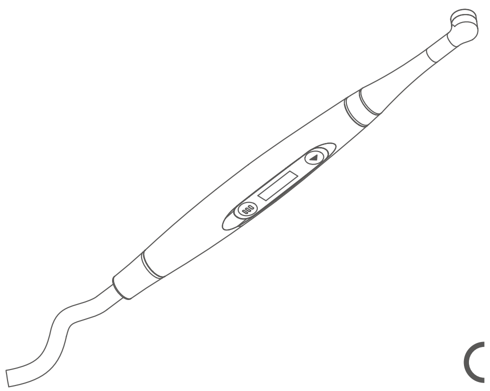
COXO®

LED Curing Lights

DB686

Q2



User Manual

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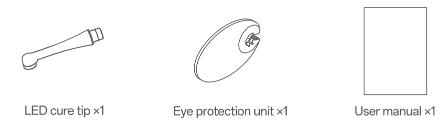


Fig1: Accessories List

1. Safety

Safety notes

Be aware of the following general safety notes and the special safety notes in other chapters of these Instructions for Use.

Warning

This alerts the user of possibility of extremely serious injury or complete destruction of the instrument as well as other property damage including the possibility of fire.

Caution

This alerts the user of possibility of minor or moderate injury or damage to the instrument.

Note

Informs the user of important points concerning operation or the risk of instrument damage.

Warning

Please read this manual carefully before using, operating, servicing and maintaining this device and keep this manual in a safe place for reference. Period of use: 15 years.

1) The device must be used within the range mentioned in the manual. If the user fails to operate according to the requirements of the manual or use the device for other purposes, the manufacturer will not bear any responsibility.
2) This device is only for use by professional dentists or nurses in medical institutions.
3) This device is one-piece and needs to be installed on a dental treatment machine for normal use.
4) Do not modify this device; any modification may damage the safety and effectiveness of the device. Only authorized technicians can repair this device.
5) If non-original accessories especially LED cure tip are used, this may be hazardous to patients or operators and damage the device.
6) To avoid electric shock, do not insert other objects into the unit.
7) Avoid liquid from entering the device while cleaning to avoid short circuits and malfunctions.
8) When the device is severe abnormal due to improper use or physical damage, stop using it immediately and turn off the power.
9) Users are not allowed to remove the battery by themselves.
10) The device has electromagnetic interference, please do not use it around patients with cardiac pacemakers or electronic surgeries.
11) The device may be interfered with by other device even if the other device meets the emission requirements of the corresponding national standards.
12) Unstable voltage and electromagnetic fields will interfere with the normal operation of the device.

Caution

1) Any patient who have retinal disease should consult an ophthalmologist before operating the device and follow all necessary safety precautions.
2) Do not use the device for intraoral illumination or transillumination of teeth; excessive heat may be generated, resulting in mucosal burns or pulpal irritation.
3) Check the device if there's worn, loose or damaged parts before every time using it, also check the light output if it is normal.
4) Before using, a disposable protective sleeve should insert the head of the host to prevent the host or other parts from contacting the patient's skin or mouth mucosa.
5) After finishing to use it, the disposable protective sleeve should be removed from the head of the host and disposed of in accordance with relevant regulations. Disposable protective sleeves are prohibited from being reused to prevent cross- infection.
6) Blue light, ultraviolet protection measures: it is forbidden to shine the light into the eyes. The light reflected from the surface of the teeth may also injure the eyes of doctors, nurses and patients. Please standardize and correctly install the eye protector unit, wear eyes protector glasses.
7) Precautions for Heat Radiation: All dental curing light devices will generate a certain heat. Long-term operation in the area near the pulp or soft tissue may cause severe injury.
8) The light source should be directly irradiated on the resin material to be cured to prevent improper irradiation position and affect the curing effect when it is in clinical use. It is forbidden to directly irradiate the oral soft tissue at close range to avoid thermal damage. Repeated long-term irradiation is not recommended for avoiding light hazards such as thermal radiation.
9) Precautions against overheating: When the device is continuously operated for a long time (multiple curing cycles), the surface temperature of the light source rod may exceed 43℃, and it should not contact the skin or mucous membranes for a short time. Avoid long-term irradiation and stop using the equipment when it has a significant increase in temperature.
10) Failure to comply with relevant environmental operating conditions may cause injury to patients or users.
11) After every time using it, please clean and disinfect reusable parts according to the instructions.

2. Intended use

- For dental clinics treatment to irradiate polymer-based restorative materials to cure them.
- The instrument must only be used in hospital environments, clinics or dental offices, by qualified practitioners.

3. Composition

It consists of a handpiece (including a tail line), LED cure tip, eye protector unit.

4. Contraindications

1) Systemic diseases (tumors, severe cardiovascular diseases, blood system diseases, immune system diseases, etc.).
2) Undergoing certain systemic and local treatments (anticoagulant therapy, chemotherapy, radiotherapy, etc.).
3) Use with caution in patients with cardiac disease, pregnant women and children.
4) Use with caution if allergic to LED light.

5. Preparation before using

5.1 Installation Method

Connect the power cord of this device to the power output interface (24V~) of the dental treatment device, tie the nylon wire to the fixed column of the dental treatment machine, and then you can use it.

Warning:

The power supply of the dental unit must be cut off during installation, and the length of the two wires should be slightly longer than the nylon wire to avoid breaking the wires.

5.2 Install Accessories

Refer to "Fig2"

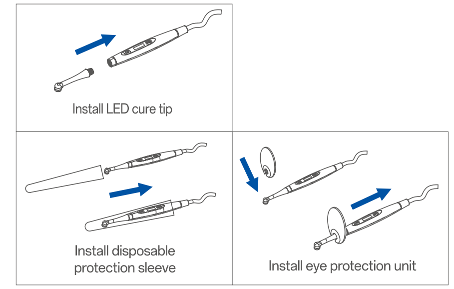


Fig2

Note:

- The LED cure tip can rotate 360°.
- If the LED cure tip is not connected or connected improperly, an error message will be displayed when the device is started: the handpiece will emit 10 beeps. And the display screen will show"E1"which means error caution, please check the LED cure tip and reconnect it.

- Using a disposable protective sleeve can protect the LED cure tip from contamination.
- Please ensure that the disposable protective sleeve is installed flat on the LED cure tip to avoid wrinkles at the light source output, which will affect the curing effect.

Caution:

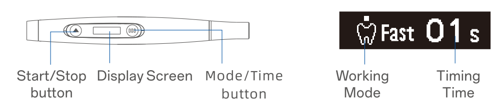
The LED cure tip contains glass products, please do not contact with hard objects and vigorously flung, so as to avoid cuts and damages after dislodging.

6. Operation

Caution:

The light generated by the device may damage eyes. Before using, please standardize and correctly install the eye protector unit and wear eyes protector to avoid unnecessary harm to you.

Explanation / Handpiece screen display



6.1 Working

The power supply of the device comes from the dental treatment machine, when the dental treatment machine is in standby mode, the device is in standby mode, touch any key to enter the working mode, when the dental treatment machine is in shutdown mode, the device is shut down with it.

Note:

When the device is not operated for 30s, it will automatically enter the hibernation state.

6.2 Mode Selection

The device has the functions of resin curing detection. Meanwhile, resin curing has three modes: Low-temperature curing, Standard curing and Fast curing.

You could long press " ☰ " Mode/Time button to switch functions/working modes.

Mode	Screen Display	Functionality
Low-temperature Mode	Low 20 s	Variable illumination output with illumination values pulsed at 600/1000 mW/cm² cycles
Standard Mode	STD 20 s	Light output at a constant illumination of 1000~1200mW/cm², used for conventional resin curing
Fast Mode	Fast 01 s	Light output at a constant illumination of 1800~2000mW/cm² fast resin curing

6.3 Curing time selection

Various curing times could be set for different working modes by short pressing " ☰ ".

Mode	Curing time (seconds)
Low-temperature Mode	5s、10s、15s、20s
Standard Mode	5s、10s、15s、20s
Fast Mode	1s、3s

6.4 Start the work

After completing the settings, short press " ▶ " start/stop button to start light curing, and press again to turn off the device.

Caution:

- The user must use eyes protector and wear goggles during the operation, otherwise it will cause injury to the eyes.
- The recommended distance between the LED cure tip and the curing surface is 3mm-5mm.
- When the temperature of the handpiece is too high, the handpiece will stop working, emits 5 beeps and the handpiece screen shows E2 overheating prompt. Please wait until it cools down completely cooled before using it.

7. Maintenance

1) Before each use, check the handpiece and LED cure tip for any damage. If so, stop using them immediately and contact our company or authorized dealers for assistance.
2) Before the first use and after each use, it must clean and disinfect handpiece, LED cure tip and eye protector.
3) After each use, please check whether there is any resin left on the lens surface of the LED cure tip to avoid affecting the service life of the LED cure tip or the curing effect.

8. Cleaning and Disinfection

Device	Handpiece, LED cure tip, eye protector unit. The procedure for cleaning, disinfection applies only to the accessories handpiece, LED cure tip, eye protector unit.
Advice	Reprocessing procedures have only limited implications 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 disposable protective sleeve and LED cure tip from the handpiece. 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. All parts cannot be cleaned and disinfected in a washer/disinfector. Only a general wipe decontamination is possible!
Manual Cleaning of handpiece, LED cure tip, eye protector unit:	Do a manual cleaning, until the instruments are visually clean. ● Recommend using 3M muti-enzyme cleaning agent at a concentration of 5mL/1L distilled water. ● Soak the soft cloth in detergent and wring it out. ● Wipe the outer surface of the eye protector unit with the soft cloth. ● Rinse eye protector unit with tap water until all visible contaminants have been removed. ● Remove any liquid residue with a lint-free cotton cloth, then dry at 30℃.

	• Checked that if the devices were clean or broken after cleaning. If the cleaning is not good enough, repeat the cleaning procedure.
Manual Disinfection of handpiece, LED cure tip, Eye protector unit:	After cleaning, wipe all device surfaces with a new single-use cloth in combination with an alcohol-based, tuberculocidal, quaternary ammonium solution,5 minute contact time, use according to disinfectant solution manufacturer`s Instruction for Use. Use a separate wipe for LED cure tip and handpiece. Ensure direct contact of device and disinfectant by pressing the wet wipes on the device after half of the required contact time. Use fresh wipes to disinfect the LED Cure Tip o-ring area, handpiece mating cavity and battery/handpiece mating seam for the entire contact time. Immediately absorb excess fluid with a dry disposable towel Wipe the devices with a sterile, clean, lint-free cloth that is well dampened with deionized water for 30 seconds to remove all disinfecting agent. Pay special attention to all seems, especially around the LED cure tip /handpiece junction. Ensure cloth is damp with deionized water for the entire 30 seconds. Discard used cloth and repeat rinsing with a new, second dampened cloth for 30 seconds. Discard second cloth and rinse with a new, third dampened cloth for a final 30 seconds. Wipe device with a fourth dry, sterile lint-free cloth to remove all fluid. Allow the devices to air dry for at least 5 minutes.
Manual Drying:	Use compressed air to blow dry the internal pipes and external surfaces separately.
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.
Storage:	Storage of disinfected instruments in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.
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.	

9. Troubleshooting

If the product functions abnormally, please refer to the following instructions for troubleshooting first. If can not be resolved, please contact your local dealer or our company.

Fault status	Possible cause	Solutions
No response from the handpiece	The connection between the main unit and the dental unit is poor	Confirm that the main and dental treatment unit are installed correctly
	Device failure	Contact the dealer or manufacturer
Insufficient light intensity	The light outlet is offset or not vertically close to the surface of the dental adhesive	Use after adjusting the position
	Residue on the end face of the LED cure tip	Clean the LED cure tip emitting surface
	The LED cure tip is damaged	Replace the LED cure tip
	LED light is damaged	Contact the dealer or manufacturer
Handpiece screen displays E1	The LED cure tip is not installed or has poor contact with the handpiece	Install the LED cure tip according to the instructions
	A non-original LED cure tip is used	Make sure to use the original LED cure tip provided by the manufacturer
	Device failure	Contact the dealer or manufacturer
Handpiece screen displays E2	The continuous working time is too long or the working interval is too short the handpiece prompts overheating	Please stop using it immediately until the device is completely cooled before using it

10. Technical Parameters

Power Input（Dental Chair dedicated output interface power supply ）	Input: 24V~ 50/60HZ
Input power	10VA
Li-ion battery	3.7V 1400mAh
Light curing classification	Class II
LED source	Voltage: 3V LED Light Power: 10W
Wavelength range	385nm~515nm
Peak wavelength	460nm
385nm ~ 515nm（blue light）Irradiance in the wavelength range	≥ 200mW/cm²
200nm ~ 385nm Irradiance in the wavelength range	≤ 200mW/cm²
Irradiance in the wavelength range above 515nm	≤ 100mW/cm²
Optical effective area	78.5mm²
Operation mode	Duty cycle: Max.T_ON: 3min, Min.T_OFF: 3min
Degree of Protection (IEC 60529)	IPX0
Classified by security	Non-AP/APG type
Protection against Electric Shock	Type B
Classified of protection against Electric Shock	Class II
Overvoltage category	Class II
Pollution degree	Class 2
Applied part	Disposable protective sleeve, material: PP (order code: 4031013)

11. Operating, storage and Transport conditions

Operating Environment

Environmental temperature	+5℃ ~ +40℃
Relative humidity	20%RH ~ 80%RH
Atmospheric pressure	80kPa ~ 106kPa
Altitude	≤2000m

Transport and storage conditions

Environmental temperature	-10℃~ +55℃
Relative humidity	≤93% RH
Atmospheric pressure	50kPa ~ 106kPa

12. Product Warranty

1) The warranty period for the handpiece, LED cure tip is 24 months from the date of purchase, the rest of accessories are not warranted.
2) This device cannot be repaired on-site by the customer, and equipment repair should be performed by professionals designated by the manufacturer.
3) Upon request, the supplier will provide circuit diagrams, component lists, legends, calibration details, or other information necessary for qualified technicians to help users repair equipment parts designated by the manufacturer for repair.
4) The following situations are not covered by the free warranty:
   - Damage caused by human factors;
   - Damage caused by force majeure;
   - Customers make unauthorized changes, dismantle or repair privately;
   - 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 conditions of use.

13. Recycling and Disposal

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

Ensure that the parts are not contaminated on disposal.
Follow your local and country specific laws, directives, standards and guidelines for disposal.
- Medical device
- Waste electrical equipment
- Packaging

14. Symbols Identification

	General warning		Caution
	Refer to operating instructions	SN	Serial number
	Type B applied part		Note
	Keep dry		Fragile, handle with care
	Keep upright		Class II equipment
	Direct current		Alternating current
	Do not dispose of the product into the ordinary municipal waste or garbage system		Indoor use only
	Start/Stop button		Mode/Time button
	Do not reuse		Manufacturer
	Wireless device	EU REP	Authorized representative in the European Community/European Union
MD	Medical device	REF	Catalogue number
CE	CE marking		Date of manufacture

15. EMC

Note

- Based on IEC 60601-1-2 concerning the electromagnetic compatibility of electrical medical devices, we must draw your attention to the following points:
- Medical electrical devices are subject to special precautions concerning the electromagnetic compatibility and must be installed and operated in accordance with the Manufacturer assembly instructions.
- High-frequency communications devices may interfere with electrical medical devices.
- Manufacturer cannot guarantee the compliance of accessories, cables, and other components not supplied by manufacturer with the EMC requirements of IEC 60601-1-2.

Caution:

- This device conforms to IEC 60601-1-2, the relevant international standard for electromagnetic compatibility (EMC). The following is the Guidance and Manufacturer's Declaration which is required by IEC 60601-1-2, the relevant international standard for electromagnetic compatibility.
- This device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.
- Portable and mobile RF communication equipment can effect the device.
- Use of other than those accompanied or specified by COXO may result in increased EMC emissions or decrease EMC immunity of the device.
- This device should not be used adjacent to with other equipment. If adjacent use is necessary, the device should be observed to verify normal operation.

Serial numbe	Cable name	Cable type	Cable length（m）	Remarks
1	Handpiece tail cord	Unshielded parallel lines	1.8	/

Guidance and Manufacturer's Declaration-Electromagnetic Emissions

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

Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group1	The device use RF energy only for their internal function. Therefore, their 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 other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
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	±8kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8kV 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	NA	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	NA	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 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 1000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and mateur 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. Recommended separation distance d=([3.5] $\sqrt{P}$)/3 80 MHZ to 800MHZ d=([7] $\sqrt{P}$)/3 800 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:
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)	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not be applicable in every case. The propagation of electromagnetic waves is subject to absorption and reflection by buildings, objects, and people.

a: The field strength of stationary transmitters such as base stations of mobile telephones and land mobile radio devices, amateur radio stations, AM and FM radio and television broadcasting stations cannot be determined based on theoretical considerations. A site study should be considered to determine the electromagnetic environment in terms of stationary transmitters: if he field strength measured at the site, at which the Device is used, exceeds the compliance levels shown above, the device should be monitored to demonstrate proper function. Should unusual performance features be observed, additional measures may be required, such as, e.g., a different alignment or different location for the Device.
b: Over the frequency range 150 kHz to 80 MHz，field strengths should be less than 3V/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 output power of the transmitter/W	Separation distance according to frequency of transmitter / m		
	150 kHz to 80 MHZ d=1.2$\sqrt{P}$	80 MHz to 800 MHZ d=1.2$\sqrt{P}$	800 MHz to 2.7 GHZ 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 transmitter rated maximum output power not listed in the table above, the recommended isolation distance, d, in meters (m), can be determined using the formula in the corresponding transmitter frequency column, where P is the maximum output power rating of the transmitter in watts (W) as supplied by the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz frequencies, the formula for the higher frequency range is used.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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