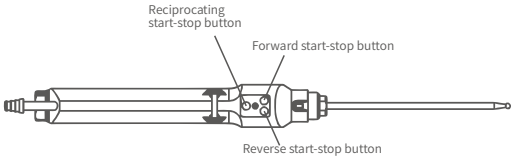
(ii).Start and stop by pressing the button on the shaver system handpiece

a.Press the switch on the back of the power control box, the display is turned on, and the information displayed on the panel is as shown in the figure below.
b.Adjust the speed with the plus or minus sign on the screen.
c.The functions of the three buttons on the shaver system handpiece are as shown in the figure below. When the hand and foot control switch button on the display screen is in the foot control state, press the forward rotation start and stop button on the shaver handle. The motor rotates forward, and then press the button again to stop the motor. The other buttons operate the same.

NOTE: After starting the motor with one button, the same button must be pressed to stop the motor. After the motor stops, you can press other buttons to start the motor.

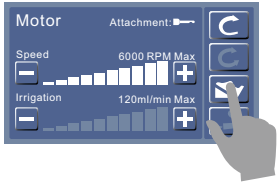


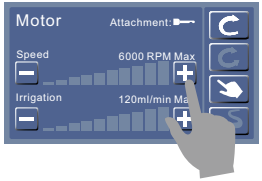




(iii).Start by pressing the button on the liquid crystal display screen

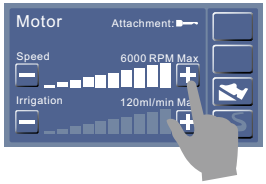
a.Press the switch on the back of the power control box, the display is turned on, and the information displayed on the panel is as shown in the figure below.
b.Press the foot control hand button switch button on the screen to switch to the hand control state.
c.Choose one-way forward and reverse or reciprocating according to your needs
d.Press the Motor Speed Plus key to start the motor. Press the speed minus key when stopped.

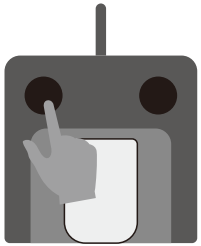


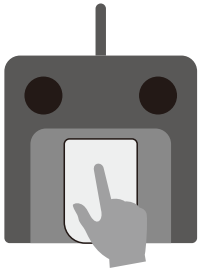


(iv).Start by footswitch

a.Press the switch on the back of the power control box, the display is turned on, and the information displayed on the panel is as shown in the figure below.
b.Choose one-way forward and reverse or reciprocating according to your needs
c.Adjust the required speed by accelerating or decelerating on the foot switch, and you can also adjust the speed by the plus or minus sign on the screen.
d.Step on the stepless speed control pedal, the motor starts to rotate. Release the pedal, the motor stops







(v).The operation of peristaltic pump

a.After startup according to flow plus or minus buttons to adjust to flow.

b. Press the stop button to start the peristaltic pump start peristaltic pump, press the button again when need to stop.

IX.Maintenance

This product is maintenance-free. It contains no parts that require maintenance by the user or manufacturer. However, the manufacturer recommends that the function and safety of the product be checked regularly by a professional or hospital technician.It must be checked once before each operation, and be recorded, analyzed and evaluated in time to ensure that the product is in good condition and guarantee the use quality.

X.Cleaning and sterilization

A.Cleaning: the protection of cleaning after use is same as sterilization, and the handpiece can be wiped clean with gauze soaked in water or alcohol and then store.

B.Disinfection: Product can be used only when passing inspection after disinfection and sterilization according to the hospital standards.

Attention: Handpiece and pedal switch are un-autoclavable.

Note: Do not soak any part of the Micro Medical Electric Drill in liquid.

Recommended handpiece disinfection method

Disinfection method	Operation	Operating conditions and environment	Sterilization time	Dry time
Moist heat sterilization	Pre-vacuum	Sterilization conditions are generally are: 132℃～134℃	⩾4min	⩾8min

Commitment

i:This instrument has no parts that can be disassembled and repaired by non- professionals. If it fails, please contact the company's after- sales service department.

ii: If you need technical information about this Micro Medical Electric Drill, please write to us.。

XI.Transport and storage conditions

Transport and storage conditions	Ambient temperature range	-10℃～+40℃
	Relatively moderate range	⩽90%
	Atmospheric pressure range	500hPa～1060hPa
Equipment operating conditions	Ambient temperature range	5℃～40℃
	Relatively moderate range	⩽70%
	Atmospheric pressure range	860hPa～1060hPa

Production date: Refer to product certificate
Service life: five years short-time running 500 times

XII.Accessories list

Prepare standard configuration and accessories according to product model number and product customer need.

Parts List				
No.	Name	Model No.	Quantity	Note
1	Handpiece	XXXX	1pcs	
2	Shaver motor	XXXX	1pcs	
3	Foot switch	XXXX	1pcs	
4	Shaving head		Several	
5	Manual		1pcs	
6	Certificate of conformity		1pcs	
7	Three certificates		1pcs	

XIII.Electromagnetic compatibility

Guidance and manufacturer´s declaration – electromagnetic emission

The RJ-PX-I is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions GB4842	Group 1	The RJ-PX-I 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.
RF emissions GB4842	Class A	The RJ-PX-I is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions GB17625.1	Not applicable	
Voltage fluctuations flicker emissions GB17625.1	Not applicable	

Guidance and manufacturer´s declaration – electromagnetic immunity

The RJ-PX-I is intended for use in the electromagnetic environment specified below. The customer or the usershould assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge GB/T 17626.2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 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 %.
Electrostatic transient / burst GB/T 17626.4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge GB/T 17626.5	± 1 kV wire to wire	± 1 kV wire to wire	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 GB/T 17626.11	0 % UT; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180° 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180° 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercialor hospital environment.If the user of the RJ-MZ-I requires continued operation during power mains interruptions,it is recommended That the RJ-PX-I be powered from an uninterruptible power supply or a battery.
Power frequency (50 Hz) magnetic field	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.

Guidance and manufacturer´s declaration – electromagnetic immunity

The RJ-PX-I is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Conducted RF GB/T 17626.6	3 V(Effective value) 150 kHz to 80 MHz	3 V (Effective value)	Portable and mobile radio frequency communication equipment should not be used in any part of RJ-PX-I, including cables, than the recommended isolation distance. The distance should be calculated by the formula corresponding to the transmitter frequency. Recommended isolation distance d=1.2 d=1.2 80MHz~800MHz d=2.3 800MHz~2.5GHz Where: p-----According to the maximum output power of the transmitter provided by the transmitter manufacturer, in watts (w); d-----Recommended isolation distance, in meters (m)
Radiated RF GB/T 17626.3	3 V(Effective value) 80 MHz to 2.5 GHz	3 V/m	The field strength of the fixed RF transmitter is determined by surveying the electromagnetic field a, and in each frequency range b should be lower than the compliance level.Interference may occur near equipment marked with symbols as beside.

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic 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 measuredfield strength in the location in which the RJ-PX-I is used exceeds the applicable RF compliance level above, the RJ-PX-I should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the RJ-PX-I .

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

Recommended isolation distance betweenportable and mobile video communication equipment and RJ-PX-I

RJ-PX-I is expected to be used in anelectromagnetic environment with controlled radio frequency radiation disturbance. According to the maximum rated output power of communication equipment, the purchaser or user can prevent electro magnetic waves by maintaining the minimum distance between portable and mobile radio frequency communication equipment (transmitter) and RJ-PX-I as recommended below interference.

Interference test	IEC60601 test level	Coincidence level	Electromagnetic
Maximum rated output power of the transmitter	Corresponding to the isolation distance of the transmitter at different frequencies/m		
	150kHz~80MHz d=1. 2	80MHz~800MHz d=1. 2	800MHz~2.5GHz d=2.3
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 the maximum rated output power of the transmitter not listed in the above table, the recommended isolation distance d, in meters (m), can be determined by the formula in the corresponding transmitter frequency column, where P is the emission provided by the transmitter manufacturer The maximum rated output power of the machine, in watts (w).

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and from structures, objects and people.