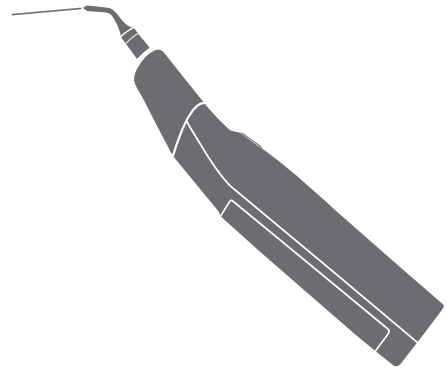
Foshan COXO Medical Instrument Co.,Ltd.
No. 17, Guangming Ave., New Light Source Industrial Base, Nanhai
National High-tech Zone, Foshan 528226, Guangdong P.R. China

coxotec@163.com 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

Ver:2.0 Revision date:20250906 AE1249

COXO®



USER MANUAL

Endo Ultrasonic Activator

Ultra Smart

Foshan COXO Medical Instrument Co.,Ltd

CE 0197

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

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 the 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 be low, 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 to 80 Mhz $d=1.2\times P^{1/2}$	80 Mhz to 800 MHZ $d=1.2\times P^{1/2}$	80 MHz to 800 Mhz $d=2.3\times P^{1/2}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1. 2	1. 2	2. 3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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 reflection from structures, objects and people.

1. Precautions

⚠ Attention

Read this operation Manual carefully before use for operating instructions

1) The instrument must be used within the scope mentioned in the manual.If the user fails to operate according to the requirements of the manual or uses the instrument for other purposes, the manufacturer will not bear any responsibility.
2) Do not damage, modify, pull,excessively bend or twist the adapter cable.
3) Only use original tip and adapters, otherwise it may cause damage to the device.
4) Do not use twisted or worn tip, and replace it in time.
5) Avoid infiltration of detergent into the instrument to avoid short circuit and malfunction.
6) When the instrument is abnormal, stop using the instrument immediately and contact the manufacturer and authorized dealer for repair, users are not allowed to disassemble and repair.
7) This instrument is not suitable for patients with cardiac pacemakers.
8) Unstable voltage and electromagnetic field will interfere with the normal operation of the instrument.
9) This instrument is only for professional dentists.

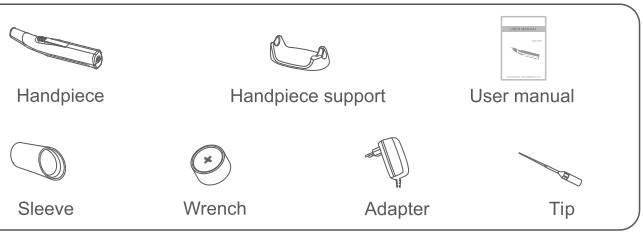
2. Intended Use

- For root canal irrigation.
- The instrument must only be used in hospital environments, clinics or dental offices, by qualified practitioners.

3. Contraindications

- This instrument is not suitable for doctors or patients who have a pacemaker (or other electrical instrument) and are warned not to use small appliances (such as electric shavers, hair dryers, etc.), and hemophiliacs
- Use with caution for pregnant women and children
- This instrument can only be used for pulpal surgery.

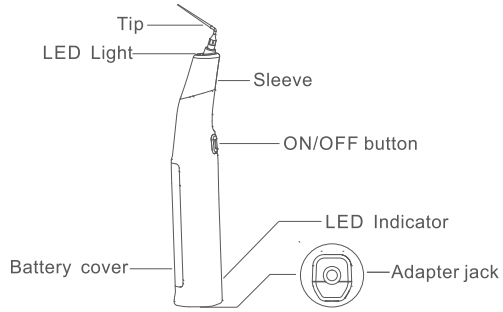
4. Product accessories



⚠CAUTION:

If the accessories of this product are damaged, please purchase original accessories and replace and use them according to user manual.

5. Components



6. Presentation

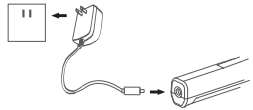
6.1 Charging

An initial 4-hour burn-in charge is needed prior to first use.

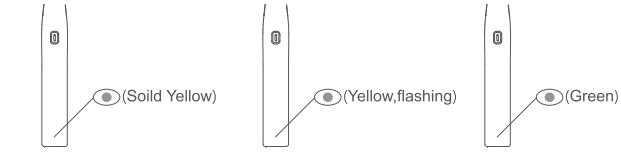
Guidance and Manufacture's Declaration – Electromagnetic Immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should assure that it is used in such an environme.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**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 V/m, 10 V/m 80 MHz to 2.7 GHz	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands 3 V/m, 10 V/m 80 MHz to 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the instrument, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=[3,5/V1]\times P^{1/2}$
Radiated RF IEC 61000-4-3	385MHz-5785MHzTest specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	$d=1.2\times P^{1/2}$ 80 MHz to 800 MHz $d=1.2\times P^{1/2}$ 800 MHZ to 2,7 GHz where the maximum is 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.			

Guidance and manufacture's declaration – electromagnetic immunity			
The instrument is intended for use in the electromagnetic environment specified below. The customer or the user of instrument should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD)IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor 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 supply lines ±1 kV for Input/ output 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 line to line	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 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT (>95% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles <5% UT (>95 % dip in UT) for 5/6 sec	<5 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT (>95% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles <5% UT (>95 % dip in UT) for 5/6 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an unit eruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of atypical location in a typical commercial or hospital environment.
NOTE:UT is the a.c. mains voltage prior to application of the test level.			

Insert adapter and connect main power supply to charge handpiece.



During charging the status of the LED indicator is as follows:

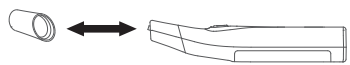


NOTE:

- The instrument is not operational during charging.
- In low battery state, handpiece will automatically shut down after 5 continuous beeps.

6.2 Put on/disassemble Sleeve

Put on sleeve manually and make sure it is installed in place, just pull it out vertically when disassembling.



NOTE:

- Avoid the small holes on the Sleeve to block LED light.



6.3 Tip Installation/Remal

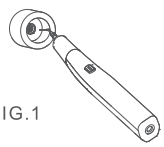
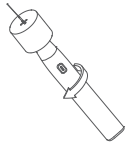


FIG.1



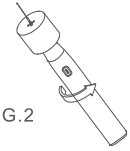


FIG.2

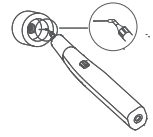
- Fix tip manually first,
- After screwing in the wrench, hold the wrench and turn the handpiece clockwise until it locks with three clicks.
- Hold the wrench and turn the handpiece counterclockwise to remove the tip.

NOTE：
- The connection must be dry.
- Only use original tip.
- Be careful when installing or removing tip to avoid scratching your hands.
- Before and after use, tip and sleeve must be cleaned, disinfected and sterilized.

6.4 Bend tip







- Slide tip through wench hole until it stops.
- Use the wrench to bend tip until wrench touchessleeve.

NOTE：
- Before bending the tip, make sure that the tip is firmly installed.

17. EMC

This product 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 instrument.

⚠CAUTION

Do not use a mobile phone or other instrument that emit electromagnetic fields, near the instrument. This may result in incorrect operation of the instrument. This instrument has been thoroughly tested and inspected to assure proper performance and operation!

This instrument should not be used adjacent to or stacked with other instrument and that if adjacent or stacked use is necessary, this instrument should be observed to verify normal operation in the configuration in which it will be used.

Guidance and Manufacture's Declaration – Electromagnetic Emission		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should assure that it is used in such an environme.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The instrument use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The instrument 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	

- Storage and Transportation conditions

Storage temperature	-10℃ - +55℃
Storage humidity	≤93%
Atmospheric pressure	50kPa-106kPa

14. Guarantee

- Service life:10years.
- The warranty period of handpiece is 24 months from the date of purchase,the warranty period of adapter is 6 months, and the rest of the accessories are not warranted.
- The supplier can provide circuit diagrams, component lists, legends,calibration rules, or other materials necessary for repair by repair technicians and repairable instrument parts designated by the manufacturer as required.

15. Recycling and Disposal

Disposal of waste instrument must comply with national regulations and standards. Ensure that all components do not produce pollution during the disposal process.

16. Symbol Identification

	Warnings/Caution		Manufacturer
	Class II equipment (Adapter)		Type B applied part
SN	Serial number	⎓	Direct current
	Fragile, handle with care		Keep away from rain
	This way up		Indoor use
	Products comply with WEEE directive		Consult instructions for use
		ON/OFF	ON/OFF button

7. Instruction

7.1 Power on/off

- Long press the "on/off" button to turn on/off instrument,the instrument enters the standby state,and LED Indicator turns to soild cyan .

NOTE:
- In standby state,the instrument will automatically shut down after three minutes inactivity.

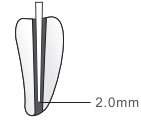
7.2 Start/stop instrument

⚠CAUTION:
- Put tip into root canal irrigation before starting, otherwise it will affect tip life.
- During operation, use a disposable protective film to keeps the waste liquid off the handpiece.

- In standby state, press the "on/off " button, instrument starts/stop to work.
- LED Indicator turns flashing cyan, LED Light turns on， and the buzzer will beep every 5 seconds.

NOTE:
- After the instrument works for 20 seconds,it will automatically enter the standby state.Press the key again to restart the instrument.
- Press the "on/off " button during work to stop instrument at any time.
- If the transducer is damaged or overloaded, the indicator turns purple.

7.3 Operation method



- Move the tip up and down using a small (2-3mm) vertical motion maintaining a distance of 2mm from working length.

- Replace the root canal irrigate every 20 seconds and irrigate each root canal three times.
- Recommended service life of the tip: 30-50 canals per tip (About 150 times).

⚠ CAUTION:

- Do not touch the root canal with tip.

8. Replacement Of Battery

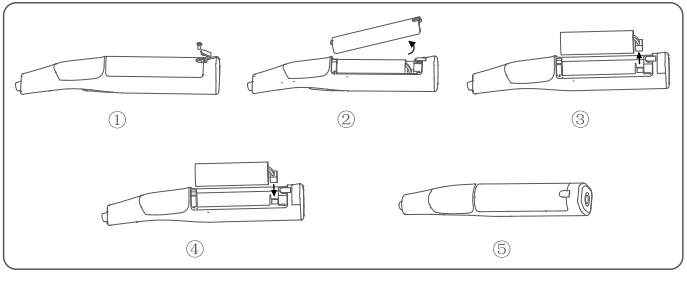
a) Open the rubber cover and then remove the screw.

b) Remove the battery cover.

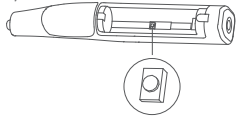
c) Disconnect the connector and remove the old battery.

d) Connect the new battery and put it in the handpiece.

e) Install battery cover, screw snd rubber cover.



⚠ WARNINGS



Prohibit non-professional maintenance personnel to touch this button.

12. Troubleshooting

Problem	Possible Cause	Action
LED indicator does not illuminate	Insufficient battery charge	Charge the Handpiece (if after several minutes, charge indicator does not come on, the battery may be expired)
	LED indicator is damaged	Contact your distributor
LED light does not illuminate	LED light is damaged	Contact your distributor
Turn power on, but the instrument does not work	Insufficient battery charge	Charge the handpiece (if after several minutes, charge indicator does not come on, the battery may be expired)
	Tip not installed	Correctly install the tip
	Tip is not fully tightened	Tighten tip with the wrench provided
	Tip may be bent, fractured or not bent at all	Replace tip
Battery does not charge	Adapter is not connected properly	Confirm whether the adapter is properly connected to the power outlet
	Battery is damaged	Contact your distributor
Battery working life is short	Battery is not fully charged	Fully charge the battery
	Battery fault	Consult your distributor

This product can be simply repaired by professional operators. If any structural parts are damaged, please contact manufacturer for repair.

13. Operating environment, Storage and Transportation Conditions

- Operating environment

Operating temperature	+5℃ - +40℃
Operating humidity	20% - 80%
Atmospheric pressure	86kPa -106kPa

Sterilization：	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. Flash sterilization is not allowed on lumen instruments
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 .
It is the duty of the user to ensure that the reprocessing processes including resources,materialsand 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.	

11. Technical parameter

Adapter	Input：AC100-240V 50/60Hz Output：DC5V 1.5A
Input power	10VA
Battery	DC3.7V 1200mAh
Tip diameter	25/02
Operating frequency	38kHz±10%
Primary tip vibration excursion	＜100um
Operation mode	Non-continuous
Classified of protection against Electric Shock	Class II(Adapter)
Protection against Electric Shock	Type B applied part
Degree of Protection(IEC 60529)	IPX0
Applied part	Tip

⚠ CAUTION:

- Only use original battery .
- Do not use a battery if it is leaking, deformed, discolored or if its label is peeled off. It might overheat.
- Turn off the power before replacing the battery.

NOTE：

- Avoid opening the rubber cover too hard.
- Do not remove the battery cover if the handpiece is wet.
- Do not tighten the cover screw too much. This could strip the threads.
- Dispose of old batteries in an environmentally safe way and in strict according to local regulations.

9. Maintenance

- Before using the instrument, check whether the tip, sleeve, adapter and other parts are damaged. If so, please stop using it immediately;
- Before using the instrument, check whether the handpiece is damaged. If so, please stop using it immediately and contact our company or authorized dealers for help;
- After using the instrument, please use a damp cloth to wipe all visible surfaces such as handpiece, tip, sleeve, and refer to Chapter 10 for cleaning, disinfection and sterilization.

10. Cleaning,Disinfection and Sterilization

Instrument：	Tip, Sleeve and Handpiece. The procedure for cleaning, disinfection and sterilization applies only to the accessories Tip and Sleeve
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 instrument. There is no limit of maximum

	allowable reprocessing cycles. The instrument should no longer be reused in case of signs of material degradation. In case of damage the instrument should be reprocessed before sending back to the manufacturer for repair.
Reprocessing Instructions	
Preparation at the Point of Use：	Disconnect tip and sleeve from handpiece. Remove gross soiling of the instrument with cold water (<40℃) immediately after use. Don't use a fixating detergent or hot water (<40℃) as this can use the fixation of residuals which may in fluence the result of the reprocessing process. Store the instruments in a humid surrounding.
Transportation：	Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.
Preparation for Decontamination：	The instrument must be reprocessed in a disassembled state. Only Tip and Sleeve can be cleaned and disinfected with automated methods and sterilized with steam sterilization process. Do not sterilize Handpiece and Adapter.The Handpiece and Adapter cannot be cleaned and disinfected in a washer/disinfector. For these parts, only general wipe decontamination is possible!
Decontamination of other parts than Tip and Sleeve.	After operation, take out Handpiece and adapter on the work bench. Soak a soft cloth completely with distilled water or deionized water, Decontamination and wipe all the surfaces of these components, until the surface of the parts the components is visually clean. For decontamination, soak a dry soft cloth with 75% alcohol. Wipe all surfaces of Handpiece, adapter and other components with the wet soft cloth for about 3 minutes. Please follow the instructions of manufacturer of disinfectant swipe the surface of the component with a dry soft lint-free cloth.
Pre-Cleaning：	Following instruction is only relevant for tip and sleeve Not use automated cleaning, disinfection and sterilization for other parts than Tip and Sleeve in this system! Do a manual pre-cleaning, until the instruments are visually clean. Submerge the instruments in a cleaning solution and flush the lumens with a water jet pistol with cold tap water for at least 10 seconds. Clean the surface with a soft bristol brush.

Cleaning：	Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better standardizing potential and industrial safety. Automated Cleaning: Use a washer-disinfector meeting the requirements of the ISO 15883 series. Put the instrumentst into the machine on a tray and start the program • 1 min pre-wash with cold water (<40℃) • emptying • 10 min washing with a mild alkaline cleaner at 55℃ • 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 ISO 17664 no manual reprocessing methods are required for these devices. If a manual reprocessing method has to be used, please validate it prior to use
Disinfection：	Automated Disinfection: Automated Thermal Disinfection in washer/disinfector under consideration of nation requirments in regards to A0-Value (see EN 15883). A disinfection cycle of 5 min disinfection at 90℃ has been validated for the device to instrument an A0 value of 3000.
Drying：	Automated Drying： Drying of outside of instrument through drying cycle of washer/ disinfector.If needed, addition manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.
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. Defective accessories should be immediately discarded. The defects include: plastic deformation and corrosion Maintenance is not required. Instruments oil must not be used
Packaging：	Pack the instruments in an appropriate packaging material for sterilization. The packaging material and system refer to EN ISO 11607.