

C01-X

CURING LIGHT

INSTRUCTIONS

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

C01-X SPECIFICATION	
F.O. LIGHT GUIDE	11 mm (dia.)
LIGHT WAVELENGTH	390~430 nm & 440~480 nm
APPLICATION	General / Ortho
MAXIMUM LIGHT INTENSITY	2000 mW/cm ²

- Contents:**
- C01-X Curing Light Handpiece with Charging Station
 - C01-X-1 11 mm Fibre Optic Light Guide
 - C01-2 Protective Light Shield
 - C01-4 Autoclavable Tack Rings (6 pcs)
 - 123M Disposable Curing Light Sleeves Medium (100 pcs)
 - C01-X-LH Handpiece Lower Half including battery
 - USB Type-C plug cord

ENVIRONMENTAL FACTORS:

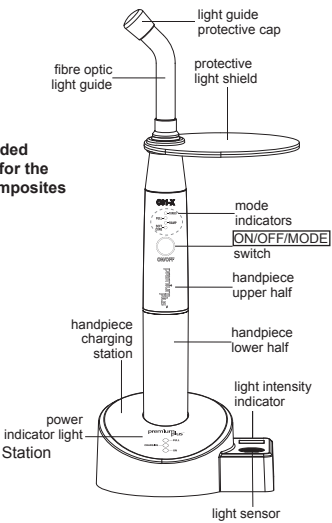
Operation: 10°C~40°C / 30%~75% relative humidity / 700hPa~1060hPa atmospheric pressure
Transportation and Storage: -10°C~55°C / 10%~95% relative humidity / 700hPa~1060hPa atmospheric pressure

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. The temperature of the applied part may exceed 41°C.
- 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 guide 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 guide 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 supply.
- Never modify the device or any of its components. Any modification may compromise its safety and effectiveness.
- The curing light is not field-repairable except changing the handpiece lower half including battery. Do not disassemble this product. Unqualified repairing or tampering with internal parts may lead to serious injury and will VOID the manufacturer's warranty.
- 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 difficult to disconnect from the USB power supply.
- Charge the device for no less than 2 hours before use if it has not been used for longer than one month.
- US Federal Law restricts this device to sale by or on the order of a health care professional/ dentist.
- Curing light shall not be serviced or maintained while in use with a PATIENT.
- The normal function of the product may be disturbed by strong electro-magnetic interference. If so, simply reset the product to resume normal operation by following the instructions. In case the function could not resume, please use the product in other location.
- Please properly dispose of this product and its accessories when use is discontinued.
- If any serious incident has occurred in relation to the use of this device, please report the incident immediately to both the manufacturer and the competent authority in your Member State.

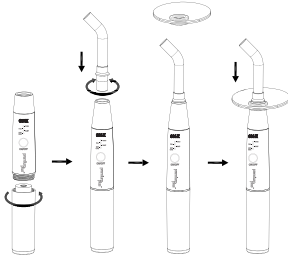
INSTALLATION:

A. CHARGING STATION:

- Plug in USB Type-C plug cord with the charging station and the USB power supply (not included, recommended 5V & 2000mA, no less than 5V & 1000mA).
- Turn on the **ON/OFF** switch at the back of the charging station.
- The Charging Station power indicator light will be on if the power is connected and the **ON/OFF** switch is in the "ON" position.

B. CURING LIGHT HANDPIECE:

- Insert 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.
- Insert the fibre optic light guide into the curing light handpiece with a TWISTING motion. Ensure the light guide fits securely in the handpiece.
- Put the curing light in the charging station as shown in the diagram on page 1. The "CHARGING" indicator light will be on if it is fitted correctly into the charging station.
- The battery is not fully charged prior to shipment. Please charge the battery for a minimum of 2 hours prior to the first use.
- When the curing light is fully charged, the "FULL" indicator light on the charging station will turn on.
- The curing light circuitry will automatically compensate for power fluctuation during use for a constant light intensity output.
- Indicator light for the current mode flashes when the battery is low and the curing light will cease working. Please recharge the curing light in the charging station.
- We recommend placing the curing light into the charging station to charge whenever the curing light is not in use.
- Continually charging the curing light will not affect the life of the battery as the unit has a built-in safety function that will stop charging when the battery is full.



C. LIGHT INTENSITY:

- The light intensity output 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

manufacturer's 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 power indicator light is on, remove the light guide protective cap from the light guide tip, clean both the light guide tip and light sensor. Hold the curing light and place the light guide tip (as shown Fig. 1-3) at a 90° angle against the light sensor next to the light intensity indicator on the charging station and switch on the curing light (Check CHANGING OF SETTINGS AND USE for how to switch on the curing light). The light intensity will be shown on the light intensity indicator (The readout is in multiples x100).

Fig.1



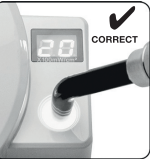
Light guide too far away. Unit will display low or no results.

Fig.2



Light guide not held flat against the light sensor. Unit will display incorrect results.

Fig.3



Light guide held flat and fitting exactly on the light sensor. Unit will display correct results.

- If the curing light intensity reading indicated is less than 20 percent of the range in manufacturer's specifications, it should be sent to a Premium Plus authorized dealer for repair. It may also indicate it is time to replace it with a new curing light.

CHANGING OF SETTINGS AND USE:

- Activate the curing light by pressing the **ON/OFF/MODE** switch ONCE, the indicator light for the last selected mode will be on.
- The curing light is preset in the factory at "FULL" mode.
- To change the mode, press and hold **ON/OFF/MODE** switch for 3 seconds, the curing light will signal with one 'beep', and the indicator light for the selected mode flashes.
- Continue pressing the **ON/OFF/MODE** switch to locate the mode required.
- The mode will be locked after 2 seconds if there are no further changes to the settings. To change, press and hold the **ON/OFF/MODE** switch for 3 seconds to unlock.
- Every start and end of a programme or every change of mode will be signaled with a 'beep'.
- The curing light will automatically turn off if it is not in operation for 1 minute. It will keep the last selected programme in memory once restarted.
- To start using the curing light, take off the protective cap from the light guide.
- Put on the disposable curing light sleeve to cover the whole curing light for cross-infection control.
- Put on the protective light shield from the top of the fibre optic light guide until it is firmly held. The curing light is now ready for operation.
- If the curing light is off, press **ON/OFF/MODE** switch to activate.
- When the preparation for curing light is ready, press **ON/OFF/MODE** switch to start using the light curing.
- After the light curing process is finished, remove and dispose the curing light sleeve for every patient.

CURING LIGHT MODE APPLICATIONS:

MODE	APPLICATION	SPECIFICATION
TURBO	Super fast curing for resin and composite that is no more than 2 mm thick. Also recommended for ceramic brackets, bonding veneers etc.	2,000 mW/cm ² for 4 seconds±10%
TURBO for TACKING*	Recommended for tack application using Tack rings with TURBO mode. Place the Tack ring onto the light guide tip and start the cure for desired time (recommended 1-4 seconds). Tack rings are included inside the box.	2,000 mW/cm ² for 4 seconds±10%
FULL	For general applications.	1,200 mW/cm ² for 10 seconds±10%
RAMP	First 0-5 seconds are ramped for general application.	20 seconds: 0-5 seconds from 0-1,200 mW/cm ² ±10% 5-20 seconds 1,200 mW/cm ² ±10%
SOFT CURE	First 0-5 seconds are ramped for more gentle processing, designed for patients sensitive to heat.	20 seconds: 0-5 seconds from 0-900 mW/cm ² ±10% 5-20 seconds 900 mW/cm ² ±10%

DEPTH OF CURE:

MODE	Intensity mW/cm²	Time	Depth Measurements	ISO 4049 Depth Measurements (-50%)
TURBO	2,000±10%	4 seconds	4.3 mm	2.15 mm
FULL	1,200±10%	10 seconds	4.4 mm	2.20 mm
RAMP	1,200±10%	10 seconds	4.2 mm	2.10 mm
SOFT CURE	900±10%	15 seconds	4.6 mm	2.30 mm

Data is only for reference, always follow the instructions from your resin and composite manufacturers.

Remarks: Above data is based on test results using an A2 shade composite. The light guide tip was placed above and pointed perpendicular to the composite. Tests were done as per ISO 4049 Standard. The samples were measured and the data was divided by two (50% of the total composite depth cured). ISO 4049 Standard requires that the results for class II restorative materials should be at least 1.5 mm for non-opaque shades and 1.0 mm for opaque shades. All resins and composites have different curing times. It is strongly recommended that you should test your composite and resin performance to determine the curing times required.

TROUBLESHOOTING:

FAULT	POSSIBLE CAUSE	SOLUTION
Curing light doesn't turn on	1. Out of battery 2. Faulty battery	1. Charge curing light in curing light charging station for minimum 2 hours 2. Replace battery
Curing light handpiece not charging when in charging station	1. Power supply not connected properly to curing light charging station 2. Charging base not turned on	1. Ensure cable and power supply are all connected properly 2. Turn ON switch at back of charging station 3. Use power supply output no less than 5V & 1000mA (suggested 5V & 2000mA)
Insufficient light intensity	1. Resin cured to fibre optic light guide tip 2. Damaged fibre optic light guide	1. Clean fibre optic light guide tip. Use barrier sleeves 2. Replace fibre optic light guide

If fault persists contact Premium Plus authorized dealer

CLEANING AND DISINFECTING:

- Turn off the curing light and disconnect the USB cord from the USB power supply.

A. CURING LIGHT HANDPIECE & CHARGING STATION:









- Use only non-alcohol based disinfectant wipes for cleaning.
- These components are suitable for cold sterilization only.












B. FIBRE OPTIC LIGHT GUIDE & TACK RINGS:

- The light guide and tack rings are autoclavable.
- Remove the tack ring from the light guide. Remove the light guide using a twisting motion. After removal, clean both the tack ring & the light guide using a water-soaked nylon brush to remove dirt or debris. Wipe them dry with a clean cloth or wipe.
- Autoclave the light guide and tack ring according to ISO 17665-1, at 121°C (250°F) for at least 15 minutes. Always follow the manufacturer's instructions for your autoclave.

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 24 months from date of purchase.

SYMBOLS:

	Symbol for "Class II Equipment"		Electronic Waste: properly dispose of when use is discontinued
	Symbol for "Manufacturer"		LOT Number
	Symbol for "Authorised Representative in EU"		Symbol for "Type B Applied Part"
	Symbol for "Authorised Representative in UK"		Follow Instructions for use

	Symbol for "Importer"	IPX0	Symbol for "protection from ingress of liquids into handpiece"
	Symbol for "Distributor"		Symbol for "Serial Number"
	Caution		Medical device
	Federal law restricts the sale of this device by or on the order of a dentist		Fragile, handle with care
	Atmospheric pressure limitation: 70kPa-106kPa		Humidity limitation: 10%-95%
	Temperature limit: -10°C-55°C		Keep dry

EMC-DECLARATION OF CONFORMITY:

WARNING:

- Do not use the device near active HF surgical equipment and RF shielded room such as the MRI room.
- 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 ME equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Note: The function of LED curing light is to cure dental resins and composites, and to output constant light. When the device is invalid or degraded due to electromagnetic disturbance, the user should stop using it immediately to ensure that there is no error caused by the product's performance failure or degradation. In this case, the user should remove the disturbance source or adjust the direction or position of the product, so that the product can work normally.

MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies

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 for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth
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 cycles	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 cycles
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
NOTE: UT is the a.c. mains voltage prior to application of the test level.		

MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY		
Immunity test	IEC 60601-1-2 test level	Compliance level
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 3Vrms (emf), 6Vrms (emf) in ISM bands between 0.15 MHz and 80 MHz 80%, 1 kHz	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 3Vrms (emf), 6Vrms (emf) in ISM bands between 0.15 MHz and 80 MHz 80%, 1 kHz
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m
Immunity to proximity magnetic fields in the frequency range IEC 61000-4-39	9 kHz to 13.56 MHz	See table 11 of standard Any one of its nominal input voltages and frequencies

MANUFACTURER'S DECLARATION - Immunity to proximity fields from RF wireless communications equipment					
Immunity test	IEC60601 -1-2 test level				Compliance level
	Test frequency	Modulation	Maximum power	Immunity level	
Radiated RF IEC 61000 -4-3	385 MHz	**Pulse Modulation: 18 Hz	1.8 W	27 V/m	27 V/m
	450 MHz	*FM+ 5 Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217 Hz	0.2 W	9 V/m	9 V/m
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18 Hz	2 W	28 V/m	28 V/m
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217 Hz	2 W	28 V/m	28 V/m
	2450 MHz	**Pulse Modulation: 217 Hz	2 W	28 V/m	28 V/m
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217 Hz	0.2 W	9 V/m	9 V/m
Note* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.					

BATTERY SPECIFICATION:

Portable, rechargeable lithium-ion battery, model: INR18490-200, 34.5 g, 2000 mAh, 3.6 V



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