

Micro Medical Electric Drill

Operating Manual **RJ-MZ-II**

RJ-020002-Rev:00



Please read this manual carefully before
use and keep it properly

TEL 0553-2673688

Registrant/manufacture : Wuhu Ruijin Medical Instrument & Device Co., Ltd.
Registrant's Residence/ Production Address: 33rd , East Wanchun Road, Wuhu
Economic and Technological Development Zone, Wuhu , Anhui Province, P.R.C.
After-sales service : 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

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 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 Wuhu Ruijin Medical Instrument & Device Co., Ltd.

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

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I. Product information

Product Name: Micro Medical Electric Drill

Product Model No.: RJ-MZ-II

Product technical requirement No.: W.X.Z.Z No.:20172040005

II. Corporate information

Registrant/manufacturer name: Wuhu Ruijin Medical Instrument & Device Co., Ltd.

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

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III. Main performance parameters

Sequence	Model No.:	Performance parameters
1	RJ-MZ-II	<p>Power Console Input Power: AC 100-240V 600VA 50/60Hz</p> <p>Speed and frequency of electric grinding, drilling, milling, sawing, planing:</p> <p>i. Grinding and milling 0-4000r/min</p> <p>ii. Drilling 0-1000r/min</p> <p>iii. Saw 0-12000 times/min</p> <p>iv. Planing 0-5000r/min reciprocating rotation or 0-12000r/min unidirectional rotation</p> <p>v. Temperature rise: temperature rise for accessible surface is less than ambient temperature 20°C after non-loading operating for 3 minutes.</p> <p>vi. No-load noise: rotating ≤75db, non-rotating ≤90db</p> <p>vii. The blades of electric grinding, drilling, sawing and planing should be heat treated, and the hardness more than HRC30</p>

IV.The structural composition

Micro Medical Electric Drill is mainly composed of power console, handpiece, attachments, pedal switch, grinding drill burr, drill bit, milling blade, etc. Medical device registration certificate for the grindingdrill burr, drill bit, milling blade, etc has been acquired.

V.The scope of application

For drilling, grinding, and sawing of tissue or soft tissue during orthopedic surgery.

VI.Contraindications, precautions, warnings and explanatory notes

i.Contraindications

NO

ii.Precautions

- (i).The power console and pedal switch shall not be placed in the environment with high temperature and high pressure;
- (ii).Before use, make sure that the grinding drill burr is inserted and locked for straight attachment and angled attachment.
- (iii).When straight attachment and angled attachment are inserted into the handpiece for using, the grinding head locking ring on the handpiece cannot be rotated;
- (iv).When straight attachment and angled attachment are inserted into the handpiece for use, the locking ring of grinding head on the handpiece cannot be rotated;
- (v).This product is a dedicated medical device, and the user of this product must be a medical staff with comparable skills or appropriate training.

iii.Graphics and Symbols description

Supplementary external mark:  Working schedule:Short time operation
Each startup time shall not exceed 5min;

 Class II equipment;

Marking pattern description:  B-type equipment;

Description of the connection part of Power console:

A Handpiece A interface **B** Handpiece B interface **C** Handpiece C interface

 Pedal switch interface

Instructions

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.

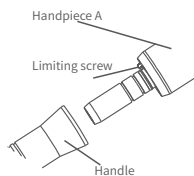
i. Installation instructions of burr

- (i). Turn the switch to "0", then insert burr into the handle, make sure the burr is inserted down to the bottom completely.
- (ii). Turn the switch to position "C" after inserting the burr, by then the burr has locked well.
- (iii). Turn the switch to "0" to remove the burr.



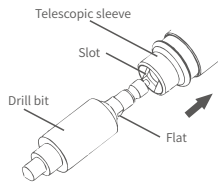
ii. Installation instructions for attachment and handpiece A

Align the limit screw hole of the front end of handpiece A with the limit screw hole of the attachment port, and then insert the attachment into the handpiece A.



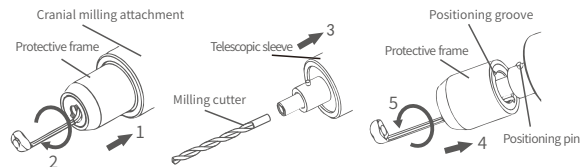
iii. Installation and removal of cranial drill

- (i). Compress the telescopic sleeve to the limit position according to the direction of the arrow shown in the figure;
- (ii). Align the flat end of the drill bit with the slot on the cranial drill, insert the cranial drill, and loosen the telescopic sleeve;
- (iii). When disassembling, compress the telescopic sleeve in the direction of the arrow shown in the figure to the limit position, and then pull out the drill bit.



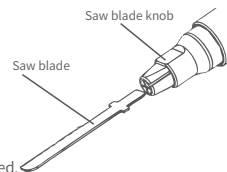
iv. Installation and removal of cranial milling

- (i). Remove the protective frame: compress the protective frame to the end in the direction of arrow 1, rotate the protective frame to the limit position in the direction of arrow 2, then pull out the protective frame in the opposite direction of arrow 1.
- (ii). Install the milling cutter: compress the telescopic sleeve to the limit position in the direction of arrow 3, insert the milling cutter, and loosen the telescopic sleeve.
- (iii). Install the protective frame: Align the positioning groove on the protective frame with the positioning pin on the cranial milling, install the protective frame in the direction of arrow 4 to the maximum position that can be compressed, and then rotate the protective frame to the limit position according to the arrow 5. Installation is complete when you hear a clicking sound.



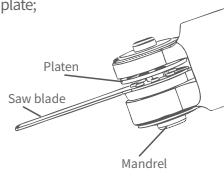
v. Installation and removal of oscillating saw

- (i). Rotate the saw blade knob
- (ii). Align the saw blade with the installation slot, loosen the saw blade knob, and the saw blade is installed;
- (iii). Conversely, the saw blade can be removed.



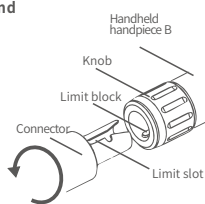
vi. Installation and removal of the reciprocating saw

- (i). Press the ejector rod upwards to lift up the pressure plate;
- (ii). Insert the saw blade into the interface along the guide direction, align the seven grooves of the saw blade with the seven bosses of the product, and press down gently to make the product bosses pass through the hole of the saw blade;
- (iii). Loosen the top rod to lock the saw blade;
- (iv). Conversely, the saw blade can be removed.



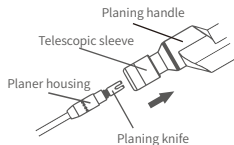
vii. Mounting and dismounting of drill, milling and saw heads and handpiece B

- (i). Align the limit slot on the machine head with the limit block on the mobile phone, rotate the knob on the mobile phone B in the direction of the arrow, and then insert the connector into the hole of the mobile phone;
- (ii). When removing the handpiece, first turn the knob on the phone in the direction of the arrow shown in the figure, and pull out the connector.



viii. Installation and disassembly of cutting head and cutting handle (Handheld handpiece C)

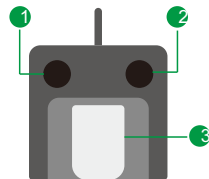
- (i). Insert the cutting knife into the cutting handle in the direction of the arrow shown in the figure, and pay attention to install it in place;
- (ii). Compress the telescopic sleeve in the direction shown in the figure, then insert the cutting knife shell into the hole of the cutting handle, and properly rotate the cutting knife shell to install it in place;
- (iii). Loosen the telescopic sleeve to lock the scalpel;
- (iv). On the contrary, remove the scalpel shell and the scalpel in turn.



VIII. Operating Instructions

I. Foot switch function

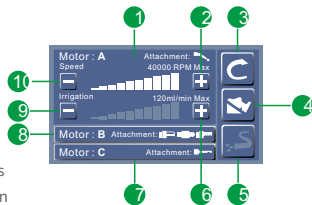
- ① Speed plus button
- ② Speed reduction button
- ③ Stepless speed control pedal



ii. Host operation

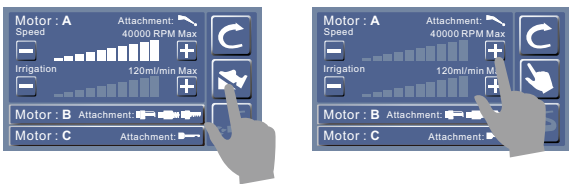
- (i). LCD display and keys

- ① Display area
- ② Speed plus button
- ③ Forward and reverse switching buttons
- ④ Hand control foot control switch button
- ⑤ Peristaltic pump start and stop button
- ⑥ Stream render button
- ⑦ MotorC function selection button
- ⑧ MotorB function selection button
- ⑨ Flow reduction button
- ⑩ Speed reduction button
- ⑪ Saw function selection button
- ⑫ Drill function selection button
- ⑬ Milling function selection button
- ⑭ Forward and reverse selection buttons
- ⑮ Planing reciprocating rotation selection button



iii. MotorA button start

- (i). Press the switch on the back of the power control box to turn on the display. After the power is turned on, the panel displays the information as shown below.
- (ii). Press the foot control manual button on the screen to switch to the manual control state.
- (iii). Press the Motor Speed Plus key to start the motor. Press the speed minus key when you need to stop.

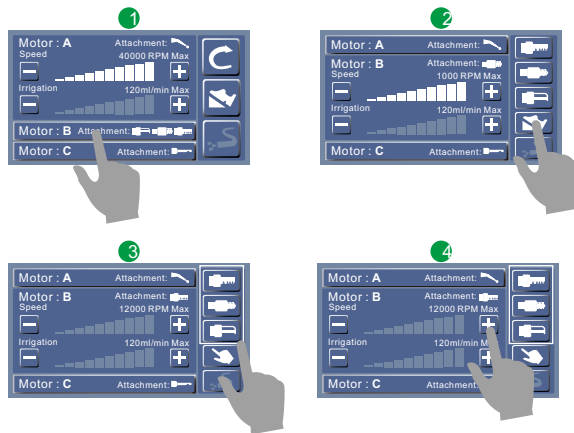


iv. Motor pedal control start

- (i). Press the switch on the back of the power control box to turn on the display.
- (ii). Depress the speed control switch on the foot switch to start the motor.

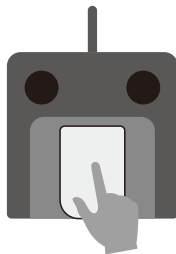
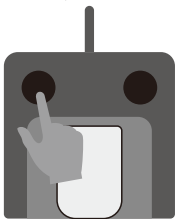
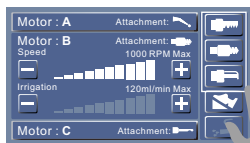
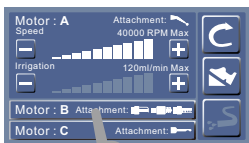
iv. MotorB motor button start

- (i). 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. Press the MotorB function option button.
- (ii). Press the foot control and manual buttons on the screen to switch to manual control.
- (iii). Select sawing, drilling or milling functions according to your needs.
- (iv). Press the motor speed plus key to start the motor, and press the speed minus key when you need to stop.



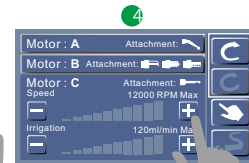
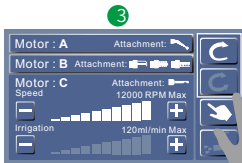
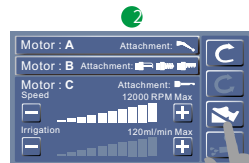
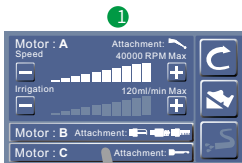
v. Motor B foot control start

- (i). 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. Press the Motor B function option button.
- (ii). Select sawing, drilling or milling functions according to your needs.
- (iii). Adjust the required speed through the acceleration or deceleration button on the foot switch, and you can also adjust the speed through the plus or minus sign on the screen.
- (iv). Step on the stepless speed regulation pedal, the motor starts to rotate, release the pedal, the motor stops running.



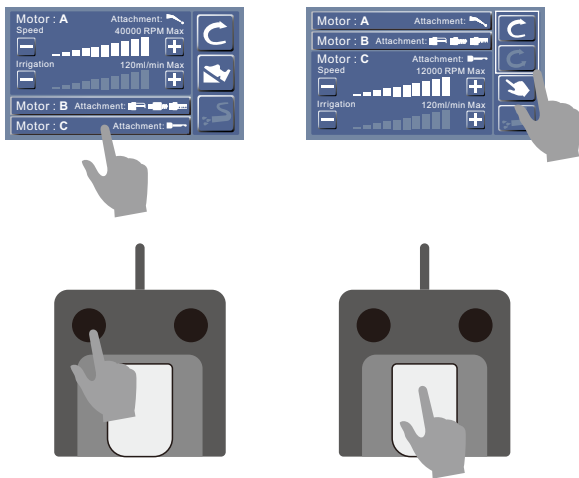
vi. Motor C button start model

- (i). 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. Press the Motor C function option button.
- (ii). Press the foot control manual button on the screen to switch to the manual control state.
- (iii). One-way rotation or reciprocating rotation can be selected as required.
- (iv). Press the motor speed plus key to start the motor, and press the speed minus key when you need to stop.



vii. Motor C pedal control starting.

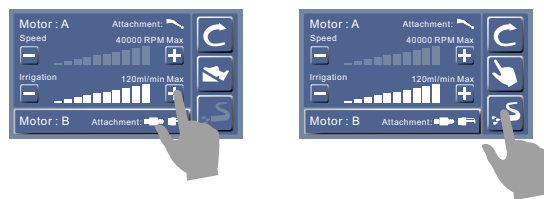
- (i). Press the switch at the back of the power control box to open the display screen. The following figure shows the information on the panel. Press the Motor C function option button.
- (ii). Select unidirectional or reverse based on site requirements.
- (iii). Adjust the required speed by the acceleration or deceleration button on the foot pedal, or by the plus or minus sign on the screen Adjust the speed.
- (iv). Step on the stepless speed regulating pedal and the motor starts to rotate; open the pedal and the motor stops.



viii. Operation of peristaltic pump

The following uses the motor in the Motor A state as an example. The operations of the peristaltic pump in other states are the same.

- (i). After startup, adjust the required flow according to the add or subtract button of flow.
- (ii). Press the start stop button of the peristaltic pump to start the peristaltic pump. Press the button again when you need to stop the peristaltic pump.



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°C~134°C	≥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°C~+40°C
	Relatively moderate range	≤90%
	Atmospheric pressure range	500hPa~1060hPa
Equipment operating conditions	Ambient temperature range	5°C~40°C
	Relatively moderate range	≤70%
	Atmospheric pressure range	860hPa~1060hPa

Production date: Refer to product certificate
Service life: three 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	According to customer needs
2	Handheld handpiece	XXXX	1-3pcs	According to customer needs
3	Attachment	XXXX	Several	According to customer needs
4	Saw cutter		Several	According to customer needs
5	Manual		1pcs	
6	Certificate of conformity		1pcs	
7	Three certificates		1pcs	

XIII. Electromagnetic compatibility

Guidance and manufacturer's declaration – electromagnetic emission

The RJ-MZ-II 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-MZ-II 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-MZ-II 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 GB1.7625.1	Not applicable	
Voltage fluctuations flicker emissions GB17625.1	Not applicable	


Guidance and manufacturer's declaration – electromagnetic immunity

The RJ-MZ-II is intended for use in the electromagnetic environment specified below. The customer or the users should 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 commercial or hospital environment. If the user of the RJ-MZ-II requires continued operation during power mains interruptions, it is recommended that the RJ-MZ-II 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-MZ-II 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-MZ-II, including cables, than the recommended isolation distance. The distance should be calculated by the formula corresponding to the transmitter frequency. Recommended isolation distance $d=1.2$ $d=1.2 \sqrt{80\text{MHz}-800\text{MHz}}$ $d=2.3 \sqrt{800\text{MHz}-2.5\text{GHz}}$ 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 measured field strength in the location in which the RJ-MZ-II is used exceeds the applicable RF compliance level above, the RJ-MZ-II should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the RJ-MZ-II.

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

Recommended isolation distance between portable and mobile video communication equipment and RJ-MZ-II

RJ-MZ-II is expected to be used in an electromagnetic environment with controlled radio frequency radiation disturbance. According to the maximum rated output power of communication equipment, the purchaser or user can prevent electromagnetic waves by maintaining the minimum distance between portable and mobile radio frequency communication equipment (transmitter) and RJ-MZ-II 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 ((P))
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.