

SPECIAL PRECAUTIONS FOR USE:

- Parkell® Curing Light emits high intensity light and must only be used as indicated in this manual.
- DO NOT look directly into the light output. Patients, clinicians, and assistants should always wear orange eye protection when the curing light is in use.
- USE CAUTION when treating patients who suffer from adverse photobiological reactions or sensitivities, patients who are undergoing chemotherapy treatment, or patients being treated with photosensitizing medication.
- DO NOT expose soft oral tissues at close proximity for more than 10 seconds in any mode. If longer curing time is required, use multiple shorter curing cycles to avoid heating soft tissue, or use a dual-cure product.
- Take extra care to avoid directing light toward soft tissues.
- Like all high-intensity curing lights, the Parkell Curing Light can generate significant heat when in use.
- This equipment is not suitable for use in the presence of a flammable anesthetic gas mixture.
- Discontinue or limit use if the patient experiences discomfort from heat.

DEVICE DESCRIPTION

The Parkell Dental Curing Light is a high intensity curing light for use with visible light-cured dental materials. It is designed with an ultra-low-profile head and a unique, ergonomically curved shape. This allows excellent access to all areas of the mouth, especially the hard-to-reach palatal and lingual surfaces.

The Parkell Curing Light uses four high-performance Light Emitting Diodes (LEDs) that emit a bright blue beam at a wavelength range of 420-480nm. The light will fully cure dental materials that contain camphorquinone (CQ) and/or 1-phenyl-1,2 propanedione (PPD) as the photo-initiator. Having an effective beam spot diameter of 10.7 mm with a user-selectable intensity of 1000 or 2000mW/cm², the Parkell Curing Light rapidly delivers complete curing of dental restorations.

The light is operated using a simple three button interface, allowing the user to control two distinct light intensities at up to three preselected timing modes. Once the curing cycle has been initiated for a 10- or 20- second timing mode, audible beep sounds occur at regular intervals to enable the operator to monitor the progress of the cure. The cycle can be terminated at any time by simply pressing the on/off button.

The Parkell Curing Light operates from a 3.7 volt, high-drain, rechargeable Lithium-Manganese (Li-Mn) battery, which is easily replaced by the user. When not in use, the curing light is stored in a convenient charging stand that is connected to a wall-mount, AC-to-DC transformer. The stand keeps the light upright, conserving valuable countertop space in the dental operatory, and eliminates the possibility of overcharging.

INDICATIONS FOR USE

The Parkell Curing Light is indicated for the polymerization of visible light-cured dental materials when used in accordance with the instructions provided, using clinically acceptable techniques.

CONTRAINDICATIONS FOR USE

The Parkell Curing Light is contraindicated for use by anyone other than a qualified, licensed dental professional trained in the placement of visible light-cured dental materials.



PRODUCT COMPONENTS:

- (1) Parkell Dental Curing Light (Stock No. D553)
- (1) Charging Stand (Stock No. D556)
- (1) Wall Mount Power Transformer / Charger (Stock No. D554)
- (2) Clear Plastic Curing Lenses (Stock No. D557)
- (1) Tacking Lens (Stock No. D558)
- (1) Plastic Barrier Sleeve Sample Pack (Bulk Refill Stock No. S130)
- (1) Instructions for Use

ALSO AVAILABLE:

- Replacement Battery (Stock No. D555)

SPECIFICATIONS

- Power Supply: Li-Mn battery, 3.7 V, 600mAh
- Wavelength Range: 420-480nm
- Light Intensity (approx.): 1000 or 2000mW/cm²
- Operation: Duty cycle of 1.5 minutes ON, 5 minutes OFF
- Dimensions (approx.): Length 9.1" (231 mm); Diameter 1" (25 mm)
- Weight (approx.): 3.1 oz (88 g)

WALL MOUNT POWER TRANSFORMER SPECIFICATIONS

- Operating Voltage: 100-240 VAC, 50/60Hz input
- Output Voltage: 5VDC
- Output Current: 2.0 A
- Dimensions: 3.4" (86 mm) x 1.8" (46 mm) x 1.3" (33 mm)
- Weight: 4.2 oz (120 g)
- Classification: Protection Class II Type B Applied Part
- Operating temperature: 15°- 30°C
- Relative humidity: 30% - 70%
- Battery Charge Time: 45 to 60 minutes

TRANSPORT AND STORAGE CONDITIONS

- Ambient temperature range: 3 - 40°C
- Relative Humidity range: 20% - 80%, non-condensing
- If storing the light for more than 14 days, remove the battery to protect the unit.

CHARGING YOUR CURING LIGHT

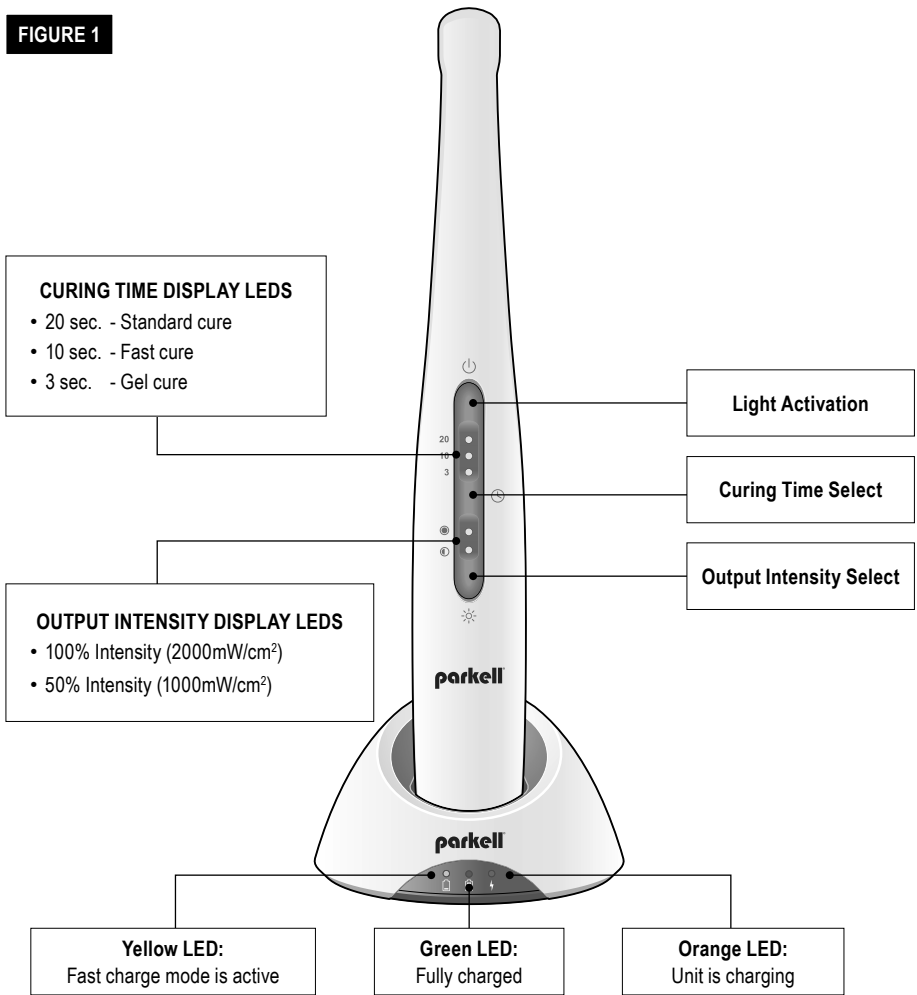
There are three Light Emitting Diode (LED) indicators on the front of the charging stand. From left to right, they are Yellow, Green, and Orange. The Orange LED indicates that the stand is plugged in, functioning normally, and receiving power from the wall power transformer. The Yellow LED indicates fast-charging mode is activated. The Green LED indicates that the curing light is fully charged.

Before using your new curing light for the first time, **let it charge for a minimum of 3 hours**. To charge the unit, connect the charging stand to the wall mount transformer, which will illuminate the Orange LED. Then insert the curing light into the charging stand, which will illuminate the Orange and Yellow LED's. When the unit is fully charged, the Orange and Green LED's will illuminate. If the light is not placed into the charging stand for a long period and the battery becomes discharged, the curing light will sound a series of beeps every few minutes to indicate it should be returned to the charging stand for continued operation.

When fully charged, the light can deliver at least seventy-two, 10-second curing cycles before needing to be recharged. Parkell recommends that the light be stored in the stand when not in use since it will not overcharge.

Use only the original Parkell charging stand and battery. The use of non-Parkell AC/DC wall plug adapters/chargers or non-Parkell batteries may result in damage to the unit and void the unit's warranty.

FIGURE 1



OPERATING THE CURING LIGHT

- The light is controlled using three buttons on the control strip on the back of the unit. They cycle between the color-coded LED mode indicators on the strip (Figure #1).
- To set the desired mode, press the **OUTPUT INTENSITY SELECT** Button to cycle between 1000 and 2000mW/cm². Then, select the curing time by pressing the **CURING TIME SELECT** Button to cycle between 3, 10 and 20 seconds. The preprogrammed modes are listed in the table in the section below. Remember that, for patient safety, the 2000mW/cm² intensity will **ONLY** illuminate for 3 seconds.
- To start the light in the most recently selected curing mode, press and release the **LIGHT ACTIVATION** Button. The light will shut off automatically at the end of the curing cycle.
- To turn the curing light off at any time during a curing cycle, press and release the **LIGHT ACTIVATION** BUTTON for a second time.
- If the light is not used for 10 minutes, it will go to "sleep" to conserve the battery. All the LED indicators will go out. The unit will remember the current mode setting. One press and release of any single button will wake up the light for immediate use in the most recently selected mode.
- Due to the variation in light-cured materials, curing times will differ between products and between batches of the

same product. Review the manufacturer's product instructions for their recommended curing times, using these times as a guide. However, ALWAYS bench test new materials with your light before using them on a patient, to verify the suggested curing time.

- If the patient is new to light-cured resin dentistry, explain to them about the purpose of the blue light, the sounds they will hear, and the heat they may sense, before use.

PREPROGRAMMED TIMING CYCLES

INTENSITY (mW/cm ²)	TIME (seconds)
1000 (50%)	3, 10, 20
2000 (100%)	3

****CLINICAL NOTE:** A 10-second "rest" (or non-illumination) period is strongly recommended following: (i) illumination 1000mW/cm² for 10 or 20 seconds, or (ii) illumination at 2000mW/cm² for 3 seconds.

A GUIDE TO THE CURING LIGHT'S AUDIO SIGNALS

During the 3-second curing cycle, a beeper will sound at the end of the cycle. During the 10 and 20 second curing cycles, the beeper will sound every 5 seconds. At the end of a curing cycle, the curing light will beep and the light will automatically shut off.

CHANGING THE CURING LIGHT LENS

To remove the curing light lens, simply grasp the rim and slide the lens away from the head, as shown in figure 2. This will unlock the lens, allowing you to easily withdraw it from the head. To attach the lens, line up the slots between the lens and curing light, and then slide the lens towards the head into position until it locks in place as shown in figure 2a.

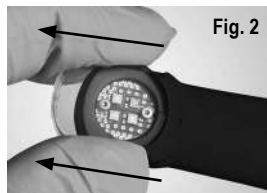


Fig. 2

The unit comes with two Clear lenses and one Tacking lens. Additional lenses may be purchased separately. Although the lenses are made of a durable, chemically-resistant plastic, they are considered consumable items, and are not covered by a warranty.

Before each use, the lens should be inspected for spots, scratches, cracks or adherent resin material that may interfere with output of the curing light. Wipe off the lens with a soft cloth wetted in appropriate disinfectant. Adherent, polymerized composite should be removed with alcohol or a non-scratching plastic spatula. Do not use any sharp or pointed tools. Periodically replace the lens when it is no longer clear or is reducing the output of the light. The curing light is meant to be used only with a disposable clear plastic barrier sleeve over the neck of the light. Samples are included in the kit, and bulk packs are available from Parkell or your dental dealer.

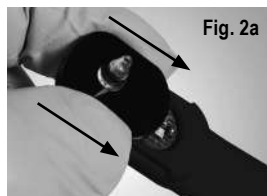


Fig. 2a

CHANGING THE BATTERY

The Parkell Curing Light uses a specially-designed, replaceable, high-current rechargeable Lithium-Manganese (Li-Mn) battery. Only replacement batteries obtained from Parkell should be used with the curing light. Use of other batteries may damage the device and **WILL VOID THE WARRANTY.**

1. Remove the battery cover, using a small screwdriver that fits snugly into the slot of the screw head.
2. Undo the screw two full turns.
3. Loosen the cover by gently pulling it away from the grip of the curing light.
4. No more than two additional turns will be needed to completely remove the battery cover.
5. Remove the old battery, taking care to note the orientation of the plus and minus tips. Dispose of it in accordance with all applicable state and local laws.
6. A new battery should be charged for 3 hours prior to use. Place the battery into the battery compartment so that the polarity (plus/minus orientation) is correct, as indicated in the battery compartment.
7. The battery door may then be replaced, and the Battery Door Screw may be carefully tightened.
8. After the battery has been replaced or disconnected for any reason, the battery protection circuitry must be reset

for the light to operate. To reset, place the curing light into the charging stand. Then remove it and set the desired curing time and a curing intensity setting.

9. Pressing the Start Button now will assure that the light is ready for operation.

CLEANING AND DISINFECTION

- Parkell highly recommends the use of single-use, curing light Barrier Sleeves (Bulk Refill Stock No. S130) to avoid surface contamination and prevent composite from bonding to the front of the lens.
- After each use, remove and discard the barrier sleeve. Clean the curing light by removing surface debris with a water-damp paper towel. Then disinfect the unit with a paper towel saturated with an EPA-registered intermediate-level ((HIV/HBV/tuberculocidal claim) hospital disinfectant. Afterwards, the chemical residue should be wiped off with a water-damp paper towel and the unit should be air-dried. **Utilize the surface disinfecting protocol of the disinfectant manufacturer, and/or consult www.CDC.gov for the most recent version of the “Guidelines for Infection Control in Dental Health-Care Settings”.**
- Parkell will not be responsible for units that have been improperly cleaned. To protect your warranty:
 - a. Do not use a steam autoclave, a dry-heat sterilizer, a chemical sterilizer nor a radiation sterilizer on any part of the curing light or its accessories.
 - b. Do not spray disinfectant directly onto the light. Always wipe the unit with a paper towel that has been dampened, but not saturated, with the appropriate chemical disinfectant.
 - c. Do not immerse the curing light or any of its accessories in disinfectant, water or other fluids.
 - d. Do not use phenolic-based disinfectants or alcohol to disinfect the light.
 - e. Always clean the light with a clear curing lens in place.







MAINTENANCE AND CARE

Other than the rechargeable battery, there are no user-serviceable components in the curing light. Only Parkell technicians are authorized to repair the unit.







CONFORMANCE TO STANDARDS

The Parkell Curing Light conforms to IEC60601-1. The device is CE marked - certified to European Medical Device Directive (93/42/EEC). Parkell's quality system is certified to ISO9001/13485, and CAN/CSA C22.2 No. 601.1.




EXPLANATION OF SYMBOLS USED

	<p>Medical Safety Classification Symbol: D553 (E) complies with Medical Class B electrical safety. This symbol is on the D553 (E) curing light, and on the packaging.</p>
	<p>Qualified User Symbol: D553 (E) is to be used only by trained dental or medical professionals. This symbol is on the packaging.</p>
	<p>Storage Temperature Symbol: Upper and lower temperature limitations: do not store or transport D553 (E) in area above 65° C (149° F) or below -34° C (-29° F). This symbol is on the packaging.</p>
	<p>Damage Symbol: Do not use if package is damaged. This symbol is on packaging.</p>
	<p>Instructional Symbol: Warning to read and follow instructions and pay attention to specific use warnings and cautions. This symbol is on the D553 (E) curing light, and on the packaging.</p>
	<p>Keep away from water.</p>




CURING LIGHT SYMBOLS







	Push-button for activation of the curing light.
	Push-button for curing cycle selection time.
	Push-button to choose one of two selectable optical intensity settings.
3	Three second curing cycle.
10	Ten second curing cycle.
20	Twenty second curing cycle.
	Indicates Parkell Curing Light is operating at 1000mW/cm ² (i.e. 50% power)
	Indicates Parkell Curing Light is operating at 2000mW/cm ² (i.e. 100% power)
	Hot surface symbol.

CHARGING BASE SYMBOLS




	Indicator showing battery is charging.
	Indicator showing battery is fully charged.
	Indicator showing charger is on.

AC TO DC EXTERNAL POWER SUPPLY SYMBOLS



	D554 complies with EU regulations for safety, electrical and electronic interference, and immunity. This symbol is on the D554 power supply enclosure.
	WEEE Compliant Symbol: Recycle - Do not discard improperly. This symbol is on the D554 power supply enclosure and on the packaging.
	Indoor Use Only Symbol: This symbol is on the D554 power supply enclosure.

	General Warning Symbol: This symbol is on the D554 power supply enclosure.
	Class II Equipment Symbol: This symbol is on the D554 power supply enclosure.
	DoE Efficiency Level VI Symbol: This symbol is on the D554 power supply enclosure.
	Regulatory Certification for Compliance Symbol: This symbol is on the D554 power supply enclosure.
	Direct Current Power Symbol: This symbol is on the D554 power supply enclosure.
	Alternating Current Power Symbol: This symbol is on the D554 power supply enclosure.

MANUFACTURE SYMBOLS

	D553 (E) is manufactured by Parkell and is on the packaging.
	Date of Manufacture Symbol: This symbol is followed by the date of manufacture. This symbol is on the D553 (E).
	Serial number of D553 (E). This symbol is on the D553 (E) curing light, and on the packaging.

REGULATORY SYMBOLS

	D553 (E) complies with EU regulations for safety, electrical and electronic interference, and immunity. This symbol is on the D553 (E) curing light, and on the packaging.
	D553 (E) meets both US and Canadian standard. This symbol is on the D553 (E) curing light.

EMC INFORMATION

This equipment is designed to be used in a dental office or clinic environment only.

WARNING: Use of this equipment adjacent to or stacked with other equipment may result in improper operation. If improper operation is observed, this equipment will need to be judiciously relocated away from the other equipment.

WARNING: Use of Wall Mount Power Transformer / Charger accessory other than specified in the "WALL MOUNT POWER TRANSFORMER SPECIFICATIONS" section of this document could result in increased electromagnetic emissions, decreased electromagnetic immunity, or improper operation of this equipment.

WARNING: Portable RF communication equipment (e.g. wireless routers) should be used no closer than 30 cm (i.e. 20 inches) to any part of this equipment, or degradation of equipment performance may result.

This equipment complies with IEC60601-1-2.

The EMISSIONS characteristics of this equipment make it suitable for use in dental or clinical office areas (CISPR 11 Class A Group 1).

WARRANTY AND TERMS OF USE

For full Warranty and Terms of Use information, please see www.parkell.com.

Parkell's Quality System is certified to ISO 13485.


EC REP

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