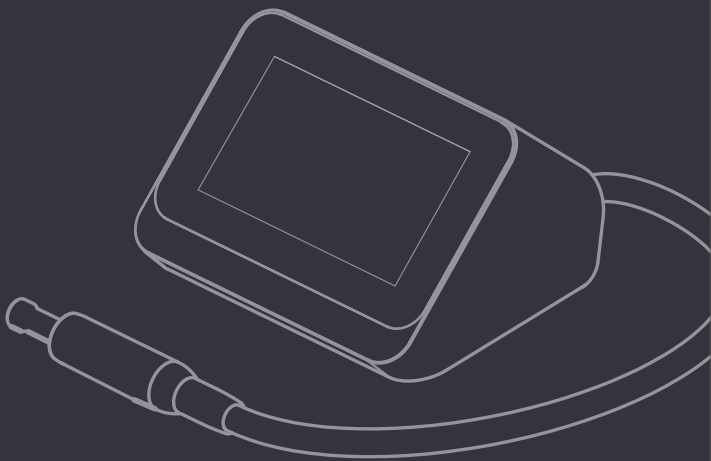
COXO®

User Manual

C-PUMA

Dental Electrical Motors



CE 0197

Contents

1. Safety

Read this manual before proceeding with the installation, use, maintenance, or other operations on the device. Always keep this manual within reach.

1) This device is only allowed to be used by professional, trained personnel, such as surgeons. Proper use of the device does not cause side effects; If used improperly, heat will be transferred to tissues, which may lead to tissue damage.
2) When using an external power supply, make sure the power voltage is according to adaptor voltage range. Improper input voltage may cause danger to the operators and the patients.
3) To avoid the risk of electric shock, the device must be connected to supply mains with protective earth.
4) The power cord plug is a mains disconnect device, it must be easily accessible at all times for disconnection in case of emergency.
5) Please use original accessories (especially motor and adaptor), otherwise the device may be damaged and even cause an injury accident for patients or operators.
6) The device is not provided sterilization and it must be cleaned, disinfected, and sterilized instrict accordance with Chapter 9 before being used for therapy.
7) If any accessories is damaged such as adapter, please contact the manufacturer or dealer to purchase and replace them according to the manual. The motor can be used with dental handpieces produced by other manufacturers with corresponding gear gear ratio s and medical device registration certificates.
8) Check the medical device for damage or loose part each time before using.
9) Perform a test run each time before using.
10) Only can install or remove parts from the motor when the motor is completely standstill.
11) To avoid electric shock or damage to the machine, do not insert other objects into it.
12) Avoid cleaning agents entering the device to prevent short circuits or malfunctions.
13) If the device malfunctions due to improper use or physical damage, turn off the machine and stop using it immediately, contact the manufacturer or authorized dealer for repairs.
14) This device (including motor) cannot be repaired on site.
15) Turn off the power switch after use. If the device is left for a long time, please drain the water in the hose.
16) The device has electromagnetic interference. Do not use it around patients with cardiac pacemakers or electronic surgery.
17) Unstable voltages and electromagnetic fields can interfere with the normal operation of the device.
18) The motor may exceed 43°C during operation, it is recommended to work for 40s and stop for 10min.
19) The service life of this device is 15 years, the production date is detailed in the batch number.

2. Intended use

The device is used for tooth preparation, cutting, polishing, caries removal and root canal enlargement.

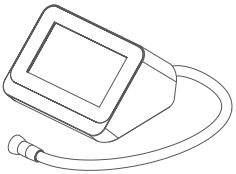
The device is intended for use by suitably qualified and trained medical, technical and specialist staff only.

3. Contraindications

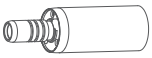
Do not use on the following patients:

- Hemophilia patients;
- The patients and doctors with heart pacemaker;
- Patients with severe systemic infection or systemic diseases such as the diseases of heart, liver, kidney, hematopoietic system, digestive system and endocrine system;
- Pregnant women, children.

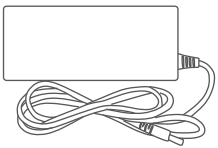
4. Standard configuration



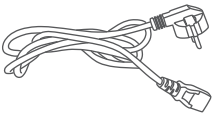
Main Unit



Motor



Power Adapter



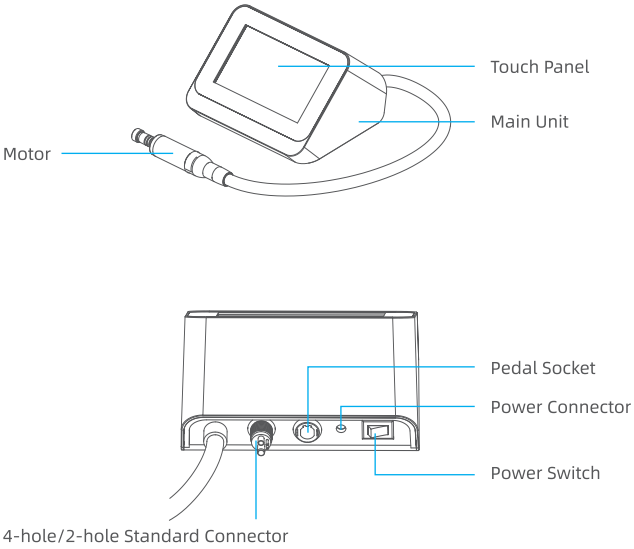
Power Cable

User Manual

Handpiece Stand

Please refer to the packing list for the quantity.

5. Description



6. Installation

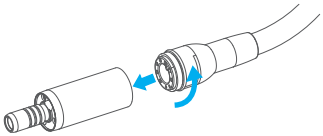
6.1 Connect the motor

a. Connect

Fully insert the motor's pins into the holes on the tube connector and tighten the end caps.

b. Removal

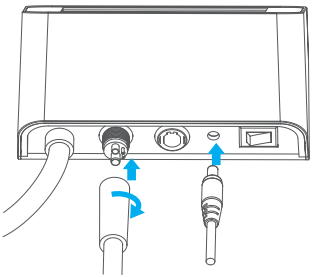
Loosen the end cap and pull the motor outward horizontally.



6.2 Connect the main unit

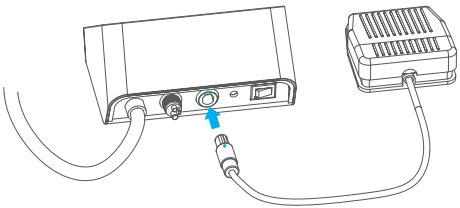
Connect the water and air hoses of the dental unit to the 4-hole standard connector on the back of the main unit and tighten the nut.

Connect the power adapter to power connector on the the back of the main unit.



6.3 Connect the electric foot pedal (optional)

Connect the electric foot pedal connector to the pedal socket on the back of the main unit.

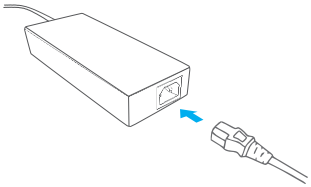


NOTE:

If both electric and pneumatic foot pedals are connected, the system will respond to the pedal that is pressed first. To avoid misuse, it is recommended to connect only one type of foot pedal or to ensure that the current pedal is fully released when switching to the other.

6.4 Connect the power supply

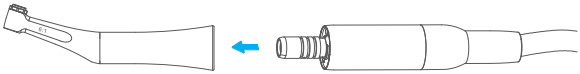
Connect the power cable to power adapter and power supply.



6.5 Connect the contra angle

Align the contra angle with the motor connector, and slide it in until it clicks securely into place.

If it is needed to remove the contra angle, pull it out vertically.



WARNING:

- The motor and contra angle handpiece will be severely worn if the handpiece is replaced during operation.
- Replace contra angle only when the motor is not running.
- All straight and contra-angle handpieces with the motor connection ISO3964 can be attached.

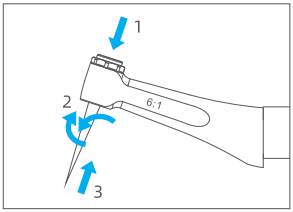
6.6 Connect the file/bur

a. Connect:

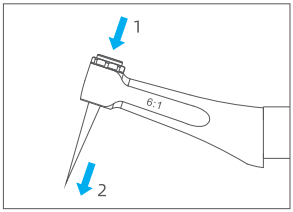
Hold down the push button on the contra angle and insert the file.
Turn the file back and forth until it slips into place.
Release the button to lock the file into the contra angle.

b. Removal:

Pressing the push button, and then directly pull out the file.



Connect



Removal

NOTE:

Contra-angle compatible with rotary and reciprocating files, with a2.35mm shaft conforming to ISO 1797-1:2011, Type 1.

6.7 Power on/off

Set the power switch to the ON position to turn on the device.

Set the power switch to the OFF position to turn off the device.

6.8 Calibrate the foot control

Click the “ ” settings button to enter the Common settings page.There are two types of calibration as follows.

6.8.1 Auto pedal calibration

Click the “Start” button, and then follow the prompts.

If calibration fails, you can follow the prompts to calibrate again.

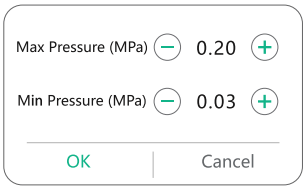
6.8.2 Manual pedal calibration

Click the “ +/- ” button to adjust the max/ min air pressure value.

Click the “Start” button.

Maximum Pressure：Air pressure when the motor reaches maximum level.

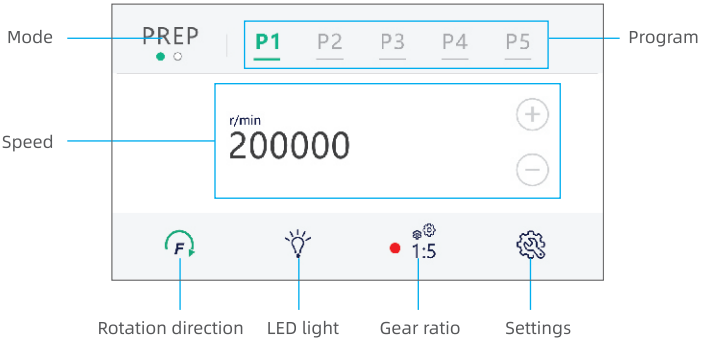
Minimum Pressure：Minimum air pressure required for motor start.



7. Operation

The device has two modes: PREP and ENDO, and you can click the mode button to select the desired mode.

7.1 Preparation mode（PREP）



7.1.1 Select a program

Click the P1-P5 button to select the desired program.

7.1.2 Set the motor speed

Click +/ - to increase or decrease the value.

7.1.3 Turn on/off LED light

Click the light button to change the brightness of the LED on motor handpiece.

There are three levels:

7.1.4 Select rotation direction

Click the direction button to switch between forward and reverse rotation of the motor.

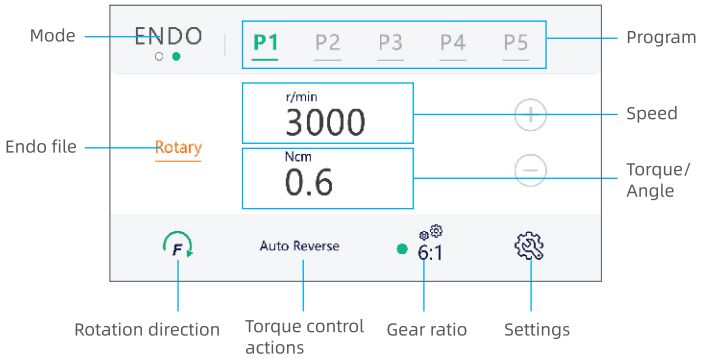
7.1.5 Select gear ratio

NOTE:

- The gear ratio set by the user will be automatically saved.
- Up to 5 ratios can be switched in the main interface, if you need to modify the ratios, please refer to 8.2.1 Common Gear Ratio for details.

Click the Gear Ratio button and select the same ratio as the connected contra angle.

7.2 Endodontic mode（ENDO）



CAUTION:

- Before using the ENDO Mode, ensure that the water and spray in the dental chair have been completely switched off.
- Do not start the motor when installing/removing the file.
- Do not confuse reciprocating files with continuous rotary files.
- Please maintain the counter angle correctly, otherwise it may cause torque deviation.

NOTE:

- In ENDO mode, a 6:1 contra angle is recommended.
- Follow the manufacturer's instructions for use of endodontic files.

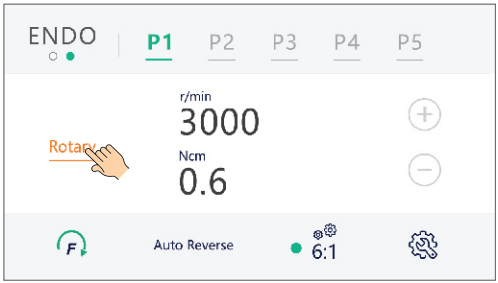
- Before using the ENDO mode, refer to 6.4 Connect the Contra Angle and 6.6 Connect the file/bur to complete the connection.
- When using a new contra-angle it is recommended to calibrate following 8.2.2 Torque calibration.

7.2.1 Select a program

Click the P1-P5 button to select the desired program.

7.2.2 Set the Endo file type

Click the Endo file button to select the same file as the connected file.
Each program can be set to the following two files.



Rotary	Continuously rotate in one direction, can be adjusted to forward or reverse.
Reciprocating	Reciprocating according to the set speed, angle, etc. Suitable for using reciprocating root canal files.

7.2.3 Adjust speed and torque/angle

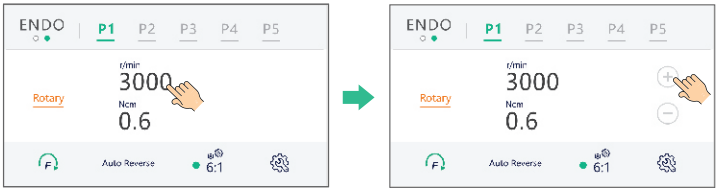
CAUTION:

- Please set the appropriate speed, torque or rotation angle according to the parameters of the file.
- When the motor is running, the speed, torque and angle values cannot be adjusted.
- The Endo file type shown on the screen must always match the File in use.

Click the speed or torque value on the screen, the value flashes.

Click the "+/-" button to increase or decrease the value.

The change will be saved automatically. Press the blank area of the screen to exit the setting status.



① Rotary

Speed range(6:1): 250-3000r/min

Torque range: 0.6Ncm-6Ncm

② Reciprocating

Speed range: 250,350,450r/min

Angle range: F: 30°-330°/R: 30°-330°

7.2.4 Select motor direction

Click the direction button to switch between forward and reverse rotation of the motor.

Forward

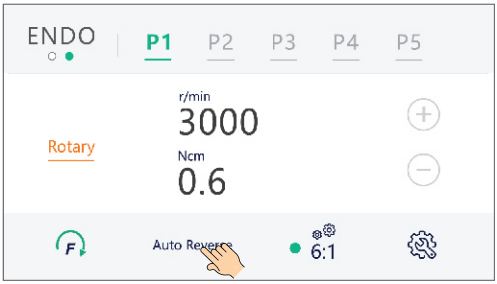
Reverse

NOTE:

"Reciprocating" program cannot select the motor rotation.

7.2.5 Set the torque control type

Click the button to set the torque control type.There are 3 types: Auto Reciprocate, Auto Reverse, Auto Stop.



Auto Reverse	During operation, the load reaches the preset torque limit value, the motor handpiece will automatically rotate in the reverse direction. If the load is removed after auto reverse rotation, it returns to the normal rotation again.
Auto Stop	If the load is removed after auto reverse rotations, it stops.
Auto Reciprocate	During operation, the load reaches the preset torque limit value, the motor handpiece will automatically reciprocate rotation. If the load is removed after auto reciprocate rotation, it returns to the normal rotation again.

CAUTION:

- Torque control action cannot be adjusted when the motor rotation is reversed.
- The torque control action cannot be adjusted when the programme is set to "Reciprocating" .

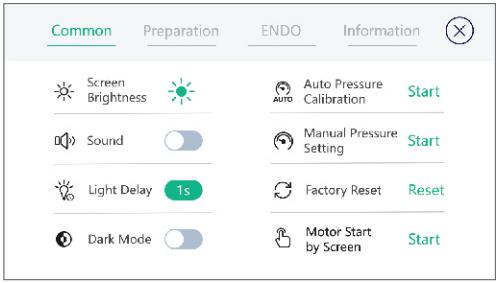
7.2.6 Select gear ratio

Click the gear ratio button and select the same ratio as the connected contra-angle.

8. Settings

Click the settings button to enter the settings page, which contains four sections: Common Settings, Preparation Settings, ENDO Settings, and Device Information.

8.1 Common settings



8.1.1 Screen brightness

Click the brightness button to adjust the screen brightness. There are 3 levels of brightness available.

8.1.2 Sound

Click the button to turn off or on the screen sound.

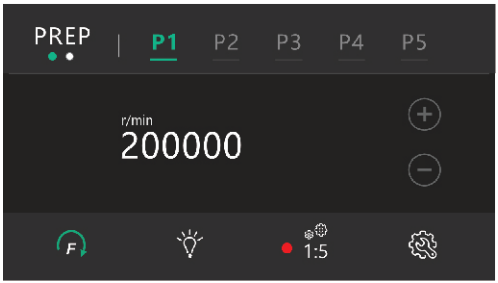
8.1.3 Light delay

Click the button to adjust the delay time. There are 4 levels available.

0s 1s 3s 5s

8.1.4 Dark mode

Click the button to enter the dark mode, and press the button again to restore the light mode. The dark mode is shown below:



8.1.5 Factory reset

Click the “Reset” to restore factory settings.

NOTE:

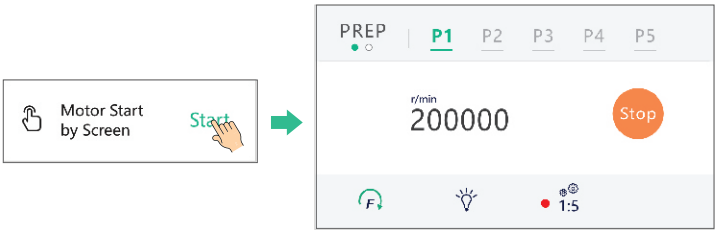
Factory reset will clear all data set by user and cannot be restored.

8.1.6 Click the motor to start

CAUTION:

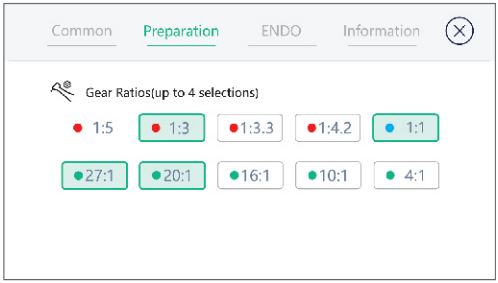
This function is only for demonstration, do not use it for normal treatment.

- Click the “Start” button, the screen will automatically switch to the last used program, and the motor start running.
- Click the “Stop” button, and the motor stops running.
- If you need to restart, repeat the above steps.



8.2 Preparation and ENDO Settings

8.2.1 Common gear ratio



The system has preset several gear ratios for the Preparation and ENDO mode.

The user can select and set the commonly used ratios in the settings page.Once set, you can easily select these ratios for operation in the mode.

1:3 Unselected 1:3 Selected

The gear ratio of PREP mode:

Gear Ratio	Speed range	
1:5	10000r/min-200000r/min	Default
1:3	6000r/min-120000r/min	
1:3.3	7000r/min-120000r/min	
1:1	2000r/min-40000r/min	
1:4.2	9000r/min-170000r/min	
27:1	100r/min-1500r/min	
20:1	100r/min-2000r/min	
16:1	200r/min-2500r/min	
10:1	200r/min-4000r/min	
4:1	500r/min-10000r/min	

The gear ratio of ENDO mode:

Gear Ratio	Speed range	
6:1	250r/min-3000r/min	Default
4:1	400r/min-3000r/min	
10:1	150r/min-3000r/min	
16:1	150r/min-2500r/min	

8.2.2 Torque calibration

CAUTION:

- Calibration is needed after sterilizing the contra angle.
- Calibration is recommended before each treatment.

Calibration is required to ensure the motor parameters are accurate.

- Connect the 6:1 contra-angle correctly.
- Enter the Endo Settings page, Press “Start” button to start.
- If “Complete” is displayed, calibration is complete.
- If “Failed” is displayed, calibration is failed. The device cannot be used until the fault is removed.

NOTE:

If calibration fails, refer to 11. Troubleshooting. If it still cannot be solved, please contact your local dealer.

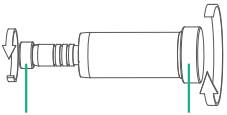
9. Cleaning, disinfection and sterilization

NOTE:

Before the first use and after each use, the reusable parts must be handled according to the following cleaning, disinfection and sterilization steps.

Device:	Main unit and Motor cord
Warning:	Do not use automatic methods to clean and disinfect the Main unit and Motor cord. Do not sterilize the Main unit and Motor cord.
Surface cleaning and disinfection	• It is recommended to clean and disinfect the Main unit and Motor cord surfaces with 75% alcohol after use. • Soak the cloth in a 75% alcohol container and wring it out to remove excess water. • Wipe the surface of the Main unit and Motor cord at least 3 times with a wet rag, paying special attention to gaps and hidden areas of activity, wipe until it is visually clean.

Device:	Motor and Handpiece stand
Warning:	Only the Motor and Handpiece stand can be cleaned and disinfected with automated methods. Only the Motor and Handpiece stand need to be sterilized with a steam sterilization process.
Advice:	Reprocessing procedures have only limited implications to a surgical instrument. The limitation of the numbers of reprocessing procedures is therefore determined by the function/wear of the device. There is no limit of maximum allowable reprocessing cycles. The device should no longer be reused in case of signs of material degradation. In case of damage the device should be reprocessed before sending back to the manufacturer for repair. The components should be reprocessed after each use.
Reprocessing Instructions	

Preparation at the Point of Use:	Disconnect the Motor from the Motor cord. Remove Handpiece stand. Screw the Motor Cap to the Motor and the protection plug to the Motor connection.  Remove gross soiling of the instrument with cold water (<40°C) immediately after use. Don't use a fixating detergent or hot water (>40°C) as this can cause the fixation of residuals which may influence the result of the reprocessing process. Store the instruments in a humid surrounding, if required.
Transportation:	Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.
Pre-Cleaning:	Do a manual pre-cleaning, until the instrument are visually clean. Clean the surface of the Motor and Handpiece stand under running water with a soft bristol brush.
Manual Cleaning (For US):	Recommend using 3M multi enzyme cleaning agent at a concentration of 5mL/1L distilled water. Soak the soft cloth in detergent and wring it out. Remove any liquid residue with a lint-free cotton cloth, then dry at 30°C. Checked that if the devices were clean or broken after cleaning. If the cleaning is not good enough, repeat the cleaning procedure. Do not put the Motor into a container containing a cleaning solution. If the internal liquid is not cleaned and the drying is incomplete, the intemal parts may be corroded.

Automated Cleaning (For EU):	Use a washer-disinfector meeting the requirements of the ISO15883 series. Put the instruments into the machine on a tray and start the program. • 1 min pre-washing with cold water (<40°C) • emptying • 10 min washing with a mild alkaline cleaner at 55°C • emptying • 1 min rinsing • emptying The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr Weigert) Note Acc to en ISO17664 no manual reprocessing methods are required for these devices. If a manual reprocessing method has to be used, please validate it prior to use.
Manual Disinfection (For US):	• Wipe disinfection is recommended to ensure that the disinfectant is used for a limited period of time. • Place a lint-free cotton cloth into a container of 75% alcohol and wet it completely, pick it up and twist it gently to dry it. Wipe down the motor and cable at least 3 times, making sure that all surfaces have been wiped down with a damp cloth. • Do not soak in disinfectant containers for disinfection.
Automated Disinfection (For EU):	Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to AO-Value (see EN 15883). A disinfection cycle of 5 min disinfection at 93°C has been validated for the device to achieve an AO value of 3000.
Manual Drying (For US):	Use compressed air to blow dry the internal pipes and external surfaces separately.

Automated Drying (For EU):	Dry the outside of instrument through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel.
Functional Testing, Maintenance:	Visual inspection for cleanliness of the instruments and reassembling, functional testing according to instructions of use. If necessary, perform reprocessing process again until instrument is visibly clean.
Packaging (For US):	Please the sterilization bags which are approved for its efficacy by FDA. Recommended sterilization bag: SlGMA SterilizationPouch and Roll 510(k) Number:K202462.
Packaging (For EU):	Pack the instruments in an appropriate packaging material for sterilization. The packaging material and system refer to EN IS0 11607.
Sterilization (For US):	Sterilization method: Gravity-Displacement Steam Cycle Sterilization conditions: 135°c,10 minutes Drying Time: 30 minutes
Sterilization (For EU):	Sterilization of instruments by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO 17665) under consideration of the respective country requirements. Minimal requirements: 3 min at 134 °C . In EU, 5 min at 134 °C is required. Maximal sterilization temperature: 137°C
Storage:	Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures refer to label and instructions for use.
Reprocessing validation study information	The above-mentioned reprocessing process (cleaning, disinfection sterilization) has been successfully validated.
Additional Instructions: None	
It is the duty of the user to Make sure that the reprocessing processes including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly.	

10. Maintenance

10.1 Periodical maintenance

Perform periodical maintenance checks every three months, referring to the check sheet below. If any abnormalities are found, contact the manufacture or local dealer.

Point to check	Details
Main unit	Check the main unit for damage before use. If so, stop using it immediately and contact our company or an authorized dealer for help.
Cord	If any cord coating shows signs of wear, please contact manufacturer or an authorized dealer for assistance.
Motor	Operate for 1 minute and make sure there is no abnormal heating, sound, or vibration.

10.2 Replace LED

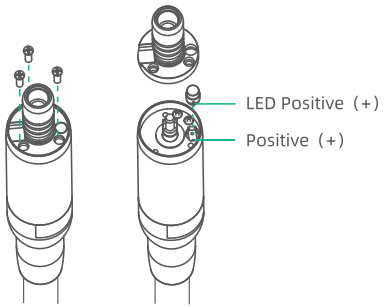
NOTE:

LED works depends on the correct installation of positive and negative poles; If the LED emits red light or does not work, try to rotate it 180° and reinstall it.

WARNING:

Do not touch the LED that has just finished working. Wait for it to cool down.

- Unscrew the screws on the motor and remove the damaged LED light;
- Insert the new LED into the groove, press it into place, and tighten the screws.



10.3 Replace O-rings

NOTE:

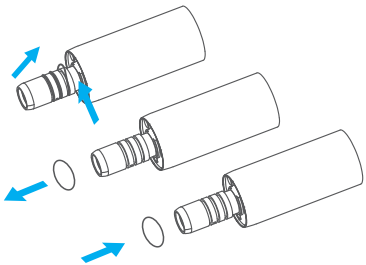
If the handpiece is difficult to connect to the motor, or if you detect an air/water leak, the Motor insert O-rings may be damaged and should be replaced.

WARNING:

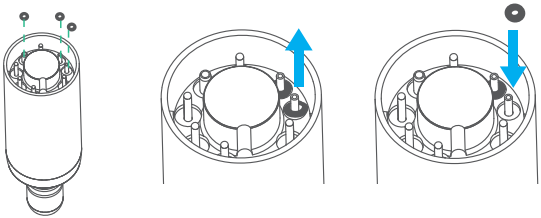
- Do not replace the O-ring when the motor or handpiece working.
- Do not use Vaseline or silicone grease on the O-rings.

Remove the O-ring and replace the new one.

① Motor connector



② Motor inner tube



11. Troubleshooting

Malfunction	Possible causes	Solution
E1: Pressure Error	Depress the foot pedal before turning on the device.	Release the foot pedal and restart the device.
E2: Motor overload	The load exceeds the maximum output of the device.	Reduce motor load.
E3: Motor failure	The motor drive circuit is abnormal. The motor cord is abnormal. The motor working current is abnormal.	Restart the device. If the problem persists, contact the dealer or company for repair.
E4: Motor overheating	The continuous use time of motor is too long or the load is too large.	Reduce the load of the motor and allow it to cool down.
E5: Screen communication failure	The main control circuit is abnormal. Screen and motherboard connecting wires are abnormal.	Restart the device. If the problem persists, contact the dealer or company for repair.
Calibration failed	The resistance of the contra-angle handpiece is too high.	If the calibration fails multiple times, please replace with a new contra angle handpiece.

12. Operating, transportation and storage conditions

Operating environment

Ambient temperature	+5℃ ~ +35℃
Relative humidity	≤80%
Air pressure	80kPa — 106kPa
ALT	≤2000m

Transportation and storage conditions

Ambient temperature	-10℃ ~ +35℃
Relative humidity	≤93%
Air pressure	50kPa — 106kPa

13. After-sales service

13.1 Terms and conditions of warranty

1) The warranty period for the main unit is 24 months from the date of purchase, the accessories (power adapter and power cord) of the product are warranted for 6 months, and the remaining accessories are not warranted.

2) The supplier can provide circuit diagrams, component lists, legends, calibration details, or other information necessary for qualified technicians to repair the equipment parts that are designated as repairable by the manufacturer upon request.

3) The following situations are not covered by the free warranty:

- Damage caused by human factors;
- Damage caused by force majeure;
- Unauthorized changes, disassembly or repair by the user;
- Any damage caused by failure to use and maintain in accordance with the instructions for use;
- Failure or damage caused by forcible use of this product beyond normal use conditions.

13.2 Disclaimer

The manufacture will not be responsible for accidents, unit damage, or bodily injury resulting from:

- Repairs made by personnel not authorized by the manufacture.
- Any changes, modifications, or alterations of its products.
- Maintenance or repairs using parts or components other than those specified by the manufacture and other than in their original condition.
- Operating the unit in ways other than the operating programs described in this manual or resulting from the safety precautions and warnings in this manual not being observed.
- Workplace conditions and environment or installation conditions which do not conform to those stated in this manual such as improper electrical power supply.
- Fires, earthquakes, floods, lightning, natural disasters, or acts of God.

14. Disposal of medical device

The instrument and its packaging are designed to be as environmentally friendly as possible.

Follow your local and country-specific laws, directives, standards and guidelines for disposal.

> Medical device

> Waste electrical equipment

> Packaging

15. Technical specifications

Main Unit

Adapter	Input: 100-240V ~ 50Hz/60Hz
	Output: 30V ⎓ 2.4V
Main Unit	30V ⎓ 2.4V
Input power	100VA
System pressure	0.8 to 5 bar
Air supply pressure	2.5 to 4 bar
Water supply pressure	2 to 4 bar
Cooling water flow rate	>50mL/min
Cooling air for motor	6-9 NL/min
Overvoltage category	Class II
Pollution Degree	Degree 2
Operation mode	Duty cycle: Max.T_ON: 40s, Min.T_OFF: 10min
Classified of protection against Electric Shock	Class I
Degree of protection against Electric Shock	Type B applied part
Classified by security	Non-AP/APG type

Electrical Motor

Range of speed（1:1）	2000r/min~40000r/min
Torque output	≥2N·cm
Length of motor cord	2.0m
Application part	Motor Handpiece: aluminium（6063）

16. Symbol definition

	General warning		Caution
	Note		Refer to instruction manual/ booklet
SN	Serial number		Type B applied part
	Direct current		Alternating current
ON	Power on	OFF	Power off
	Fragile, handle with care		Keep dry
	Vertical up		Special dispose of waste electrical and electronic equipment
	Thermal-Disinfection		Sterilizable in a steam sterilizer at 134°C
MD	Medical device		Foot pedal
	Manufacturer		Date of manufacture
	Spray air		Spray water
CE 0197	CE Mark		

17. Guidance and manufacturer's declaration--EMC

NOTE:

This device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this device can be affected by portable and mobile RF communications device.

WARNING:

- Do not use a mobile phone or other devices that emit electromagnetic fields, near the device. This may result in incorrect operation of the device.
- This device has been thoroughly tested and inspected to assure proper performance and operation!
- This device should not be used adjacent to or stacked with other device and that if adjacent or stacked use is necessary, this device should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer's declaration - electromagnetic emission		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	The device use RF energy only for their 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 device is suitable for use in all establishments, including domestic establishments directly connected to the public low-voltage power supply network with specific requirement.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance & Declaration — electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that they are used in such an environment.

Immunity test	IEC 60601 test level	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	Floor 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 lines	Mains power quality should be that of atypical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	±0.5 kV & ±1 kV differential mode ±0.5 kV, ±1 kV & ±2 kV common mode	Mains power quality should be that of atypical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95% dip in U_T) for 0.5 cycle <5 % U_T (>95% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles <5% U_T (>95 % dip in U_T) for 5/6 sec	<5 % U_T (>95% dip in U_T) for 0.5 cycle <5 % U_T (>95% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles <5% U_T (>95 % dip in U_T) for 5/6 sec	Mains power quality should be that of atypical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that device be powered from a unit eruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m, 30 A/m	3 A/m, 30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

Guidance & Declaration-electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m, 10 V/m 80 MHz to 2.7 Ghz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1)	3 V/m, 10 V/m 80 MHz to 2.7 Ghz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1)	Recommended separation distance $d= [3,5/1]\times\sqrt{P}$ $d= 1.2\times\sqrt{P}$ 80 MHZ to 800MHZ $d= 2.3\times\sqrt{P}$ 800 MHZ to 2.7GHz 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 1: At 80 MHz and 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.

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 instrument is used exceeds the applicable RF compliance level above, the instrument should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the instrument.

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

Recommended separation distances between portable and mobile RF communications equipment and device.

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

Rated maximum output power of transmitter(W)	**Separation distance according to frequency of transmitter**		
	150 kHz ~ 80 MHz $d = 1.2\times\sqrt{P}$	80 MHz ~ 800 MHz $d = 1.2\times\sqrt{P}$	800 MHz ~ 2.5 GHz $d = 2.3\times\sqrt{P}$
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 distanced in meters (m) can be estimated using the equation applicable to the frequency of transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to transmitter manufacturer.

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

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

COXO®

Foshan COXO Medical Instrument Co.,Ltd.
No. 17, Guangming Ave., New Light Source Industrial Base, Nanhai National High-tech Zone, Foshan 528226, Guangdong P.R. China
www.coxotec.com

EU REP **Lotus NL B.V.**
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
E-mail: info@lotusnl.com
Tel: +31644168999

User Manual Ver: 1.2
Software Ver: 1.0.1
Date: 2025.06.06
AE0951