







OPERATION MANUAL





Foshan COXO Medical Instrument Co., Ltd.

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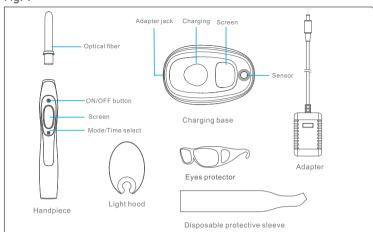
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Fig. 1



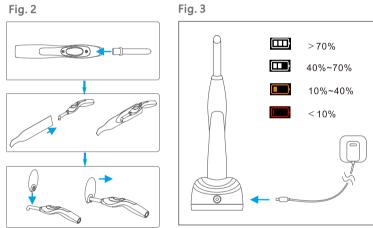
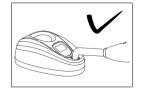
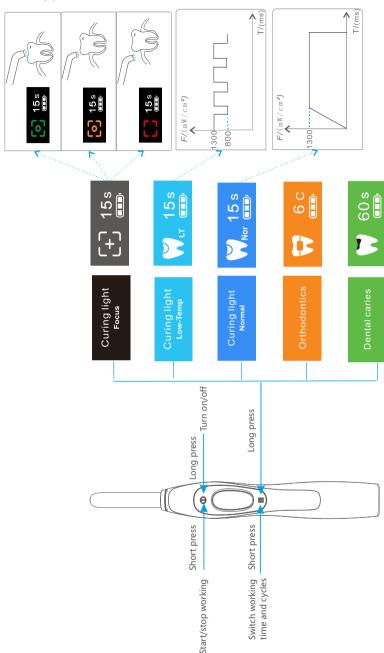


Fig. 4









1. Safety



Before using, operating and maintaining this device, please read this manual carefully.

- 1) The device must be used within the scope mentioned in the manual. If the user does not operate according to the instructions or use the device for other purposes, the manufacturer will not bear any responsibility.
- 2) 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) Do not modify this device, any modification could compromise the safety and effectiveness of the device
- 4) Use of non-original accessories, especially optical fiber, power adapters or batteries, may be dangerous to the patient or operator, and may cause damage to the device.
- 5) Make sure the power outlet is accessible at all times for emergency disconnection.
- 6) To avoid electric shock, do not insert other objects into the device.
- Avoid liquids entering the inside of the device to avoid short circuits and malfunctions.
- 8) Immediately stop using and turn off the device when improper use or physical damage causes serious abnormalities in the device.
- 9) There is low voltage inside the charging base, use it only in dry conditions. Do not use if the charging base or handpiece is wet. Only authorized technicians should service this device.
- 10) Keep device clean and dry.
- 11) Users cannot remove the battery by themselves.
- 12) The device has electromagnetic interference, please do not use it around a patient with a pacemaker or electronic surgery.
- 13) Even if other devices meet the emission requirements of the corresponding national standards, the device may still be interfered by other devices.
- 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 use.



NOTICE

- 1) Patients with a history of retinal disease should consult an ophthalmologist before operating this device and follow all necessary safety precautions.
- 2) Do not use the device for intramural lighting or dental trans-illumination, as excessive heat may be generated, causing mucous membrane burns or pulp irritation.
- 3) Do not point light into eyes. Light reflected from tooth surfaces can also damage the eyes. Please use protective goggles.
- 4) Heat Radiation Precautions: All dental light curing devices generate some degree of heat. Prolonged manipulation in the area near the pulp or soft tissue can cause serious injury.
- 5) For long-term operation of the device (multiple curing cycles), the surface temperature of the Optical fiber may exceed 45.5°C. Should not come into contact with skin or mucous membranes for a short time.
- 6) Failure to comply with relevant environmental operating conditions may result in patient or user injury.
- 7) Inspect device for worn, loose, or damaged parts before every use.
- 8) After each use, maintain the reusable parts according to the instructions.

2. Intended use

- 1) It is used in irradiated dental clinics for polymer-based restorative materials to make them cured.
- 2) This device must only be used in hospital environments, clinics or dental offices by professional dentists.

3. Contraindications

- 1) Systemic diseases (tumors, severe cardiovascular diseases, diseases of the bloo d system, diseases of the immune system, ...)
- 2) Certain systemic or local treatments are underway (e.g. anticoagulation, chemotherapy, radiotherapy, ...)
- 3) Ask the patient if a pacemaker or other system has been implanted before treatment!

4. Preparation

4.1 Installation

Refer to "Fig. 2"



TIPS:

- The Optical fiber can be rotated 360°.
- When Optical fiber is undetected, the screen shows E1.
- Please ensure that the disposable protective sleeve is mounted flat on the Optical fiber.



A CAUTION:

- The Optical fiber is fragile, please do not contact hard objects.
- The Optical fiber connected to the handpiece by magnetic suction, do not shake vigorously!

4.2 Charging

Refer to "Fig. 3"



A CAUTION:

- When the power of the Handpiece is extremely low, it will automatically shut
- The battery power of the Charging base is only displayed during illuminance
- Please use the original Charging base, Adapter and Lithium battery, otherwise it may cause damage to the battery and control circuit.
- · Forbid charging in humid environment.
- please charge the device at least once a month.
- When the handpiece is charged abnormally, the charging base screen displays E3, please solve according to 'Troubleshooting'

4.3 Illuminance measurement

Refer to "Fig. 4"

Short press ON/OFF button to start measurement.



- The illuminance measurement ranges from 500-3500 mw/cm².
- When charging base battery is low, the adapter can be connected to use the illuminance measurement function.



5. Operation



WARNING:

Make sure install the original light hood correctly in order to avoid the harm of blue light to the eyes. It is forbidden to aiming light at eyes directly.

5.1 Power ON/OFF

Long press the ON/OFF button to turn on/off.



TIPS:

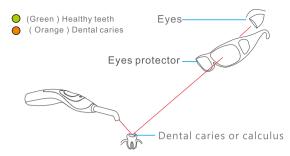
- When the device is not operating for a while, it will go into sleep.
- Pick up the device or press the ON/OFF button to enter the standby state.

5.2 Mode and selection

- 1) The device has three functions: Curing light, Orthodontics, and Dental caries detection. Among them Curing light has three modes: Focus, Lowtemperature curing and Normal curing.
- 2) The working mode can be automatically memorized.

5.3 Working

- 1) Long press the Mode/Time button to switch mode.
 - A. Curing light: for curing of composite resins, curing time: 5s/10s/15s/20s;
 - Focus: Automatically indicate whether the spot is accurately focused on the tooth surface during operation.
 - Low temperature: Variable illumination output, illumination value to 800 / 1300 mW / cm² cycle switching.
 - Normal: Light output at a constant illumination of 1300mW / cm² for normal and fast resin curing.
 - B. Orthodontics: for bracket bonding, illumination value > 3000 mW / cm²;
 - C. Dental caries:



- 2) Press the Mode/Time button to set the working time or cycles.
- 3) Press the ON/OFF button to start working and press it again to stop.



TIPS:

- To ensure accurate detection results, please turn off the external light
- Fluorescence or brown color near the pulp when removing deep caries.
- After removal of the caries, it is recommended to check the oral cavity again.
- When the handpiece temperature is too high, it will stop working and issue a warning. Please wait for complete cooling before use.



WARNING:

Users must wear eyes protector during surgery.



6. Cleaning, Disinfection and Sterilization

6.1 Cleaning

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



- During manual cleaning, visually check whether the end face of the Optical fiber is stained with dirt. If there is any dirt, please use a plastic material instead of a metal tool to carefully remove it immediately.
- Do not let any hard objects touch the end face of the Optical fiber to avoid scratches.

6.2 Disinfection

- 1) The Handpiece surface can be disinfected by wiping with 75% ethanol.
- 2) The Optical fiber rods and goggles can be soaked in 75% ethanol for 30 minutes for disinfection.



Do not use chlorine-containing disinfectants or use ultrasonic cleaning.

6.3 Drying

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

6.4 Sterilization

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



- The handpiece and Light hood are strictly prohibited from sterilization;
- The maximum sterilization temperature cannot exceed 136°C.

7. Maintenance

- Before each use, check whether the Optical fiber and other components are damaged. If so, please stop using it or replace the components immediately.
- 2) Before each use, check whether the handpiece is damaged. If there is any damage, please stop using it immediately and contact our company or authorized dealer for help.
- To prevent cross-infection, the Optical fiber must be cleaned, disinfected and sterilized before or after use.
- 4) During the cleaning process, prevent liquid or other foreign objects from entering the handpiece, Charging base and Optical fiber.
- 5) When cleaning the Charging base, disconnect the power supply.
- 6) After each use, please check whether there is any resin remaining on the mirror surface of the Optical fiber, so as not to affect the life of the Optical fiber or affect the curing effect.

8. 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 | |
|---|---|--|--|
| Control unit not responding | Battery needs charging | Charging, especially for the first time or long time unused, please increase the charging time | |
| | Battery is damaged | Contact the dealer or the manufacturer | |
| Not charging after connecting | Poor contact with power supply | Check the adapter connection to the Charging base | |
| the adapter | Adapter use error | Check the specifications of the adapter | |
| | Adapter is damaged | Replace adapter | |
| Shorter usage time after charging | Battery aging | Contact the dealer or manufacturer to replace the battery | |
| Illuminance measurement | The light exit is offset or not vertically close to the test window | Adjust the position and then retest | |



| displays " < 500mW/cm²" | There are residues on the end surface of the Optical fiber | Cleaning the Optical fiber end face | |
|--|--|---|--|
| | The Optical fiber is damaged | Replace Optical fiber | |
| | Dental caries mode selected | Select the curing mode and then retest | |
| | Low battery | Retest after charging | |
| | LED is damaged | Contact the dealer or the manufacturer | |
| No Optical fiber detected, the | The Optical fiber is not installed or in poor contact with the handpiece | Install the Optical fiber according to the instructions | |
| screen shows E1 | Use the non-original Optical fiber | Be sure to use the original Optical fiber equipped with the manufacturer. | |
| The handpiece is overheated, and the screen displays E2 | Continuous working time is too long or working interval is too short | Continuous working time is too long or working interval is too short. | |
| Charging base screen displays E3 | Abnormal charging of handpiece, or foreign matter in charging port / bottom of handpiece | Remove foreign matter or reconnect adapter | |

9. Technical Specifications

| | Input: 100-240V ~ 50/60Hz | |
|--|---------------------------|--|
| Adapter | Output: DC 5V 1.5A | |
| Input power | 10VA | |
| Lithium battery | 3.7V 2200mAh | |
| Wavelength range | 385~515nm | |
| Peak wavelength | 460nm | |
| 385nm~515nm(Blue-ray) optical radiation wavelength range | ≥200mW/cm² | |
| 200nm~385nm optical radiation wavelength range | ≤200mW/cm² | |
| Above 515nm optical radiation wavelength range | ≤100mW/cm² | |
| Optical effective area | 50mm² | |
| LED power | 10W | |
| Operation mode | Non-continuous | |
| Degree of protection | IPX0 | |

| Classification by degree of safety in use of flammable an aesthetic gas mixed with air or with nitrous oxide | Non-AP / APG type |
|--|--|
| Protection against Electric Shock | Туре В |
| Classifications of protection against Electric Shock | Class II device when charging |
| Receiving frequency | 130kHz |
| Transmission frequency | 130kHz |
| Modulation type | None (fixed frequency, fixed duty cycle) |
| Frequency characteristic | Sine wave |
| Effective radiated power | 2.1W |

Operation environment

| Operation temperature | 5°C— 40°C | |
|-----------------------|----------------|--|
| Operation humidity | 20%— 80% | |
| Atmospheric pressure | 86kPa — 106kPa | |

Storage and Transportation conditions

| Storage temperature | -10°C—55°C | |
|----------------------|----------------|--|
| Storage humidity | ≤93%RH | |
| Atmospheric pressure | 50kPa — 106kPa | |

10. Guarantee

- The warranty period of the handpiece, Optical fiber and Charging base is 24
 months from the date of purchase, the accessories (Adapter) provided with
 the product are guaranteed for 6 months, and the rest of the accessories are
 not guaranteed.
- 2) Not covered by this warranty: Damage arising from improper use (operation with incorrect current/ voltage, unsuitable power point, breakage, cleaning by other than the recommended methods), normal wear and defects which have a negligible effect on the value or operation of the appliance.
- 3) This warranty becomes void if repairs are undertaken by unauthorized persons.
- 4) The supplier can provide circuit diagrams, component lists, legends,



calibration rules, or other materials necessary for repair by qualified technicians and repairable instrument parts designated by the manufacturer as required.

11. 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.

12. Symbols

| A | Warning/Caution | (1) | NOTE |
|-----------|------------------------------------|------------|---------------------------------|
| † | Type B applied part | (3) | Refer to the instruction manual |
| Ť | Keep dry | SN | Serial number |
| <u>11</u> | This way up | Ţ | Fragile, handle with care |
| | Direct current | | Class II device |
| X | Product comply with WEEE directive | | Indoor use |
| 0 | On/Off button | ~ | Alternating current |
| ((o)) | Wireless device | 000 | Mode/Time select button |

13. Guidance and manufactures declaration

- 1) This information is required by the 4th edition of IEC 60601-1-2.
- The Unit needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
- 3) Portable and mobile RF communications device can affect the Unit.
- 4) The use of accessories, transducers and cables other than those specified by

- manufacturer, may result in increased emissions or decreased immunity of the Unit.
- 5) The Unit should not be used adjacent to or stacked with other device and that if adjacent or stacked use is necessary, the Unit should be observed to verify normal operation in the configuration in which it will be used.
- 6) Per IEC 60601 1-2, no additional environmental operating conditions are required for normal use.

| No. | Name | Cable length(m) | Whether to block | Remark |
|-----|---------------------|-----------------|------------------|--------|
| 1 | Adapter output line | 1.6 | No | |

Guidance and manufacture's declaration - electromagnetic emission

DB686 Honor is intended for use in the electromagnetic environment specified below. The customer or the user of DB686 Honor should assure that it is used in such an environment.

| Emission | Compliance | Electromagnetic environment - guidance | |
|---|------------|--|--|
| RF emission CISPR 11 | Group 1 | DB686 Honor 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 device. | |
| RF emission CISPR 11 | Class B | DB686 Honor is suitable for use in all | |
| Harmonic emissions IEC 61000-3-3 | Class A | establishments, including domestic establishments directly connected to the public | |
| Voltage fluctuations/flicker emission IEC 61000- 3-3 | Complies | low-voltage power supply network with specific requirement. | |

| Guidance and Manufacture's Declaration -Electromagnetic Immunity | |
|--|--|
| The DB686P Honor is intended for use in the electromagnetic environment specified below. The customer or the user of DB686 Honor should assure that it is used in such an | |
| environment. | |

| environment. | | | |
|--|------------------------------|----------------------------|--|
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - guidance |
| Electrostatic discharge (ESD) IEC 61000-4-11 | ±6 kV contact ±8 kV air | ±6 kV contact ±8 kV air | Floors should be wood, concrete or ceramic tile. If floor are sleeved with synthetic material, the relative humidity should be at least 30%. |
| Electrostatic fast transient/burst | ±2kV for adapter ±1kV for | ±2kV for adapter | Mains power quality should be that of a typical commercial or hospital |



| IEC 61000-4-11 | Input/output lines | | environment. | | |
|--|---|---|---|--|--|
| Surge IEC 61000-4-11 | ±1kV differential mode voltage ±2kV common mode voltage | ±1kV 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 instrument requires continued operation during power mains interruptions, it is recommended that the instrument be powered from a unit eruptive 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 DB686 Honor is intended for use in the electromagnetic environment specified below. The customer or the user of DB686 Honor should that it is used in such an environment. | | | | | | |
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - guidance | | | |
| Conducted RF GB/T 17626.6 Radiated RF GB/T 17626.3 | 3 Vims 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz | 3 Vims 150 kHz to 80 MHz 6 Vims in ISM bands | Portable and mobile RF communications device should be used no closer to any part of the 0B686 Honor, including cables, then the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ d = $1.2\sqrt{P}$ 80 MHz to 800 MHz d = $2.3\sqrt{P}$ 800 MHz to 2.5 GHz | | | |

| | 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, 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 DB686 Honor is used exceeds the applicable RF compliance level above, the DB686 Honor should be observed to verify normal operation If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the D8686 Honor.

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 DB686 Honor.

The DB686 Honor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the u ser of the DB686 Honor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications device(transmitters) and the DB686 Honor as recommended below, according to the maximum output power of the communications device.

| Rated maximum output power of transmitter(W) | Separation distance according to frequency of transmitter | | | |
|---|---|---|--|--|
| | 150 kHz to 80MHz d=1.2×P ^{1/2} | 80MHz to 800MHz d=1.2×P ^{1/2} | 800MHz to 2.5GHz d=2.3×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 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.

where P 1s the maximum output power rating of the transmitter in watts(W)

manufacturer and d is the recommended separation distance in meters(m). Field strengths from fixed RF

according to the transmitter