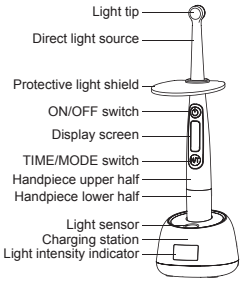
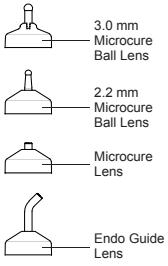
C03-C

CARBOLITE CURING LIGHT INSTRUCTIONS



Intended use: This curing light is intended for use by trained dental professionals for the purpose of light curing dental resins and composites

C03-C CARBOLITE SPECIFICATIONS	
DIRECT LIGHT SOURCE	10 mm (dia.)
LIGHT WAVELENGTH	385 ~ 515 nm
APPLICATION	General/ Ortho



Contents:
- C03-C Curing Light with charging station and built-in light intensity indicator
- C03-C-2 Protective Light Shield
- 228 Disposable Curing Light Sleeves (100 pcs)
- C03-C-3 USB-C Power Adaptor 100 - 240V
- C03-C-4 Battery 1900mAh
- C03-C-5a Endo Guide Lens
- C03-C-5b 3.0mm Microcure Ball Lens
- C03-C-5c 2.2mm Microcure Ball Lens
- C03-C-5d Microcure Lens

ENVIRONMENTAL FACTORS:
Operation: 5ºC~40ºC / 30%~75% relative humidity/ 700hPa~1060hPa atmospheric pressure.
Transportation and Storage: -20ºC~55ºC / 10%~95% relative humidity / 700hPa~1060hPa atmospheric pressure.

PRIOR TO INSTALLATION AND START-UP OF THE UNIT READ THESE INSTRUCTIONS CAREFULLY.

This device must be used in strict conformity with these instructions. The manufacturer rejects all liabilities if instructions are not followed or if the device is used for any other applications.

⚠ WARNINGS AND CAUTION:
- High intensity curing lights produce more heat. This is a direct indication of the power of the light being emitted.
- The light radiation produced by this type of device can be dangerous and MUST NOT be pointed at the eyes.
- The light produced by this device must be directed only at the zone to be treated in the oral cavity.
- When using the device for more than 10 seconds, do not keep the light tip in one position. It is always recommended to use a dental syringe to blow a cold air flow on the area during long periods of curing. This will maintain a lower temperature for the composite and surrounding area, particularly when using rubber dam so as to avoid any rubber dam breakage due to heat built-up.
- Uninterrupted exposure times of the same tooth surface in excessive time and direct contact with oral mucosa or skin must be strictly avoided. Polymerization at intermittent intervals is recommended.
- Avoid the light tip coming into contact with any soft tissue in the mouth and do not expose soft tissue to the light being emitted for more than 2 seconds or burns may occur.
- There are many variables (distance and angle between the light tip and composite, area, shade thickness and type etc.) affecting composite curing times. It is recommended to place and cure a maximum of 2 mm for each composite placement. The light tip should be placed approximately 1-2 mm above the composite or resin and pointed perpendicular to the tooth surface.
- Using a barrier sleeve on the curing light will reduce light intensity by 5-10% affecting curing times.
- Always use protective shields and eyewear during curing light operation.
- Do not use the device near a heat source. Do not use solvents, detergents or flammable products to clean or immerse the device in, this may damage the device or cause a short-circuit.

- Prevent any liquid from entering the curing light, charging station or power adaptor.
- Never modify the device or any of its components. Any modification may compromise its safety and effectiveness.
- The curing light is not field-repairable. Do not disassemble this product. Unqualified repairing or tampering with internal parts may lead to serious injury and will VOID the manufacturer's warranty.
- Use only with the adaptor provided by the manufacturer.
- Check the device before every use. Do not use the device if it is damaged in any way. The continuous use of a damaged device may cause injury or improper results.
- Do not place the device in a position where it is difficult to disconnect from the power supply.
- Charge the device for no less than 4 hours before use.
- When the device is not in use, turn off the power switch and unplug the power plug.
- Charge the device for no less than 2 hours before use if it has not been used for longer than one month.
- The light intensity should be checked regularly with the light intensity meter.
- If the device is used continuously for 60 seconds with the light intensity greater than 1,200 mW/cm², it is recommended to allow the device to cool down before resuming use.

INSTALLATION:

A. CHARGING STATION:
- Plug in the power adaptor connection to the back of the charging station.
- The light intensity indicator screen on the charging station will display the charging status if the power and the power supply is turned on.

B. CURING LIGHT HANDPIECE:
- Put the battery (included in the box) inside the lower half of the handpiece. Connect the handpiece upper and lower halves together by screwing the lower half into the upper half. Ensure the handpiece is connected securely.
- Put the curing light onto the charging station as shown in the above diagram. The "CHARGING" indicator will display on the light intensity indicator screen on the charging station if the curing light is seated correctly in the station.
- The battery is not fully charged prior to shipment. Please charge the battery for a minimum of 4 hours prior to the first use.
- The curing light circuitry will automatically compensate for power fluctuation during use for a constant light intensity output.
- The display screen of the curing light handpiece will display the battery/ charging status of the curing light.
- When the curing light is fully charged, the FULL battery indicator light on the curing light will be displayed.
- When the battery is low, the battery symbol on the curing light handpiece display screen starts to flash and the curing light will cease working.
- Please recharge the curing light in the charging station.
- Do not connect the charging station to the power adaptor while not charging the device. Do not use the device while charging.

C. LIGHT INTENSITY:
- The light intensity should be checked regularly with the light intensity indicator that is built into the charging station. The light intensity output should be within the ranges indicated in our specifications. This provides a general indication and a benchmark but not an accurate reading.
- To check the light intensity, make sure the charging station is connected to the power supply and the light intensity indicator screen is on. Hold the light tip of the curing light at a 90° angle against the light sensor on the charging station and switch on the curing light (Check CHANGING OF SETTINGS AND USE for how to switch on this curing light). The light intensity will be shown on the light intensity indicator screen.
- If the curing light intensity reading indicated is less than 20 percent of the range in our specifications, it should be sent to a Premium Plus authorized dealer for repair. It may also indicate the device is past its service life and should be replaced.

CHANGING OF SETTINGS AND USE:
- Activate the curing light by pressing the ON/OFF switch.
- To change the mode, press the TIME/MODE switch and hold for 1 seconds. Select NORMAL, HIGH, TURBO, ORTHO, PULSE, RAMP, CHECK or SOFT modes by continually pressing and hold for 1 seconds to locate the mode. Refer to the Table ''CURING LIGHT MODE APPLICATIONS" for the applicable mode settings.
- To change the time, press the TIME/MODE switch for 0.5 seconds. Time can be selected in different increments for NORMAL, HIGH, TURBO, ORTHO, PULSE, RAMP, CHECK and SOFT modes. Refer to the Table ''CURING LIGHT MODE APPLICATIONS'' for the applicable time settings.
- Left or right-handed operation: In the standby mode select the SOFT mode for 15 seconds. After pressing the ON/OFF switch, the output will start. Immediately press and hold the ON/OFF switch, the light output will turn off and the display will switch between the left and right-handed operation.

- Every start and end of the program or every change of time or mode will be signaled with a "beep".
- The curing light will automatically turn off if it is not in operation for 2 minutes. It will keep the last selected program in memory once restarted.
- The operation can be stopped at any time before the countdown ends by pressing the ON/OFF switch.
- Put on the disposable curing light sleeve to cover the entire curing light for cross infection control. The curing light is now ready for use. Press the ON/OFF switch to activate the curing light if the display screen is off. When the preparation for light curing is ready, press the ON/OFF switch to start using the curing light.
- After the light curing process is finished, remove and dispose the curing light sleeve for every patient.

CURING LIGHT MODE APPLICATIONS:

MODE	APPLICATION	SPECIFICATION
NORMAL	For general applications.	1,200 mW/cm² for 5, 10, 15, 20 seconds ±10%
HIGH	For quick curing to ensure enough curing depth. Resin and composite that is no more than 2mm thick. Also recommended for ceramic brackets, bonding veneers etc.	2,000 mW/cm² for 1, 3, 5 seconds ±10%
TURBO	For super fast curing of resin and composite that is no more than 2mm thick. Also recommended for ceramic brackets, bonding veneers etc.	3,000 mW/cm² for 1, 3 seconds ±10%
ORTHO	For orthodontic applications. 3 second mesial + 3 second distal for metal brackets resin bonding (with 1 sec blink in-between).	**Ort x 05** 2,500 mW/cm² for 5 x 3 seconds with 1s interval ±10% OR **Ort x 10** 2,500 mW/cm² for 10 x 3 seconds with 1s interval ±10%
PULSE	Pulse effectively reduces heat generation, efficiently dissipates heat shrinkage and ensure comfort during treatment.	1,200 mW/cm² for 5, 10, 15, 20 seconds with 0.2 seconds off ±10%
RAMP	First 0-5 seconds are ramped for general applications.	1st five seconds from 0-1,200 mW/cm² next 5, 10, 15 seconds 1,200 mW/cm²
CHECK	For detecting caries, calculus and cracked teeth.	Purple light for 30 or 60 seconds
SOFT	First 0-5 seconds are ramped for more gentle processing, designed for patients sensitive to heat.	900 mW/cm² for 5, 10, 15, 20 seconds ±10%

CURING LIGHT LENSES APPLICATIONS:

MICROCURE LENS	For curing small and medium sized filling materials and to tack curing veneers.
2.2mm & 3.0mm MICROCURE BALL LENS	Holds matrix against contact while curing composite for Class II restorations.
ENDO GUIDE LENS	For curing apex position on the tooth and other limited areas.

TROUBLE SHOOTING:

FAULT	POSSIBLE CAUSE	SOLUTION
Device not turning on.	1. Out of battery. 2. Faulty battery.	1. Charge curing light for no less than 2 hours. 2. Replace with new battery.
Insufficient light intensity.	Resin remaining on the surface of the light tip.	Clean light tip and remove any resin.
The device is not charging when connected to the charging station.	1. The power adaptor is not connected correctly. 2. Faulty/incompatible power adaptor. 3. Faulty charging station.	1. Check the connection. 2. Change the adaptor. 3. Connect power adaptor directly into the bottom of the curing light handpiece to confirm if charging station is at fault. If yes, replace charging station.
Shorter operating time when fully charged.	Battery capacity decreased.	Replacement battery required. Contact authorised Premium Plus dealer.
Mode indicator flashes when charging.	Low voltage.	Charge for longer than 15 minutes.

If fault persists contact authorised Premium Plus dealer.

CLEANING AND DISINFECTING:

- The curing light and charging station can only be cleaned with a non-alcohol based disinfectant wipe for cold sterilization only.
- The device is not suitable for steam and high pressure sterilization. It may result in damage to the device.
- Switch off the curing light and disconnect the charging station from the power supply.
- Remove the disposable barrier sleeve and dispose of it in accordance with applicable legal requirements.
- Remove any residues, clean with clean water or neutral sterilized liquid. Do not soak.
- Do not use highly volatile and diffluent solvent.

WARRANTY: Curing light is warranted to the original purchaser against any defective workmanship and materials under accepted installation, use, and service for a period of 12 months from date of purchase.

SYMBOLS:

CE	CE Mark	MD	Medical Device
	Date of manufacture		Refer to instruction manual/booklet
LOT	LOT Number		Caution
SN	Serial Number		Keep dry
REF	Catalogue number		Fragile, handle with care
	Manufacturer		Class II Equipment
EC REP	EU Authorised Representative		Type B Applied Part
	Importer	IPX0	Protection from ingress of liquids into handpiece rating
	Distributor		Electronic Waste: properly dispose of when use is discontinued
-20°C +55°C	Temperature limit: -20°C ~ +55°C	10% 93%	Humidity limitation: 10% ~ 93%
70kPa 106kPa	Atmospheric pressure limitation: 70kPa ~ 106kPa		

EMC-DECLARATION OF CONFORMITY:

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS	
Emissions test	**Compliance**
RF emissions; CISPR 11	Group 1
RF emissions; CISPR 11	Class A
Harmonic emissions; IEC 61000-3-2	Not Applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY		
Immunity test	**IEC 60601-1-2 Test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/ burst IEC 61000-4-4	±2 kV power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV power supply lines Not applicable 100 kHz repetition frequency
Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0° 0 % UT; 250/300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE UT is the a.c. means voltage prior to application of the test level.		

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY						
	Test Frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**IEC 60601-1-2 Test Level (V/m)**	**Compliance level (V/m)**
Radiated RF IEC 61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380-390	TETRA 400	Pulse modulation 18 Hz	27	27
	450	430-470	GMRS 460, FRS 450	FM ± 5kHz deviation 1 kHz sine	28	28
	710	704-787	LTE Band13, 17	Pulse modulation 217 Hz	9	9
	745					
	780					
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28	28
	870					
	930					
	1720	1700-1990	GSM 1800, CDMA 1900, GSM 1900, DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28	28
	1845					
	1970					
	2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28
	5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9
	5500					
	5785					

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY				
Radiated RF IEC 61000-4-39 (test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	**Test frequency**	**Modulation**	**IEC 60601-1-2 Test Level (A/m)**	**Compliance level (A/m)**
	30 kHz	CW	8	8
	134,2 kHz	Pulse modulation 2.1 kHz	65	65
	13,56 kHz	Pulse modulation 50 kHz	7,5	7,5

WARNINGS:

- Do not use near active HF surgical equipment and in the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

LIST OF CABLES:

No.	Name	Length	Shielded or not	Detachable or not
1	Power adaptor output cable	1.2m	No	Yes

REPLACABLE ACCESSORIES:

No.	Name	Model Specification	Connection method
1	Power adaptor	C03-C-3	Plug
2	Battery	ICR 18500	Battery connector

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