

Content Overview Intended Use Main Technical Parameters Product Structure Instruction for Use Contraindications, Precautions, Warnings and Prompt Instructions Maintenance, Cleaning and Disinfection Transportation and storage Packing list Malfunction and Troubleshooting Environmental Protection Electromagnetic Compatibility (EMC)

OI/Overview

This product is an integrated dental electrical motor control equipment. It uses a precision electric motor as the main power source and is equipped with a high-brightness LED as the light source. This product has the following characteristics: no periodic maintenance, micro-vibration and low noise, simple operation, and easy use. Simply connect the original water pipe, mist pipe, and air pipe branch to the motor, and the other branch of the air pipe to the drive module, user can use the original air-powered control system, with different deceleration or acceleration handpieces to complete most of the clinical treatment.

02/Intended Use

Intended use of the Dental Low-voltage Electrical Motors:

Drive dental handpiece, control the rotation speed of dental handpiece.

O3/Main Technical Parameters

No-load speed range: 2000-40000 (r/min) continuously stepless speed regulation

The error in the clockwise and counterclockwise direction of rotation is not more than $\pm 10\%$

Mode 1:1 speed range: 2000-40000 (r/min)
Mode 1:5 speed range: 10000-200000 (r/min)
Mode 4:1 speed range: 500-10000 (r/min)
Mode 16:1 speed range: 125-2500 (r/min)
Mode 20:1 speed range: 100-2000 (r/min)

Rated power input: AC100~240V Rated frequency: 50Hz/60Hz Rated torque: ≥2N.cm Maximum noise: ≤65dB

When the water pressure is 200kPa (2.0bar), the water flow rate is not less than 50mL/min

Air flow is not less than 1.5L/min

When the air pressure is 250kPa~500kPa (2.5bar~5.0bar), the maximum air flow does not exceed

40L/min.

At the recommended working pressure of 250MPa,

water consumption is 40ml/min, air consumption is 1.5L/min,

spray capacity is more than 50ml/min.

The connection between the motor and the handpiece conforms to the requirement of ISO 3964.

Interface for motor and handpiece: ISO E type international standard interface, matching the dental straight handpiece and contra-angle handpiece.

Recommended light source: MD-6BL-IL09 LED light.

Declaration for steam sterilizing: This product is not suitable for steam sterilization.

Safety Features

- a) Classification according to the type of protection against electric shock: Class II;
- b) Classification according to the degree of protection against electric shock: partly Type B applied;
- c) Classification according to the degree of protection against liquid input: ordinary equipment;
- d) According to the safety level when used in the case of flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide: equipment that cannot be used under these two conditions;
- e) Classification by operation mode: Intermittent operation
- f) Electromagnetic compatibility (EMC) is classified into Group 1 Type B according to IEC 60601-1-2;
- g) Rated voltage and frequency of the equipment: AC100~240V, 50/60Hz;

Recommended working mode, classification, environmental conditions:

Ambient temperature: +5°C~+40°C

Relative humidity: ≤80%

Atmospheric pressure: 86kPa~106kPa

O4/Product Structure

The Dental Low-voltage Electrical Motors consists of a Brushless Electrical Motor, Motor, and connection tube, and power adapter.

Structure diagram:

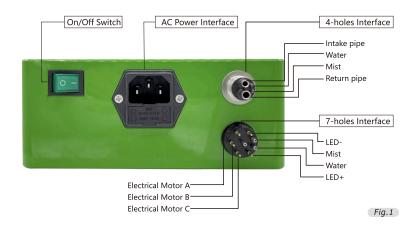


05/Instruction for Use



1.Connection

- ① Connect the power adapter provided with the machine to the power interface of the Motor, and connect the power cord to the power supply;
- ② Connect the dental treatment table and the 4-holes interface of the Motor with the 4-holes connection tube, and tighten the nut.
- ③ Insert the connector of the 7-holes multi-purpose connection tube into the 7-holes interface of the Motor, and tighten the nut.
- ④ Insert the Brushless Electrical Motor into 7-holes interface, tighten the nut.
- ⑤ Connect the interface as shown in Figure 1.



2. Operating Method

As shown in Figure 2-1 and 2-2, according to operate the control panel, touch "Startup Switch" to start or stop the motor; adjust forward and reverse rotation by pressing "Forward/Reversed Rotation Button"; Touch "Gear Ratio Choice" to select speed range, and adjust speed by turning "Rotary Switch"; switch to foot switch of dental chair via touching "Foot Switch".



FWD/REV

Power Lamp

Fig.2-2

Rotation Speed Adjustment

3. Method of disconnecting handpiece

Tightly hold with motor, pull forward the handpiece or straight handpiece, as Figure 3 shown.

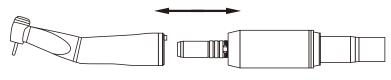


Fig.3

O6/Contraindications, Precautions, Warnings and Prompt Instructions

 This product is limited to the use of qualified dentist for dental treatment. This product can be equipped with various manufacturers' straight or contra-angle handpieces that conform to ISO standard Type E connectors.

/ CAUTION: Do not reverse the direction before the motor is completely stopped, so as not to affect the life of the motor. Connect or disconnect the handpieces after the motor has completely stopped.

- 2. It is strictly forbidden to modify or disassemble this product without authorization, and it is strictly forbidden to collide or drop the motor.
- 3. Before clinical treatment, start the machine in advance to check whether there is shaking, vibration, heat, etc., and it can only be used for clinical treatment after confirming that it is normal. If any abnormality is found during the inspection, stop using it immediately and contact the seller or maintenance personnel in time.
- 4. After lubricating the handpiece, do not connect it directly to the motor. The handpiece should be placed upright for a while, and then connected to the motor after the excessive cleaning lubricating oil has completely drained. It will cause the motor to malfunction if the oil flows into the motor.
- 5. Do not lubricate for the interior of the motor.
- Assemble and disassemble the straight and contra-angle handpiece after the motor has completely stopped.
- Absolutely prohibit to use ions water (super-oxidized solution, hydrogen peroxide) or disinfectant for cleaning, soaking and wiping.
- 8. The product cannot be used in the case of a mixture of flammable anesthesia and air or a mixture of flammable anesthesia and oxygen or hydrogen oxide.
- 9. This Motor is designed and produced specifically for the treatment of drilling, tapping and grinding in the dental field, and is not used for other purposes;
- 10. Since the driven handpieces by this Motor is rotating at high speed, be sure to read the manual carefully and master the correct operation method before use;
- 11. The product may interfere with the operation of the pacemaker when using. If you have any questions about the treatment of patients with pacemakers, please consult a specialist in the Cardiology Center.
- 12. The ME EQUIPMENT or ME SYSTEM is suitable for professional healthcare facility environments

- 13. Warning: Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
- 14. Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- 15. Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- 16. Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- 17. This product is not support to field service.
- 18. This product will not produce electromagnetic interference to the equipment in the same use environment, nor will it be subject to electromagnetic interference in the general use environment. However, please avoid using it in a complex electromagnetic environment with strong magnetic fields and strong electric fields.
- 19. This product cannot be disassembled for on-site maintenance.
- 20. The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.

07/Maintenance, Cleaning and Disinfection

1. Method of maintenance

- ① Replace the O-ring: Remove the deteriorated O-ring at the motor insertion position, and correctly insert the new O-ring into the O-ring slot.
- ② Replace the LED light: Unscrew the three mounting screws of the Type E connecter of the electrical motor, remove the Type E connecter from the electric motor, and take out the light; Then install the new light, assemble the Type E connecter in the electric motor, screw and tighten the mounting screws.

2. Recommended lubricating method

Depend on the actual conditions of use, regularly lubricating the connecting shaft of motor. Note: It is strictly forbidden to lubricate for the interior of the motor.

3. Recommended cleaning and sterilizing method

Please disinfect the product more than once a day, and be sure to follow the following procedures: Use a brush (metal brush is prohibited) to clean the dirt on the surface of the motor, and then wipe it with cotton soaked with alcohol for disinfection.

The performance of the motor must not deteriorate after 250 repetitions of disinfection.

/ NOTICE: Handpiece need be performed high-temperature and high-pressure sterilization after each use. Absolutely forbid to use ions water (super-oxidized solution, hydrogen peroxide) or disinfectant for cleaning, soaking and wiping.

/ WARNING: 1. High temperature, high pressure and chemical sterilization are prohibited for this product.

2. It is strictly forbidden to lubricate for the motor.

08/Transportation and storage

1.) Storage conditions: This product should be stored in a well-ventilated, dry, cool, away from heat source, and no corrosive gas indoor.

Ambient temperature: -40°C ~ 55°C

Humidity: ≤80%

Air Pressure: 50 ∼ 106kPa

The well-ventilated place without sunshine, rain, dust, corrosive gas, volatile matter.

- 2.) Environmental conditions: no sunlight, no rain, no dust, no corrosive gas, no chemical volatiles, and a well-ventilated place.
- 3.) Attention should be paid during transportation and storage: keep the side of screen upward, and prevent wet.

09/Packing List

No.	Name	Quantity
1	Brushless Electrical Motor	1
2	Connection tube (1 meter)	1
3	Motor	1
4	Quality label	1
5	Uses manual	1
6	Power Adaptor	1

IO/Malfunction and Troubleshooting

Malfunctions	Cause	Troubleshooting
The body of the straight or contra-angle handpiece rotates when working.	The O-ring of the connection tube of the motor head is deteriorated.	Replace the O-ring
Handpiece failing to spray mist	Spray hole blockage	Clean and drain the hole with probe
Handpiece leaking water	Sealing washer aged or not tightened	Replace aged parts, tighten pipe nut
Handpiece failing to work	Not power on	Check the connection of power

The product is composed of high-precision accessories. If it is malfunctioned, stop using it immediately, forbid to repair it without qualified technical person, and contact the seller in time.

II/Environmental Protection

The metal part of the product is disposed as scrap metal. Synthetic materials, electrical components and printed circuit boards are disposed as waste electrical appliances. Relevant materials must be disposed in accordance with local laws and regulations and should be disposed in consultation with the local company that specializes in waste disposal.

12/Electromagnetic Compatibility (EMC)

/ CAUTION:

- Conforms to the EMC requirement of standard IEC 60601-1-2:2014+A1:2020.
 User should install and use the product according to the EMC information provided by the user manual.
- Portable and mobile RF (Radio Frequency) communication equipment may affect performance of the MD-6. Avoid strong electromagnetic interference when using the product, such as close to mobile phones, microwave ovens, etc.
- The guidelines and manufacturer's declaration are detailed in the attachment.

/ WARNING:

- MD-6 should not be used close to or stacked with other equipment. If it must be used close or stacked with other equipment, it should be observed to verify that the MD-6 can operate normally under the parameter of the equipment.
- Except for MD-6 cables sold by manufacturers as spare parts for internal components, using the accessories and cables other than those specified may result in an increase in RF emission or decrease immunity.

Guidelines and manufacturer's declaration-electromagnetic emissions

MD-6BL-IL09 is expected to be used in the following electromagnetic environment, and the purchaser or user should ensure that it is used in this electromagnetic environment:

Emission test	Compliance	Electromagnetic environment-guidance	
RF emissions CISPR 11	Group 1	MD-6BL-IL09 uses RF energy only for its internal functions. Therefore, the RF emission is extremely low, and the possibility of causing interference to nearby electronic equipment is very small.	
RF emissions CISPR 11	Class A	MD-6BL-IL09 is suitable for use in all installation environments, including domestic installation environments, and installation environments that are	
Harmonic emissions IEC 61000-3-2	Not Applicable	directly connected to domestic public low-voltage power supply network.	

Voltage fluctuations/ flicker emissions IEC 61000-3-3

Not Applicable

MD-6BL-IL09 is suitable for use in all installation environments, including domestic installation environments, and installation environments that are directly connected to domestic public low-voltage power supply network.

Guidelines and manufacturer's declaration-Electromagnetic immunity

MD-6BL-IL09 is expected to be used in the following electromagnetic environment, and the purchaser or user should ensure that it is used in this electromagnetic environment:

Immunity test	IEC 60601 Test grade	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	The ground should be wood, concrete or ceramic tiles. If the ground is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV power supply lines Not applicable 100 kHz repetition frequency	Grid power supply should have the quality that is able to be used in typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode ± 0.5 kV, ± 1 kV, ± 2 kV common mode	±0.5 kV, ±1 kV differential mode Not applicable	Grid power supply should have the quality that is able to be used in typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle. 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. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25cycles; Single phase: at 0°. 0 % UT; 250 cycle	Grid power supply should have the quality that is able to be used in typical commercial or hospital environment. If the user of MD-6BL-IL09 needs continuous operation during the grid power interruption, it is recommended to use uninterrupted power supply or battery power supply to supply power.
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz	The PFMF should have the same level characteristics as the PFMF at typical location in a typical commercial or hospital environment.

Note: UT refers to the AC grid voltage before the test voltage is applied.

Guidelines and manufacturer's declaration-Electromagnetic immunity

MD-6BL-IL09 is expected to be used in the following electromagnetic environment, and the purchaser or user should ensure that it is used in this electromagnetic environment:

Immunity test	IEC 60601 Test grade	Compliance level	Electromagnetic environment-guidance	
Conducted RF IEC61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communication equipment should not be used closer to an part of the MD-6BL-IL09, including cables, than the recommended isolation distance. The distance is calculated by the formula corresponding to the frequency of the transmitter. Recommended isolation distance: $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ $80Mhz-800Mhz$ $d=2.3\sqrt{P}$ 800Mhz-2.5GHz in the formula:	
Radiated RF IEC61000-4-3	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	P- maximum rated output power of the transmitter, provided by the transmitter manufacturer, in watts (W); d - Recommended isolation distance, in meters (m)b The field strength of the fixed R transmitter is determined by surveying the electromagnetic field (c), and in each frequency range d should be lower than the compliance level. Interference may occur near to the equipment marked with the following symbols:	

Note 1: At 80MHz and 800MHz, the higher frequency range formula is used.

Note 2: These guidelines may not be suitable for all situations. Electromagnetic transmission is affected by absorption and reflection of the buildings, objects, and human bodies.

a Theoretically, it is unable to accurately predicted the field strength generated by fixed transmitters such as base stations for wireless (cellular/cordless) telephones and terrestrial mobile radios, amateur radios, AM and FM radio broadcasts, and television broadcasts. In order to evaluate the electromagnetic environment of the fixed RF transmitter, the electromagnetic environment shall be considered to investigate on-site. If the measured field strength of the MD-6BL-IL09 is higher than the above applicable RF compliance level, the MD-6BL-IL09 should be observed to verify its normal operation. If abnormal performance is observed, supplementary measures may be necessary, such as re-adjusting the direction or position of the MD-6BL-IL09.

Within the frequency range of 50KH to 80MHz, the field strength should be less than 3V/m.

Guidelines and manufacturer's declaration-Electromagnetic immunity

MD-6BL-IL09 is expected to be used in the following electromagnetic environment, and the purchaser or user should ensure that it is used in this electromagnetic environment:

	Test Frequency (MHZ)	Band (MHZ)	Service	Modulation	IEC 60601- 1-2 Test Level (V/m)	Complianc e level (V/m) (V/m)
Radiated RF IEC61000- 4-3 (Test	385	380-390	TETRA 400	Pulse modulation 18 Hz	27	27
	450	430-470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28	28
specificatio ns for	710		LTE Band 13, 17	Pulse modulation 217 Hz	9	9
ENCLOSURE PORT	745	704-787				
IMMUNITY	780					
to RF wireless	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 18 Hz	28	28
communicat ions equipment)	870					
	930					
	1720	1700-1990		Pulse modulation 217 Hz	28	28
	1845					
	1970					
	2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28
	5240		WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9
	5500	5100-5800				
	5782		-,··			

Guidelines and manufacturer's declaration-Electromagnetic immunity

MD-6BL-IL09 is expected to be used in the following electromagnetic environment, and the purchaser or user should ensure that it is used in this electromagnetic environment:

	Test Frequency (kHZ)	Modulation	IEC 60601-1-2 Test Level (A/m)	Compliance level (A/m)
Radiated RF IEC61000-4-39	30	CW	8	8
(Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	134.2	Pulse modulation 2.1 kHz	65	65
	13.56	Pulse modulation 50 kHz	7.5	7.5