## COXO®



## Safety



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Before using this device, please read the following information carefully.

- The device must be used within the scope mentioned in the manual. If the user does
  not operate according to the instruments or use the device for other purposes, the
  manufacture will not bear any responsibility.
- When using an external power supply, please confirm whether the voltage is within the voltage range marked by the power adapter, otherwise it may cause injury to the operator or the patient.
- 3) Please use original parts, otherwise it will damage the device or even cause injury accidents.
- 4) To avoid electric shock, do not insert other objects into the device.
- 5) Avoid liquids entering the inside of the device to avoid malfunctions.
- 6) Immediately stop using and turn off the device when improper use or physical damage causes serious abnormalities in the device.
- 7) Please use original power adapter. Other power adapter will result in damage to lithium battery and control circuit.
- 8) Keep device clean and dry.
- 9) The handpiece cannot be autoclaved.
- Please use disposable injection needles conforming to YY/T 0587-2018, and anesthetic conforming to ISO 11499.
- 11) Users cannot remove the battery by themselves.
- 12) Do not modify this device, any modification may compromise the safety and effctiveness of the device.
- 13) The device has electromagnetic interference, please do not use it around a patient with a pacemaker or electronic surgery.
- 14) Unstable voltage and exposure to electromagnetic fields can interfere with the normal operation of the device.
- 15) For the disposal of accessories such as batteries, please obey local regulations.

  16) This instrument is only for professional dentist use

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## Intended use



- 1) This device is intended for use only in subcutaneous or intramuscular injections of local anesthetic for dental applications. It should not be used for intravascular (IV) or other routes of administration. This device should be used only by practitioners who are familiar with, and observe applicable labeling regarding the use of local anesthetics for dental applications.
- 2) This device needs to be used in conjunction with disposable injection needle and anesthetic.
- This product is only suitable for use in hospitals and clinics and must also be used by qualified dentists.

## Contraindications



- 1) Patients with active periodontal disease are prohibited from intra-ligament injections.
- 2) The dentist with a pacemaker is disabled.
- 3 ) Patients with cardiac pacemakers (or other electrical equipment) and warned not to use small appliances (such as Electric razors, hair dryers, etc.) are disabled.

# Installation/Removal of the cartridge holder



#### Installation



#### NOTE

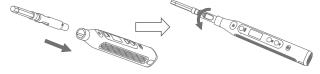
- This device must use the original factory equipped cartridge holder, otherwise it will not work or cause undesirable consequences.
- Do not install/remove the cartridge holder when the handpiece is in operation.
- According to the clinical needs, select the disposable injection needle for oral cavity, and then tighten clockwise.



2) Put the anesthetic into the cartridge holder.

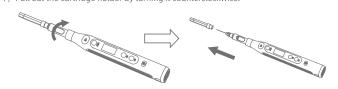


3) Insert the cartridge holder into the handpiece and turn it clockwise so that it snaps tightly against the handpiece. Gently pull the cartridge holder out to confirm that the cartridge holder is firmly installed.



#### Removal

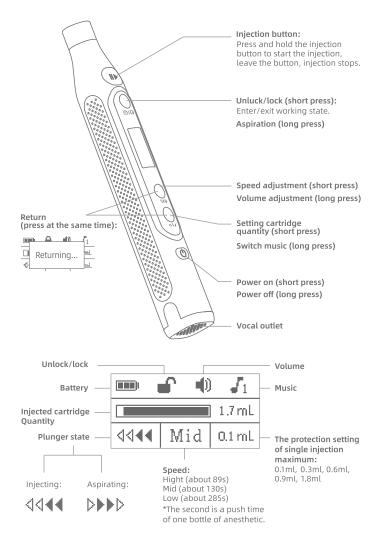
1) Pull out the cartridge holder by turning it counterclockwise.



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Use





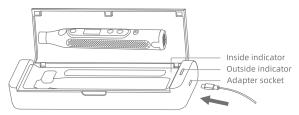
# https://stomshop.pro/

# Charging



Charging the handpiece through the charging stand, the charging stand can be charged through an external adapter.

#### Charging status:



- ♦ Inside indicator (Charging stand power status):
  - A (No adapter connected): Steady green: full charge Steady orange: no full charge Orange flashing: low charge Light off: no charge
- Outside indicator (Handpiece power status):
- A (No adapter connected): Orange flashing: charging Light off: no charge

- (Adapter connected): Orange flashing: charging Steady green: full charge
- B (Adapter connected):
  Orange flashing: charging
  Steady orange:
  handpiece not in charging stand
  Steady green: full charge

## Maintenance



Check the O-ring daily for signs of wear and replace the worn O-ring immediately.

# Cleaning, Disinfection and Sterilization



### Cleaning

- 1) Handpiece: Wipe off any visible residue with a clean damp cloth wrung out.
- 2) Cartridge holder: Rinse off with tap water and finally dry with a dry cloth.

#### Disinfection

- 1) The handpiece surface can be disinfected by wiping with 75% ethanol.
- 2) The cartridge holder can be soaked in 75% ethanol for 30 minutes for disinfection.

### Drying

Please dry immediately after cleaning and disinfection. It is recommended to use compressed air to dry.

#### Sterilization

- 1) Serializable components: cartridge holder.
- 2) Package with a sterilization bag according to EN ISO 11607 standards before sterilization.
- 3) Sterilization method: Pressure steam sterilization is commended.
- 4) Sterilization conditions: 134°C, more than 5 minutes.

# Troubleshooting



This device does not contain user-maintained parts, and device maintenance should be carried out by designated professionals. If the fault cannot be resolved, please contact your local dealer or our company.

Malfunction	Possible cause	Solution
Aspiration is abnormal	O-ring wear	Please replace the O-ring immediately.
Screen display"	The plunger has reached the maximum stroke  The plunger has reset the plunger to the initial statement of the maximum stroke reset the plunger to the initial statement of the plunger has reset the plunger to the initial statement of the plunger has reached the plunger h	
Plunger abnormal"	There is a foreign object stuck in the plunger	Remove the cartridge holder, check the plunger, and then start and test.
The screen displays E1	Plunger connection failure	Contact the dealer or the manufacture.
The screen displays E2	There is a foreign object stuck in the plunger	Remove the cartridge holder, check the plunger, and then start and test.
	Plunger damage	Contact the dealer or the manufacture.
The screen displays E3	Motor code feedback error	Contact the dealer or the manufacture.

# Technical Specifications \_\_\_



Adapter	Input: 100-240V ~ 50-60Hz 0.5A Max
Adapter	Output: DC 5V 2A
Handpiece lithium battery	3.7V 220mAh
Charging stand lithium battery	3.7V 800mAh
Operation mode	Short time

Classifiedof protectionagainstElectriGhock	Class II
Protection against Electric Shock	Type B applied part
Degree of Protection (IEC 60529)	IPX0
Classified by security	Non-AP/APGtype

# Operation, storage and transportation environment



Operation temperature 5°C-40°C		Storage temperature	-10°C−55°C
Operation humidity	20%-80%	Storage humidity	≤ 93%
Atmospheric pressure	86kPa-106kPa	Atmospheric pressure	50kPa <b>–</b> 106kPa

# Symbols



$\triangle$	Caution/ Warning	聋	Keep dry	<b>③</b>	Consult instructions for use
	Direct current	<u> </u>	This way up	SN	Serial number
	Class II device	<b>†</b>	Type B applied part	Ī	Fragile, handle with care
4	Indoor use	X	Special disposal of waste electrical and electronic equipment		

# 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.

### Guarantee



Handpiece and Charging stand warranty time for 24 months from the date of purchase, the product with accessories (adapter) warranty for 6 months, the rest of the accessories do not warranty.





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Ver: 1.1 Date: 2023.05.04 AE0417

## Guidance and manufacture's declaration--EMC



#### NOTE:

- The device meet the EMC requirements of YY0505 standard.
- The user shall install and use according to the EMC information provided in the delivered file. Portable and mobile RF communication devices may affect the device performance. Avoid strong electromagnetic interference when used, e.g. near cell phones, microwave ovens, etc.
- The guidelines and manufacture's statement are attached.



#### CAUTION:

Immunity tost

- The device should not be used in close proximity to or stacked with other device. If they must be used in close proximity or stacked, they should be observed to verify that they work properly in the configuration they are used in.
- Use of accessories and cables other than those sold by the device manufactures as spare parts for internal components may result in increased the device emissions or reduced immunity.

Number	Name	Length(m)	Shielding	Note
1	Adapter output cord	1.5	NO	

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.					
Emission test Conformance Electromagnetic environment - guidelir					
RF emissions CISPR11	Group 1	The device 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 in electronic device.			
RF emissions CISPR11	Class B	The device is suitable for use in all			
Harmonic emissions IEC 61000-3-2	Class A	establishments, including domestic establishments directly connected to the public low-voltage power supply network with specific requirement.			
Voltage fluctuations/flicker emission IEC 6100-3-3 Complies	Complies				

#### Guidance and Manufacturer's Declaration - Electromagnetic Immunity The device is intended for use in the electromagnetic environment specified below. The customer

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or the user of the device should assure that it is used in such an environment. Electromagnetic environment

Compliance level

immunity test	TEC 6060 T test level	Compliance level	- guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 air	Floors should be wood, concrete or ceramic tile. If floor are sleeved with synthetic material, the relative humidity must be at least 30%.
Electrical fast transient/burs t IEC 61000-4-2	± 2kVforpowerlines ± 1kVforinput/output lines	± 2kVforpowerlines	Mains power quality should be that of a typical commercial or hospital environment.
Surges according to IEC 61000-4-5	± 0.5 kV & ± 1 kV differential mode ± 0.5 kV, ±1 kV & ± 2 kV common mod	± 0.5 kV & ± 1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power input lines IEC 61000-4-11	<5 % UT ( > 95% dip in UT) for 0.5 cycle. 40 % UT (60% dip in UT) for 5 cycles. 70 % UT (30% dip in UT) for 25 cycles. <5 % UT ( > 95% dip in UT) for 5 s.	<5 % UT ( > 95% dip in UT) for 0.5 cycle. 40 % UT (60% dip in UT) for 5 cycles. 70 % UT (30% dip in UT) for 25 cycles. 5 % UT ( > 95% dip in UT) for 5 s.	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 recommend that the device be powered from a unit eruptible power supply or a battery.
Power frequency(50/ 60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Notes II is the a	e maine valtage priorite	application of the test I	evel.

Note: U<sub>⊤</sub> is the a.c. mains https://stomsnop.pro/

#### Guidance and Manufacturer's Declaration - Electromagnetic Immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducte d RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands 3 V/m 80 MHz to 2.7 GHz	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands 3 V/m 80 MHz to 2.7 GHz	Portable and mobile RF communications device 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. Recommended separation distance $d = 1.2\sqrt{P}$
Radiated RFIEC 61000-4-3	385MHz-5785M Hz Test specifications for ENCLOSURE PORTIMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	385MHz-5785MHz Test specifications for ENCLOSURE PORTIMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:204)	$d=1.2\sqrt{P} \qquad 80 \text{ MHz} - 800 \text{ MHz}$ $d=2.3\sqrt{P} \qquad 800 \text{ MHz} - 2.5 \text{ GHz}$ Where is the maximum output power rating of the transmitter in watts (W) according to 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 device 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 strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, mateur 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 device 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 device (transmitters) and the device as recommended below, according to the maximum output power of the communications device.

Rated maximum	Separation distance according to frequency of transmitter				
output power of	150kHz~80MHz	80 MHz~ 800 MHz	800MHz~ 2.5GHz		
transmitter (W)	$d = 1.2\sqrt{P}$	$d=1.2\sqrt{P}$	$d = 2.3\sqrt{P}$		
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 distance 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 begole.

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