COXO®

CE 0197

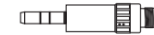
AIR-MOTORS

Operation Manual

CX235-3B

CX235-3C

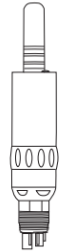
CX235-3F



Please read this operation Manual carefully and file for future reference.

Product Description

(CX235-3B)



(CX235-3C)

(CX235-3F)

⚠ WARNING

- Please read this operation manual carefully before use and file for future reference .
- This product is specialized for stomatology treatment,dont use it in other ways.
- This product is only for doctors.
- Every time you use it,please check first.If find anything unnormal,stop usingimmediately,and contact your supplier.
- Before operating low speed handpiece,pull straight head handpiece with hand to make sure handpiece connect firmly and safely.
- Ensure working pressure before running, air pressure for four bole air-motor is 0.3 MPa,for two hole air-motor is 0.25MPa
- Don't immerse handpiece in any chemical solvent or solution or by dry-heat disinfection. Sterilization by autoclave at(134t2)C&0.22MPa is sugguested.
- Run the test before use. If you find that the Straight is damaged, parts are loose, vibration, noise, fever, etc., plrase stop using it immediately.

1. User and Intended Use

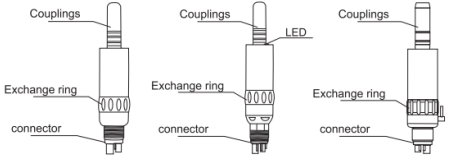
User : Qualified Professionals

Indication For Use: This medical device is intended for transmitting rotation of the power source at the direct drive ratio or at a different gear ratio , thereby running the instrument such as a bur or a reamer to cut and polish natural or artificial teeth during dental treatment.

2. Contraindications

1.Hmophilia patients should be used with caution.
2.The patient or doctor with a pacemaker is careful to use an electric motor to drive the handpiece.
3.Heart disease patients , pregnant women and children with caution.

3. Structure Composition and Packing List



Parts List		Optional accessories	
Name	Quantity	Name	Purchase code
Air Motor	1	Tubing (S-2S)	245-45
wrench	1	Handpiece oil	244-1
Tubing	1		
User manual	1		

4. Technical Date

Number	CX235-3C	CX235-3B	CX235-3F
Sprey type	Inner Spray	Inner Spray	Extemal Spray
Cooling	Water&Air cooling	Water&Air cooling	Water&Air cooling
Connector	6 hole	4 hole or 2 hole	4 hole or 2 hole
Bulb	LED	-	-
Valtage	⎓ 3.3±0.1V	-	-
Light	＞7000Lux	-	-
Air supply	< 80 Nl / min at (300 ± 100) kpa		
Rotation speed	14000-25000rpm / min at 250 kpa		
Cooling water flow	＞50ml/min at 250/Kpa		
Coupling dimensions	Comply with ISO 3964		

Note: 1)2 Hole of ISO 9168 Type 1; 4 Hole of Iso 9168 Type 2;6 Hole of ISO 9168 Type 3.

2) The maximum temperature of the handpiece does not exceed 60℃

5. Connecting / Disconnecting Hand piece and Motor

1 . When installed , the ends of the straight，geared angle handpieces can be connected with the coupling section of the air-motors ,as shown in Fig . 1.
2 . When disassembling , grab the air-motors by hand and pull the straight , geared angle handpieces forward.

Caution

- The structure , dimensions and tolerances of low speed handpiece coupling should meet the requirements of ISO 3964-2016.
- The handpiece with the card position should be aligned withthe positioning pin on the motor as shown in the figure.
- No more than 10 minutes of contact with the patient .
- Our products can only be used in conjunction with equipment that complies with IEC 60601-1.

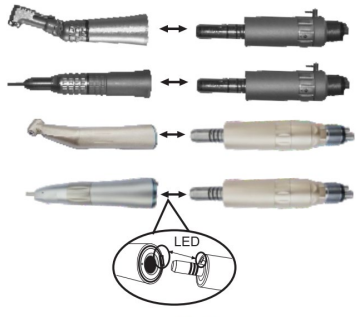


Fig.1

6.Switch

1 . Positive rotation : turn the switch ring to the [F] side (Fig . 2).
2 . Negative rotation : turn the switch ring to the [R] side (Fig . 3).
3 . When the switch ring between [F] and [R] , the motor will stop rotating.

Fig.2

Fig.3

Fig.4

7.Water Supply

- Inner channel water spray low speed handpiece
  Connect the 2 / 4 / 6 hole handpiece tubing according the 2 / 4 / 6 hole shape , then can be usedafter connected closely , firmly (Fig 5-1 , Fig5-2).

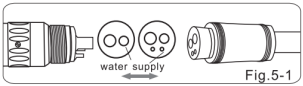


Fig.5-1

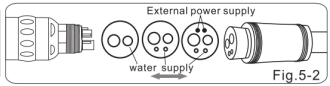


Fig.5-2

- External water spray low speed handpiece

When need the water supply , attach one end of the plastic tube to the water intake on themotor , and the other end to the water inlet on the contra angle or straight handpiece.

Because the length of plastic tube is a little longer , please cut according to the trim size before using (Fig . 6) .

Connect the handpiece tubing according the hole shape (2 hole or4 hole) , then can be used after connected closely , firmly (Fig . 7)


Fig.6

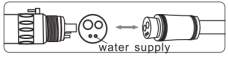


Fig.7

Environment-friendly fiber optic handpiece tube

If the dental unit don' t have the optical fiber system , please insert our optical fiber tubing and electricity board in the the dental unit , then it can use our optical fiber handpiece , and include the high speed handpiece which compliance with international standards.

(6 hole) Fig.8

Electricity board

1 . Power in : 12-24V

2 . Power out : 2.5-3 5V (adjustable)

3 . Output delay : 0-12s (adjustable)

4 . Linkage air pressure : P > 0 . 2mpa

5 . Control ways : 2 ways

Fig.9

Install external power supply

Optic Fiber Inner Cannel Low Speed Handpiece

1 . Connect power in line with POWER in 12-24V end.

2 . Electricity lines from the tube connect with the power out end (L1 or L2) of theelectricity board.

3 . Connect the electricity board and the air in tube with a T-Connrctor.

4 . Air 1 corresponding to L1 , and Air 2 to L2.

5 . Connect the electricity , step on the foot controller , the indicator light is on , fiber optic illuminated handpiece work see figure 8 for more detail.

Notice : A : work air (air in)

W : water in

C : pulverization

D : air return

It must follow the drawing to insert the optical fiber system.

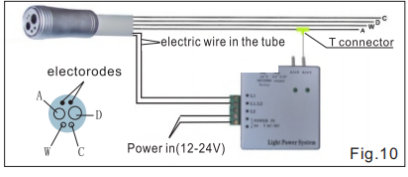


Fig.10

8.Cleaning, Disinfection and Sterilization

Device:	Air Motors
Advice:	Reprocessing procedures have only limited implication to this dental instrument. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. From the processing side there is no maximum number of allowable reprocessing. 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.
Reprocessing Instructions	
Preparation at the Point of Use:	Disconnect the handpiece from tube. 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.
Transportation:	Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.
Preparation for Decontamination:	The devices must be reprocessed in a disassembled state, as far as possible.
Pre-Cleaning:	Do a manual pre-cleaning, until the instrument 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 instrument into the machine on a tray. Connect the instrument with the WD by using suitable adapter and start the program: ● 4 min pre-washing with cold water (<40℃) ● emptying ● 5 min washing with a mild alkaline cleaner at 55℃ ● emptying ● 3 min neutralising with warm water (>40℃) ● emptying ● 5 min intermediate rinsing with warm water (>40℃) ● emptying The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weight). Note Acc. to EN ISO 17664 no manual reprocessing methods are

	required for these device. If a manual reprocessing method has to be used, please validate it prior to use.
Disinfection:	Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0 value (see EN 15883). A disinfection cycle of 5 min disinfection at 93℃ has been validated for the device to achieve an A0 value of 3000.
Drying:	Automated Drying: Drying of outside of instrument through drying cycle of washer/ disinfector. If needed, additional 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, if required. Functional testing according to instructions of use. If necessary, perform reprocessing process again until instrument is visibly clean.

	Before packaging and autoclaving, make sure that the handpiece has been maintained acc. to manufacturer’s instruction.
Packaging:	Pack the instruments in an appropriate packaging material for sterilization. The packaging material and system refer to EN ISO 11607.
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. Minimum requirements: 3 min at 134℃ (in EU: 5 min at 134℃) Maximum sterilization temperature: 137℃. Drying time: For steam sterilization, we recommend a drying time of 15 to 40 minutes. Choose a suitable drying time, depending on the autoclave and load. Refer to the autoclave’s instructions for use. After sterilization: a. Remove the product from the autoclave. b. Let the product cool down at room temperature for at least 30

	minutes. Do not use additional cooling. Check that the sterilization wraps or pouches are not damaged. 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. Refer to test reports: - FOSHAN COXO_Cleaning Disinfection Validation Report - FOSHAN COXO_Sterilization Validation Report_Straight Handpiece, Air Motors - FOSHAN COXO_Sterilization Validation Report_High-speed air turbine handpiece
Additional Instructions: None	
It is the duty of the user to ensure 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.	

Lubrication

1.Handle oil lubrication

1) Align the grease fitting with the air inlet of the mobile phone ,and press it after pressing; the fuel injection pipe must be upright when injecting.

2) Place the handset head down.

3) Spray the cleaned lubricant to the machine head.

⚠ Note : Once you see any dirt on the machine head , repeat the entire hygiene and maintenance procedures!

2.Movement of the movement : The movement should pay attention to oil maintenance to prevent impurities and rust

⚠ Note : The recommended period of lubrication is before and after each sterilization !

Before sterilizing . please clean . disinfect and lubricate the Air-motor!

9. Environment Conditions

Operating environment:

Ambient temperature: +5°C +40°C

Transportation and storage conditions:

Ambient temperature: -10°C +55°C

Relative humidity: 20% - 80%RH
Air pressure: 860hPa-1060hPa

Relative humidity: ≤93%RH
Air pressure: 500hPa-1060hPa

10. Standard Symbols


Warning


Caution


Certified to MDD93/42/EEC

Autoclave


Thermo-Disinfector


Type B applied part

Batch code

Serial number


Class II equipment


Manufacturer


Refer to Instruction Manual/Booklet


Do not dispose of with domestic waste

Authorized representative in the European Community

11. Life Expectancy

Expected service life is 5 years . (see the label for production date)

12. Recycling and disposal

Recycling

COXO places special emphasis on environmental responsibility, the handpieces and packaging are designed to be as environmentally friendly as possible.

Disposal of the handpieces

-Dispose of old equipment according to the laws ,regulations and standards of your country (region).

-Ensure that all parts are free from contamination during disposal.

13. Troubleshooting

Trouble	Possible Cause	Solution
Body of straight head and contra angle rotates during motor running	O-ring on the nose of motor wears	Change o-ring
Handpiece fail to spray water	Spray hole blockage	Clean with probe
Water leakage of handpiece	O-ring and washer aged	Change aged parts andfasten the screw bolt of connecting hose
Handpiece fail to rotate	Motor reversing ring fail to be moved to the proper position	Clean and lubricate .,move the pollutants by hand

This product can be repaired by professional maintenance personnel on site, and accessories required for maintenance are purchased from COXO ordistributors. Our service center can offer technical assistance to you.

14. Warranty

COXO grants the user a 12 months guarantee for its complete product range, except ball bearing (3 months guarantee) from the date of invoice issued. Maintenance over the term of guarantee will be at the customer's charge.

COXO will not be responsible for damage or injury resulting from:

- Excessive use.
- improper manipulation of the product, or modification to product carried out by persons not authorizes by COXO.
- Fail to follow the instuction to install,operate and maintenance the handpiece.
- Damage of chemical,electrical or electrolysis due to improper autoclaving and storing.
- improper working pressure or used beyond dental treatmen
- abnormal water , gas connections.

15. Guidance and manufacturer's declaration-EMC

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

⚠ **Caution:**

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

Guidance and Manufacture's Declaration – Electromagnetic Emission		
The High-speed air turbine handpiece is intended for use in the electromagnetic environment specified below. The customer or the user of the High-speed air turbine handpiece should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	The High-speed air turbine handpiece 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 emission CISPR 11	Class B	The High-speed air turbine handpiece 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	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and Manufacture's Declaration – Electromagnetic Immunity			
The High-speed air turbine handpiece is intended for use in the electromagnetic environment specified below. The customer or the user of High-speed air turbine handpiece 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 ±4 kV, ±8kV,±15 kV air	±8 kV contact ±4 kV, ±8kV, ±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	Not applicable	Mains power quality should be that of atypical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV & ±1 kV differential mode ±0.5 kV, ±1 kV & ±2kV common mode	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	100 % U_T (100% dip inU_T.) for 0.5 cycle 100 % U_T (100% dip inU_T.) for 1 cycle 30 % U_T (70% dip in U_T) for25/30 cycles 100 % U_T (100% dip inU_T.) for 250/300 cycle	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the High-speed air turbine handpiece requires continued operation during power mains interruptions, it is recommended that the High-speed air turbine handpiece be powered from a 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 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 and Manufacture's Declaration – Electromagnetic Immunity			
The High-speed air turbine handpiece is intended for use in the electromagnetic environment specified below. The customer or the user of High-speed air turbine handpiece 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 Bands 3 V/m 80 MHz to 2.7 GHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the High-speed air turbine handpiece, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d=1.2\times P^{1/2}$ $d=1.2\times P^{1/2}$ 80 MHz to 800 MHz $d=2.3\times P^{1/2}$ 800 MHz to 2.5 GHz

Radiated RF IEC 61000-4-3	385MHz- 5785MHz Test 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)	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 High-speed air turbine handpiece is used exceeds the applicable RF compliance level above, the High-speed air turbine handpiece should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the High-speed air turbine handpiece.

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 High-speed air turbine handpiece

The High-speed air turbine handpiece is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the High-speed air turbine handpiece can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the High-speed air turbine handpiece 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 to 80 MHz $d=1.2\times P^{1/2}$	80 MHz to 800 MHz $d=1.2\times P^{1/2}$	800 MHz to 2.5 GHz $d=2.3\times P^{1/2}$
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.

NOTE1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

EC REP

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

Foshan COXO Medical Instrument Co., Ltd
TEL: 0086-757-66692058
FAX: 0086-757-81800058
E-mail: coxotec@163.com
Http://www.coxotec.com
Ver: 4.0 Rev. Date: 2024.0806