

COXO[®]



Foshan COXO Medical Instrument Co.,Ltd

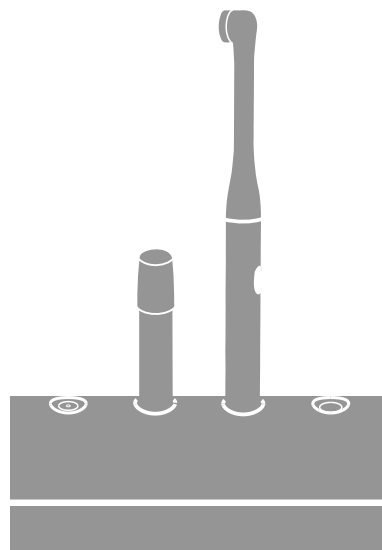
Address: BLDG 4, District A, Guangdong New Light Source Industrial Base, South of Luocun Avenue, Nanhai District, Foshan, 528226 Guangdong, China



Wellkang Ltd

The Black Church, St. Mary's Place, Dublin 7, D07 P4AX, Ireland

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COXO[®]


USER MANUAL

DB686 CURING LIGHT

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Guidance and manufacturer's declaration - electromagnetic immunity

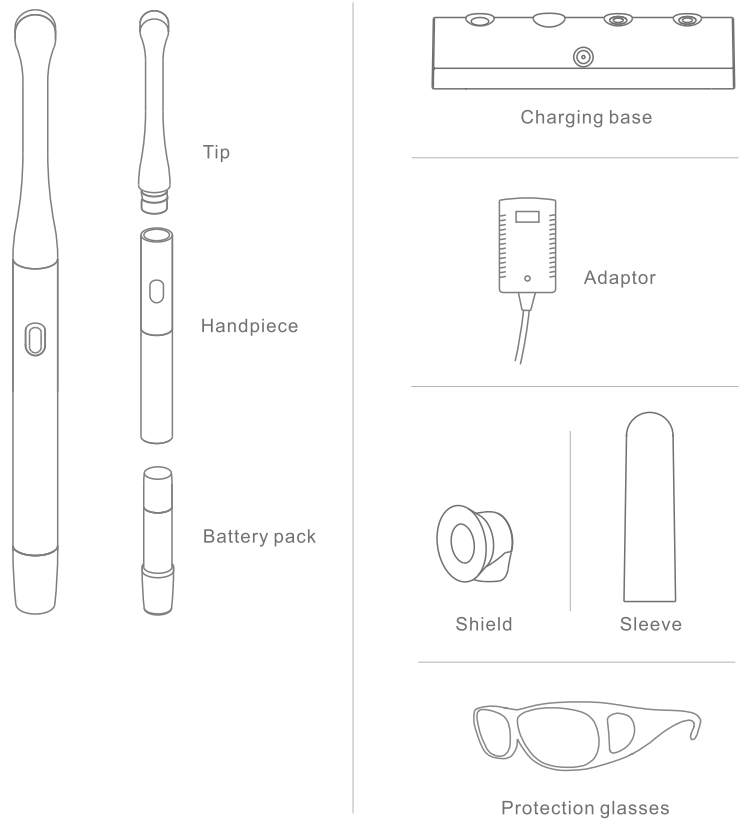
The Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Unit should assure that it is used in such an environment.

IMMUNITY Test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000 4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter</p> <p>Recommended separation distance</p> $d = ([3.5] \sqrt{p})/3$ $d = ([3.5] \sqrt{p})/3 \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = ([7] \sqrt{p})/3 \quad 800 \text{ MHz to } 2,7 \text{ GHz}$
Radiated RF IEC 61000 4-3	10 V/m 80 MHz to 2,7 GHz	10 V/m	<p>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).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p>

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 Unit is used exceeds the applicable RF compliance level above, the Unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [System Name here].
^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

1. PRODUCT CONTENTS LIST



2. PRODUCT DESCRIPTION

The device is a cordless pen style, LED light polymerization device and caries detector for use by dental professionals in dental offices or dental laboratories.

- Small size and lightweight ergonomic design.
- Compact cordless design and exchangeable battery pack.
- Individually adjustable LED tips, rotatable by 360°.
- LED tip design providing excellent intra-oral access.

Indications

- For light activated polymerization of dental materials such as composites, luting cements, and sealants using visible light.
- For dental surgery, according to the particular uofscence property of the degradation product from the bacteria on the caries, it is easier to target and remove the infected substance on the tooth.

Contraindications

The device is contraindicated for use in patients prone to photobiological reactions (including patients with solar urticaria or erythropoietic protoporphyria) or those currently undergoing treatment with photosensitizing pharmaceuticals.

Compatible Materials

The device is designed to cure materials initiated with CQ and/or other initiators absorbing violet light, 405-480nm wavelength. See polymer-based restorative material manufacturer's complete directions for use for specific product compatibility and curing recommendations.

















Guidance and manufacturer's declaration - electromagnetic emissions		
The Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Unit should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11	Group 1	The Unit uses 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 CISPR11	Class B	The Unit is suitable for use in all establishments, including including domestic establishments 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 - Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Unit 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, ± 4, ± 8, ± 15 kV air	± 8 kV contact ± 2, ± 4, ± 8, ± 15 kV air	Floors 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	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000 4-5	± 0.5, + 1 kV line(s) to line(s) ± 0.5, ± 1, ± 2 kV Line(s) to earth	± 0.5, + 1 kV line(s) to line(s) ± 0.5, ± 1, ± 2 kV Line(s) to earth	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	0 % UT for 0,5 cycle 0 % UT for 1 cycle 70 % UT for 25/30 cycles 0 % UT for 250/300 cycles	0 % UT for 0,5 cycle 0 % UT for 1 cycle 70 % UT for 25/30 cycles 0 % UT for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Unit requires continued operation during power mains interruptions, it is recommended that the Unit be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000 4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

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.

- This warranty becomes void if repairs are undertaken by unauthorized persons.

Symbol Identification

	Caution		Warning
	Manufacturer		European Union agent
	Serial number		CE marked product
	Type B applied part		Do not reuse
	Keep dry		Fragile
	Vertical up		Class II product
	Direct current		Refer to instruction manual
	Special disposal of waste electrical and electronic equipment		Autoclave

Electromagnetic Compatibility Precaution

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.
- Portable and mobile RF communications equipment can affect the Unit.
- The use of accessories, transducers and cables other than those specified by manufacturer, may result in increased emissions or decreased immunity of the Unit.
- The Unit should not be used adjacent to or stacked with other equipment 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.
- Per IEC 60601-1-2, no additional environmental operating conditions are required for normal use

3. SAFETY NOTES

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



Safety

This is the safety alert symbol. It is used to alert you to potential personal injury hazards. Obey all safety messages that follow this symbol to avoid possible injury.



Warnings

Never modify the Device or any of its equipment. Any modification may compromise safety and effectiveness.

Handpiece

- When use the caries detector function, don't see the light with your eyes without protection, it's harmful to your eyes. In order to avoid the eyes getting in touch with the light directly, please assemble the eye protector.
- Do not use a damaged device; e .g. if among other things, the glass covers of the LED tip is scratched, broken or missing.
- The eye protection shields will wear over time. Exchange defect shield against spare shields included in the package or available as refill
- Only authorized technicians should repair the handpiece or battery pack.

Charging base

- Low voltages are present inside the charging base. Use only under dry conditions. Do not use if the charging base or handpiece is wet. Avoid short circuit between contact pads on the charging base. Only authorized technicians should repair the charging base.
- Do not use for voltages different from the range indicated on the charging base and power adapter.
- Always make sure handpiece, tips, and battery pack is completely reprocessed and thoroughly dry before inserting it into the charging base

Battery pack

- Prevent battery from short circuit during use and storage.
- Keep electrical contacts clean and dry.
- Do not remove battery pack from hand piece during operation.

Application

- Do not use the device for intraoral illumination or dental transillumination. Excessive heat may develop, causing burns to mucosa or pulpal irritation.
- Under curing of material may lead to post-operative sensitivity and/or premature restoration failure.
- Caries detector is intended to locate caries, not for definitive diagnosis.

Precautions

This product is intended to be used only as specifically outlined in these Instructions for Use.

- Do not use a Device which has not been properly reprocessed. Protect the Device from gross contamination by applying the single use barrier sleeve. Barrier sleeves are intended for single use only in order to prevent cross-contamination.
- Never aim the light directly at unprotected soft tissues, as this may cause injury or irritation. Do not aim the light at eyes. Light reflected from the tooth surface may also injure eyes. Use the eye protection shields supplied with the unit or protection glasses.
- Limit the action of the light to the area being treated.
- All dental curing lights cause a certain degree of heat development. Extended operation in areas near the pulp or soft tissues may result in severe damage. In these circumstances, do not cure for more than 10 seconds at a time without taking precautions such as air cooling.
- During heavy use (multiple curing cycles with 30s or less dwell between cycles), it is possible for the probe tip, which is an applied part, to reach up to 50° C. There should be no adverse effects resulting from short-term contact with intact skin or mucosa.
- Use only Manufacturer supplied power supply, power cord, charging base and battery. Use of any accessories other than specified in these Directions for Use may result

7. TECHNICAL DATA, WARRANTY TERMS

Technical Specifications

AC supply	AC100-240V / 50-60Hz
Charging Base Power input	5V, 1.5A
Operation Ambient temperature	5 °C - 40 °C
Operation Humidity	20% - 80%
Transport and Storage temperature	-10 °C - 55 °C
Transport and Storage Humidity	≤93% (non-condensing)
Battery performance	<ul style="list-style-type: none">• Recharge time: Approximately 2 hours.• 3.7V, 300 mAh
Curing light intensity	More than 1500 mW/cm ²
Output peak wavelength range	380 nm - 520 nm
Handpiece dimensions (with battery & tip)	Length 19.7cm; Width 1.35cm
Weight Handpiece with battery pack	75.5 grams

Classifications

Type of protection against electric shock Class II

Degree of protection against electric shock Type B Applied Part

According to medical device directive: I (Rule 12) (IEC 60601)

Disposal of Unit

For environmental reasons, dispose of device and battery according to local environmental guidelines or regulations.

Warranty terms

- Manufacturer grants a 2-year warranty on all components of the unit except the battery. The battery is covered by a 1-year warranty. The warranty commences on the date of purchase. Within the warranty period, Manufacturer will eliminate free of charge any defects in the appliance resulting from faults in material or workmanship either by repairing or exchanging parts or exchanging the whole device at Manufacturer's discretion .
- Not covered by this warranty: Damage arising from improper use (operation with incorrect

6. MAINTENANCE

Light output monitoring

- Make sure that the LED aperture is clean and scratch-free; otherwise light output will be reduced and may be insufficient for proper curing of the material.
- The light intensity should be checked frequently to ensure appropriate curing by using the radiometer incorporated into the charging base.

- Note:**
- The light radiometer can only be used to measure the curing light. For caries detection light, the measured value is inaccurate.
 - Before measuring, please turn the Rotary switch to **Cure**.
Do not continue to use if light output is below reference intensity.

Battery

- When the battery light shows solid orange the battery is charging. Upon complete recharging, the battery light remains permanently green. The battery needs approximately 2 hours to be fully recharged.
- If the battery pack needs to be replaced, simply pull the battery pack by pulling it from the main housing along its longitudinal axis.

General maintenance

- A thin coating of petroleum jelly may be applied to tip O-rings and charging base battery post as needed to facilitate insertion and removal.
- Inspect and replace worn or damaged O-rings as needed to maintain optimal performance.

in damage to the Device and its components.

- Sterilizing the Device, components and accessories will cause component damage and may cause bodily injury. The eye protection shields may be autoclaved.
- Failure to follow recommendations for environmental operating conditions could result in injury to patients or users
- Inspect equipment before each use for worn, loose or damaged parts.
- There are no user serviceable parts except the O ring attached to the coupling end of the light tips. Opening any of the components may result in unsafe operation and will void the warranty
- This device must not be used in the presence of a flammable anesthetic gas mixed with air, oxygen or nitrous oxide.
- User should not touch the patient and accessible charging base contacts simultaneously. Wear suitable protective eyewear, mask, clothing and gloves. Protective eyewear is recommended for patients.
- Do not spray disinfectant or other fluid directly onto the light, tips, battery, charging base, power supply or cord.
- Prevent liquids from entering the curing light body (handpiece), battery back, and charging base.
- Do not place the system on or next to a radiator or other heat source. Excessive heat may damage the system's electronics.

Adverse Reactions

- Prolonged unfiltered exposure to the light source may cause damage to the eye. (See Warnings).
- Prolonged contact with soft tissue may cause injury or irritation to the tissue. (See Warnings).
- Medical conditions such as solar urticaria, erythropoietic protoporphyria or cataract surgery may be aggravated by exposure to emitted light. (See Contraindications, Precautions).

4. STEP-BY-STEP INSTRUCTIONS

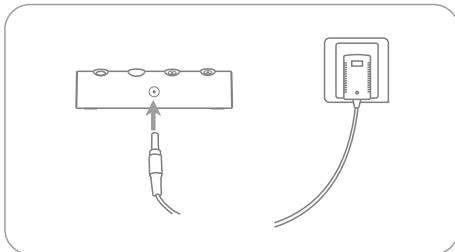
Installation

1. Attach the tip to the handpiece by firmly pressing tip into handpiece opening while slightly rotating at the same moment.
2. Adjust the LED tip: The LED tip is rotatable by 360°, thus the position of light emission may be individually adjusted.
3. Insert battery pack into the handpiece.



Charging

1. Connect the charging base to the adaptor cord.
2. Make sure power socket used for power connector is accessible at all times in case of necessary emergency disconnection.
3. Insert the battery onto the charging base.



- Full Cycle: 134°C for 3 minutes 30 seconds.
- Follow manufacturer's instructions for loading and operation cycle.

Drying

For handpiece, tip and Charging Base

Wipe the devices dry with a sterile, clean, lint-free cloth. Allow the components to fully air dry before storage.

For Light Shield

Use the drying cycle of the autoclave, minimum 30 minutes. Allow the components to fully air dry before storage.

Maintenance, Inspection and Testing

- Visually inspect to ensure that all contamination has been removed. Visually inspect power supply and cord for damage.
- Components that are damaged, worn, or distorted such as the O-rings should be discarded and replaced.

Storage

Store the components at room temperature, away from moisture or excessive humidity.

Disinfection

1. After cleaning, wipe all device surfaces with a new single use cloth in combination with an alcohol based, tubercuicidal, quaternary ammonium solution, 5 minute contact time, use according to disinfectant solution manufacturer's Instruction for Use. Use a separate wipe for 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.
2. Use fresh wipes to disinfect the probe tip or ring area, handpiece mating cavity, and battery/handpiece mating seam for the entire contact time. Use care to ensure cleaning agent is applied only to the top of the cavity interior. Ensure only minimal cleaning agent enters the cavity that houses the electrical pins. Immediately absorb excess fluid with a dry disposable towel.
3. 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 seams, especially around the probe 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.
4. Wipe device with a fourth dry, sterile lint-free cloth to remove all fluid.
5. Allow the devices to air dry for at least 5 minutes

Packaging

No particular requirements.

Sterilization

For handpiece, tip and Charging Base

- Sterilization is not allowed.
- Do not subject components to Steam autoclaving or liquid chemical sterilant immersion. Component damage will occur.

For Light Shield

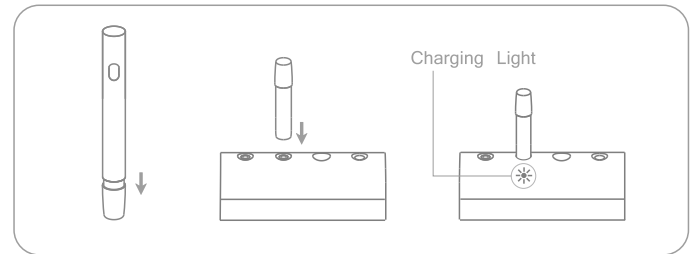
- After manual cleaning, and any optional disinfection or Automated Washer-Disinfecter cycle, steam autoclaving is required.
- Prevacuum Steam Sterilization:

Note: The device comes with two batteries. It is recommended that the battery not being used is stored on the charging base so that it is fully charged when needed.

4. Charging Light.

Note: No light with battery on top indicates missing contact.

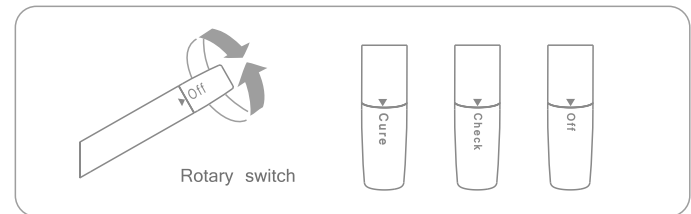
- **Solid orange:** Battery is charging
- **Solid green:** Battery is fully charged



Operation at a glance

Rotary switch: The battery pack is also a rotary switch. You can choose different functions by operating it.

- **Cure:** Curing light
- **Check:** Caries detector
- **Off:** Power off



Indicator lights: under the Key, solid light or flashing means different functions

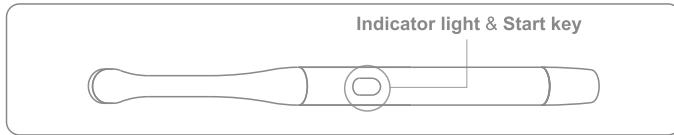
- **Solid green:** Curing light
- **Slowly flashing green:** Caries detector
- **Fast flashing green:** Battery has low power

Note: If the battery has low power, it must be exchanged to continue to operate.

Start key: Starts or disrupts working.

- **Cure:** Press once for 10 second cycles, Double press for 20 second cycles.
- **Check:** Press once for 30 second cycles, Double press for 60 second cycles.

Note: After no key operation for 3 minutes in standby mode, the unit will automatically sleep to save power. Press the Start key to wake up.

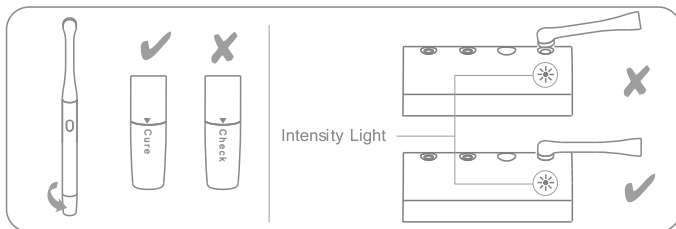


Curing Light radiometer

There is a light radiometer on the charging base to test the intensity of the curing light.

- Note:**
- The light radiometer can only be used to measure the curing light. For caries detection light, the measured value is inaccurate.
 - Before measuring, please turn the Rotary switch to **Cure**.

- **Solid orange:** Light output is below 1000 mW/cm² and not adequate (e.g. wrong positioning, contaminated, or scratched lens).
- **Solid green:** Indicates irradiance of at least 1000 mW/cm².



1. Remove eye protection Shield.
2. Remove protective barrier sleeve and discard.
3. Scrub with an impregnated wipe or disposable towel soaked with an alcohol based, tuberculocidal, until it is free of visible residues.
4. **Special Note:** use care when cleaning the mating surfaces of the probe tip and handpiece. Use only a moist impregnated towel.

- For the tip: Vigorously scrub the area near the o ring with a fresh wipe. Ensure fluid covers o ring and surrounding crevices. When cleaning the mating surface, ensure that cleaning agent only contacts the sides that fit within the handpiece (with O-ring). Avoid applying cleaning agent to the electrical contacts on the bottom of the probe tip.
- For the handpiece mating cavity: Use a fresh wipe to clean mating groove directly below the surface. Use care to ensure cleaning agent is applied only to the top of the cavity interior. Ensure only minimal cleaning agent enters the cavity that houses the electrical pins. Do not allow fluid to pool in the cavity around the contact pins. Immediately absorb excess fluid with a dry disposable towel.
- For the battery and handpiece mating seam: Use a fresh wipe to clean mating groove. Remove all visible soil, ensuring fluid penetrates all crevices. Use fresh wipes to rub fluid into the crevices. Do not allow solution to penetrate the casing. Discard used wipes. Additional wipes may be used.
- Do not remove battery pack from light handpiece. Do not attempt disassembly of charging base.

5. Remove cleaning solution residue with a damp cloth.
6. Allow the devices to air dry for at least 5 min.

For Light Shield

1. Scrub with hot water and immerse shield in a pH-neutral, phosphate-free cleaning detergent solution. Clean with a soft brush for at least 30 seconds until free of all visible contamination.
2. Rinse under running potable water.
3. Dry with a lint-free single-use cloth.

5. Cleaning, Disinfecting and Sterilization



Cross-contamination

- Do not reuse single use products. Dispose of in accordance with local regulations.
- The barrier is designed for single use and must be disposed of after each use in accordance with local regulations. The barrier is not a replacement for cleaning, disinfection, and sterilization.



Electrical short-circuit or dangerous malfunction

- Safeguard handpiece against liquid penetration during cleaning and disinfection.



Warnings

- The Shield should be removed and cleaned / disinfected / sterilized. The handpiece, tips and charging base are not Sterilizable by autoclave. The unit cannot tolerate high-level disinfection procedures.
- Intermediate-level disinfection is appropriate for the handpiece, tips and charging base.
- Do not clean or disinfect with chlorine bleach/sodium hypochlorite (corrosion of contacts) or Lysol® Brand I.C.™ Disinfectant Spray (cracking of charging base).
- Disconnect the power supply plug from the power outlet and charging base unit prior to cleaning/disinfection.

Preparation before cleaning

Always disassemble Tip from handpiece before processing. Use moderate force to pull the probe tip from the handpiece.

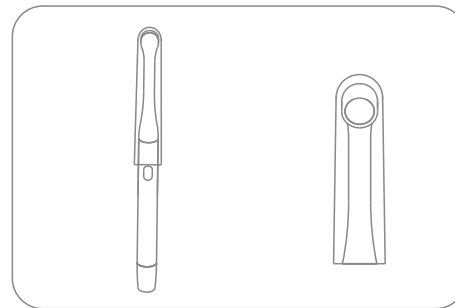
Cleaning

Do not use automated washer/disinfectors for reprocessing all the parts. Component damage will occur. They have to be manually cleaned.

For handpiece, tip and Charging Base

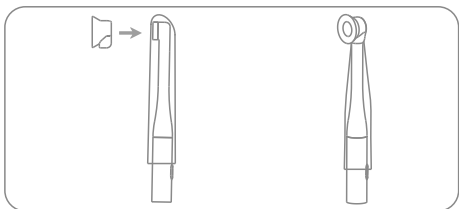
Preparation before operation

1. Protect LED tip from gross debris single use barrier protection sleeve. Make sure that the lens is not blocked by crinkles or seam of the sleeve.



Cross-contamination

- Ensure the disposable polyethylene barrier protection sleeve has been correctly applied over the entirety of the LED tip.
 - The Polyethylene barrier Sleeve does not replace cleaning and disinfection of the dental instruments.
2. Attach the eye protection shields supplied with the unit in combination with barrier protection sleeves. Hold the tip over the opening of the shield and turn the tip against the shield by 90° into its final position.
 - Always make sure eye protections shields are securely fixed to unit to avoid accidental aspiration (press eye protection shield firmly into correct position). Always make sure eye protection shields are properly mounted on unit without covering the light aperture.
 - Always make sure the eye protection shields are securely fixed to the tip to avoid accidental aspiration (press the eye protection shield firmly into correct position)
 - Always make sure light aperture is not covered by the eye protection shields



3. Use suitable, light filtering safety glasses



High Intensity Light - Eye Damage

- Do not press activation button until properly positioned intraorally.
- Be sure everyone within the operating arena (patients, operators, assistants) is wearing appropriate protective filtering eyewear.
- Do not look directly at the light while it is activated.

Operation - Curing light

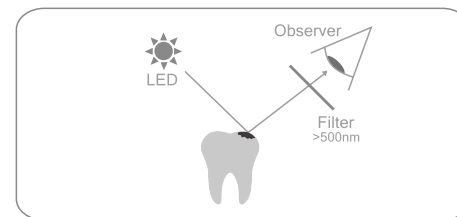
1. Operate the rotary switch to **Cure**;
2. The LED tip should be positioned as closely as possible to the restoration. Avoid shadowing by angulating the long axis accordingly. Fix correct position.
3. Polymerization: press the Start key to activate light.
 - Press once for 10 second cycles
 - Double press for 20 second cycles.
4. To stop curing light before the end of the cycle, press Start key at any time.
5. Please refer to respective material's Instructions for Use and apply curing times specified for 1000 mW/cm².

Operation - Caries detector

1. Operate the rotary switch to **Check**;
2. The distance between the light and the tooth should be about 5-10mm.
3. Check: press the Start key to activate light.
 - Press once for 30 second cycles
 - Double press for 60 second cycles.
4. Tooth will be displayed fluorescent when the light touches it; the fluorescent results

of the light probe provide information about the cavities surface, which can aid treatment. The substance that with different health degree will show some difference on colors, the fluorescent green area indicates the healthy substance; the fluorescent red shows the caries.

5. To stop check light before the end of the cycle, press Start key at any time.



6. Treatment

- Unit assists operators when excavating caries in already open cavities and functions as a visual detection and monitoring tool. It works by highlighting carious tooth material in fluorescent red and healthy tooth material in fluorescent green.
- Unit cannot assess initial caries.
- Use Unit if an initial diagnosis has been made and a decision has already been made on how the caries is to be treated and if the cavity is open.
- The fluorescent results of Unit provide extensive information, which can be used for treatment. The final decision as to whether treatment is performed and how long it should last is made by the user.
- Avoid external sources of light to ensure that the distinction between red and green fluorescence is clearly maintained. Turn the OP lights away or switch them off while using Unit.
- While excavating a deep caries, the fluorescent light may appear brown near the pulp. The reason for this has not been fully established. In this case in particular, a further detection tool (e.g. probe) can be used to decide on the course of treatment.
- After removing carious tooth material, we recommend checking the cavity with Unit before finishing the process.