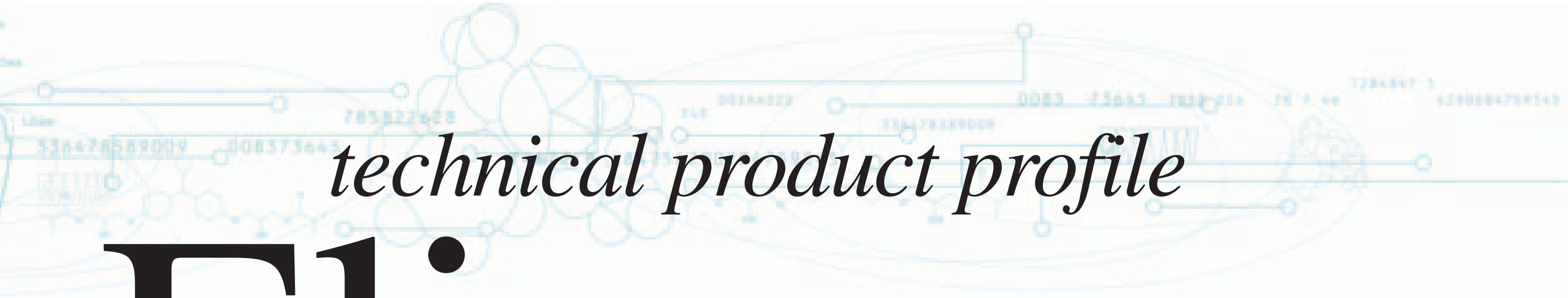
3M ESPE

Elipar™ FreeLight 2
LED Curing Light



technical product profile

Elipar™

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Introduction

The long-term success of clinical composite restorations depends on complete and appropriate polymerization, optimal materials, and a suitable dentin bonding system.

The efficiency of light-initiated polymer curing is generally discussed in terms of radiation flux density, or light intensity (mW/cm^2). High light intensities were required for complete composite polymerization, particularly for deep cavities. Incomplete polymerization allows deterioration of mechanical and physical material properties, and increases both water absorption and susceptibility to discoloration.

The effective range of the light emission spectrum that can initiate polymerization is narrow. Though halogen lamps are the most frequently used dental polymerization devices, only a small part of their wide spectral emission occurs in the useful range. Much of the light emitted from these lamps is, therefore, ineffective and may cause unwanted increases in tooth temperature.

Unlike halogen lamps, light emitting diodes (LEDs) combine specific semi-conductors to produce blue light. LEDs generate a narrow emission spectrum ideally suited for the polymerization of dental composites.

Overview of Light Curing Technologies

The effectiveness of blue light in light curing of dental composites has been known since the 1970s. Halogen lamps are the most frequently used source of light for this purpose. Blue light with wavelengths between 410 and 500 nm is of central importance because the absorption maximum of the sensitizer component of most dental material photoinitiator systems (camphorquinone) occurs in this range (465 nm). When camphorquinone is exposed to light in the presence of an amine-based co-initiator, radicals are formed, initiating polymerization.

At present, the following three major technologies for light curing of materials are used in dental practice:

- Halogen lamps
- Plasma arc lamps
- LED lamps

Key differences, benefits, and drawbacks of these three light sources are compared below.

Halogen Lamps

The physical basis for light production is that heated objects emit electromagnetic radiation. In the case of halogen lamps (the most commonly used light source for polymerization of dental materials), light is produced when an electric current flows through a thin tungsten filament. Because the filament acts as a resistor, the passage of current generates heat. A filament heated to approximately 100°C gives off heat energy in the form of infrared radiation (long wavelengths). When the temperature is increased to between 2000 and 3000°C, a significant portion of the radiation is emitted in the visible light spectrum (shorter wavelengths).

Wien's law describes the shift in light color produced by rising temperature. Incremental increases in the temperature increase the intensity proportion of the still shorter wavelength radiation, including wavelengths in the blue light range. Therefore, with further heating a red-hot object becomes incandescent. To provide blue light for photopolymerization, halogen lamps must be heated to very high temperatures. Consequently, preferential production of blue light is not possible with this kind of technology. Further benefits and drawbacks of halogen lamps are shown in Table 1.

Table 1. Benefits and drawbacks of halogen lamps

Benefits	Drawbacks
Low cost technology	Low efficiency
Longest history in dental industry	Short service life
	High temperatures (lamp is cooled by a ventilating fan)
	Continuous spectrum must be narrowed by filter systems

Halogen lamps emit a range of wavelengths covering a large part of the spectrum, and therefore are analogous to a Planck radiator. Their collective emission results in production of white light. In order to produce light of a specific color, unwanted portions of the spectrum must be filtered out. As a result, the largest part of the radiative power of this light source is wasted.

The central drawback of halogen lights is the need to overcome waste heat produced during wide spectrum light production. In addition, since a fan cooling air current must enter and exit through slots in the frame casing, disinfection of the handpiece is compromised.

Another drawback of halogen lights is that the bulb, reflector, and filter can degrade over time, interfering with light unit power output and contributing to bulb fading. The lamp reflector may lose its reflective properties because of loss of reflective material, or deposition of surface impurities. Filter coatings may become pitted, chipped, or flaky, and the filters themselves may crack or break. Loss of these properties typically reduces light output.

Plasma Arc Lamps

Plasma arc curing lamps are also among recently developed methods for light curing. Manufacturers of these devices claim that cured materials retain mechanical properties comparable to those produced by conventional treatment, while curing times are significantly reduced.

Light produced by plasma arc lamps is different from that generated by halogen lamps. Rather than relying upon a heated tungsten filament, plasma arc lamps work by application of high voltage current across two closely placed electrodes, resulting in a light arc between the electrodes. However, Planck’s radiation law also pertains to plasma arc lamps. Like halogen lamps, plasma arc lamps emit a continuous spectrum of light, so their operating temperatures increase in proportion to the amount of blue light produced.

Table 2. Benefits and drawbacks of plasma arc technology

Benefits	Drawbacks
Shorter polymerization times	Very low efficiency
	High temperature development (lamp is situated in the base unit and cooled by a ventilating fan)
	Continuous spectrum must be narrowed by filter systems
	Expensive

LED Lamps

(such as Elipar™ FreeLight and FreeLight 2 LED Curing Lights)

In contrast to halogen and plasma arc lamps, LEDs produce visible light by quantum-mechanic effects. LEDs comprise a combination of two different semiconductors, the ‘n-doped’ and the ‘p-doped’ type. N-doped semiconductors have an excess of electrons while p-doped semiconductors require electrons, resulting in creation of electron ‘holes.’ When these two types of semiconductors are combined and a voltage is applied, electrons from the n-doped type connect with holes from the p-doped type. A characteristic light with a specific wavelength range is then emitted from the LED.

The color of an LED light, its most important characteristic, is determined by the chemical composition of the semiconductor combination. Semiconductors are in turn characterized by their band gap. In LEDs, this gap is directly utilized for light production. When electrons in the semiconductor combination move from higher to lower energy levels, the energy difference of the band gap is released in the form of a photon of light (Figure 1).

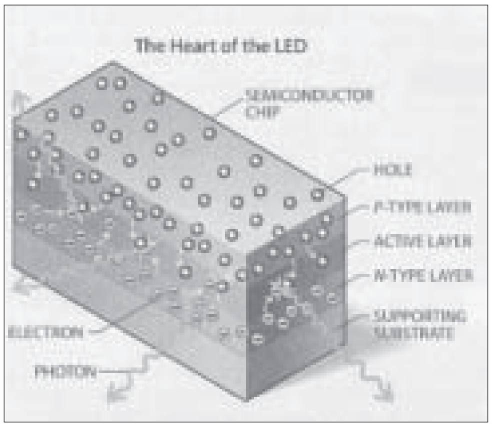

Figure 1. Structure of an LED (from Scientific American, 2, 63-67 (2001))

In contrast to halogen and plasma arc lamps, LEDs produce light with a narrow spectral distribution. This is the main difference between light produced by LEDs and other light sources, as light of selected wavelengths can be preferentially produced using LEDs with appropriate band gap energies. This innovative method of light production therefore creates a more efficient way of converting an electric current into light. Table 3 summarizes the benefits and drawbacks of LED technology.

Table 3. Benefits and drawbacks of LED technology

Benefits	Drawbacks
Consistent output, with no bulbs to change	Due to the narrow emission spectrum LEDs can only polymerize materials with an absorption maximum between 430 and 480 nm (camphorquinone as photoinitiator)
No need for filter systems	
High efficiency leads to: Low temperature development (no ventilation fan required) Low power consumption (battery-operation is possible)	
Frame can be easily cleaned, since no slots for a ventilation fan are needed	
Long service life of the LEDs	
Quiet	

LEDs offer new options in light-catalyzed polymerization of dental materials. Their use has been considered in dentistry since the development of blue diodes in the 1990s. Investigations by Fujibayashi et al, demonstrated that at a constant light intensity of 100mW/cm^2, the depth of composite curing and the degree of monomer conversion was significantly improved using an LED versus a halogen lamp.[1]

This study demonstrates that the quality of polymerization depends upon the narrow absorption peak of the initiator system, and makes the emitted spectrum an important determinant of a curing light's performance. The primary absorption curve of camphorquinone ranges from 360 to 520 nm, with its maximum found at 465 nm. Within this range, optimal emission of the light source lies between 450 and 490 nm.[2]

In conventional curing devices, most photons are emitted outside the optimal spectrum range for light curing. Without additional events, these photons cannot be absorbed by camphorquinone. In contrast, 95% of photons emitted by blue LEDs occur between 440 and 500 nm, while the emission maximum of the blue LEDs used in the Elipar™ FreeLight 2 LED curing light is approximately 465 nm, almost identical to the absorption peak of camphorquinone. Most blue LED photons can therefore interact with camphorquinone, explaining the greater depth of cure and monomer conversion noted with LED versus halogen lamps, despite their operating at an equivalent light intensity of 100mW/cm.[2]

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1. Fujibayashi K, Ishimaru K, Takahashi N, Kohno A. Newly developed curing unit using blue light-emitting diodes. Dent. Jpn, 1998, 34:49-53.

2. Nomoto R. Effect of light wavelength on polymerization of light-cured resins. Dent Mater J, 1997, 16:60-73.

At clinically relevant light intensities, a slight increase in the depth of cure was noted when composites were polymerized with an LED lamp versus a halogen lamp. This difference occurred despite use of an LED lamp with a measured output only 70% that of the halogen lamp (276 versus 388 mW/cm^2, measured between 410 and 500 nm).[3] This finding underscores the importance of considering the emission spectra of curing lamps relative to the absorption spectrum of camphorquinone when assessing the quality of light polymerization.

Technology Trends

Two key technical developments have recently taken place regarding lights used for dental curing. First, lights with fast curing capabilities now offer considerable time savings, which is extremely important to dental clinicians. However, very rapid curing claims of several seconds are controversial, as restoration quality associated with these processes does not meet conventional standards. Rapid curing devices are currently available with halogen and plasma arc lamps. The major disadvantage of these devices is that they consume large amounts of power, necessitating bulky desktop devices or traditional pistol grip hand pieces with fan and power cords. Second, LED-based curing lights have been developed for photopolymerization of dental materials. These devices are considerably more efficient than halogen or plasma arc bulbs, and their small size and portability have enhanced their market success.

The first generation LED curing lights achieved performance only comparable to that of standard halogen lights. High power LEDs have since made it possible to merge the two key technical developments in dental curing lights, allowing LED-based systems to achieve a 50% reduction in cure time. LED-based systems are now comparable in this regard to high intensity halogen or plasma arc curing lights.

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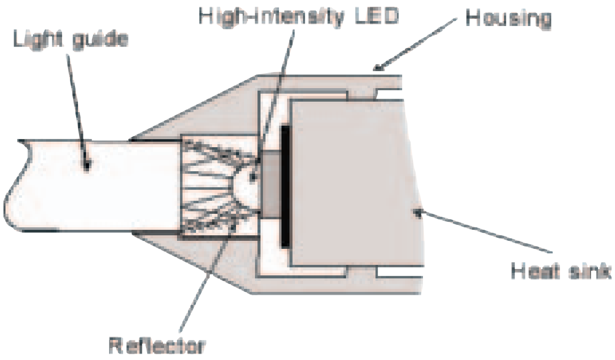
3. Mills RW, Jandt KD, Ashworth SH. Dental composite depth of cure with halogen and blue light emitting diode technology. Brit Dent J, 1999,186(8):388-391.

Technical Design

A single high-intensity LED generates light in the Elipar™ FreeLight 2 LED curing light. In contrast to conventional LEDs, a high-intensity LED uses a substantially larger semiconductor crystal, which increases both the illuminated area and light intensity, enabling a 50% reduction in cure time. Presented below are the technical requirements ensuring that the full performance of the Elipar FreeLight 2 LED curing light is maintained with a high-intensity LED.



Dissipation of heat generated by the LEDs during operation is crucial for durability of LED-based systems. With an array of several standard LEDs, heat build-up is distributed to many individual components. If a single high-intensity LED is used instead of an array of standard LEDs, this characteristic must be addressed, as heat development occurs mainly in the single LED. With the Elipar FreeLight 2 LED curing light, heat is dissipated by a heat sink of highly thermally conductive aluminum integrated in the housing. The high conductivity of this material ensures that a low LED temperature is maintained, during continuous operation of several minutes, protecting LED longevity. When the unit is turned off, heat temporarily stored in the heat sink is dissipated to the environment by interaction with the aluminium composite housing. This design dispenses with the need for fans or other means of air cooling the device.

This kind of heat management is possible only with the moderate amount of heat produced by the LED, which represents less than 5% of the amount produced by a halogen lamp. Nevertheless, heating and effective heat dissipation are crucial for the performance of a light polymerization unit based on high-intensity LED.

An efficient optical arrangement is required for delivery of the high light intensity necessary for light-induced polymerization. To do this, a conical reflector at the base of the light guide is used to ensure maximum light flux. This reflector consists of a metal-free interference reflecting foil with unique optical qualities, enabling optimum coupling of light generated by the LED into the light guide.

Indications

The Elipar™ FreeLight 2 LED curing light is a universal light polymerization device for composites, compomers, adhesives and light-cured glass ionomer materials. Effective curing of these materials by the Elipar FreeLight 2 LED curing light requires that they contain camphorquinone as a photoinitiator. Dental materials using alternative photoinitiators with absorption spectra outside the range of 430-480 nm are not compatible. Table 4 shows a list of materials that have photoinitiators compatible with the Elipar FreeLight 2 LED curing light. For each listed compatible products, the cure time indicated by the manufacturer should be reduced by 50%.

Table 4. Compatibility of common dental materials with the Elipar FreeLight 2 LED Curing Light

	Product	Compatible	Not Compatible
Restorative Composites	Admira®	x	
	Charisma®	x	
	Clearfil™ AP-X	x	
	Compoglass® F	x	
	Definite®		x
	Dyract™ AP	x	
	EsthetX™	x	
	F2000 Compomer Restorative	x	
	Filtek™ A110 Anterior Restorative	x	
	Filtek™ Flow Flowable Restorative	x	
	Filtek™ P60 Posterior Restorative	x	
	Filtek™ Supreme Universal Restorative	x	
	Filtek™ Z250 Universal Restorative	x	
	Heliomolar®	x	
	Herculite® XRV™	x	
	Point 4™	x	
	Prodigy™	x	
	Solitaire® II	x	
	SureFil™	x	
	Tetric® Bleach		x
	Tetric® Ceram	x	
	Tetric® Flow	x	
	TPH® Spectrum®	x	
	Z100™ Restorative	x	
Glass Ionomers	Fuji II™ LC	x	
	Photac™ Fil Quick	x	
	Vitremer™ Glass Ionomer	x	
Cements	RelyX™ ARC Adhesive Resin Cement	x	
	RelyX™ Unicem Self-Adhesive Resin Cement	x	
	RelyX™ Veneer Cement	x	
	Variolink® II	x	
Liners	Vitrebond™	x	
Sealants	Clinpro™ Sealant	x	
Adhesive Systems	Adper™ Prompt™ Self-Etch Adhesive	x	
	Adper™ Scotchbond™ Multi-Purpose Dental Adhesive	x	
	Adper™ Single Bond Dental Adhesive	x	
	Excite®	x	
	OptiBond Solo™ Plus	x	
	Prime & Bond® NT™	x	
	Syntac® Classic	x	

Technical Properties

The Elipar™ FreeLight 2 LED curing light is a high intensity light instrument designed for composite curing. Though halogen lamps are the standard in the field of light polymerization, the following studies demonstrate that the Elipar FreeLight 2 LED curing light offers polymerization quality equivalent to that achieved by conventional halogen lights, but achieves this goal in half the exposure time.

The properties of different restoratives evaluated included the following items:

- Mechanical properties of light-cured materials prepared using the Elipar FreeLight 2 LED curing light or Elipar™ TriLight curing light.
- The development of temperature during use of the Elipar FreeLight 2 LED curing light and halogen lamps.
- A comparison of the depth of polymerization achieved with Elipar™ FreeLight curing light, Elipar FreeLight 2 LED curing light or halogen lamps.
- The emission spectra of the Elipar FreeLight curing light, Elipar FreeLight 2 LED curing light and halogen lamps and their respective compatibility with camphorquinone.

Internal Measurements

Mechanical Properties of Light-cured Materials Prepared Using the Elipar FreeLight 2 LED Curing Light or Elipar TriLight Curing Light.

The measurements were made in the clinical research laboratory of 3M ESPE, according to ISO 4049 (resin-based filling materials). All tests were carried out with the Elipar TriLight curing light according to the manufacturers' instructions and compared to the Elipar FreeLight 2 LED curing light with a 50% reduction in the manufacturers' curing time. Table 5 summarizes the flexural strengths, e-modulus, and the depths of polymerization of the tested materials as measured for the Elipar FreeLight 2 LED curing light and Elipar TriLight curing light, respectively. The information in this table constitute representative results derived from a larger data set generated to test and verify the efficacy of the Elipar FreeLight 2 LED curing light.

Table 5. Mechanical Properties of Clearfil™ APX, Pertac™ II, Prodigy™ and Spectrum® TPH®

		Clearfil AP-X	Pertac II	Prodigy	Spectrum TPH
Flexural strength	FreeLight 2	162	107	127	124
[MPa]	TriLight	163	106	124	131
e-modulus	FreeLight 2	16747	7850	8552	9002
[MPa]	TriLight	16447	7460	7279	9300
Depth of polymerization	FreeLight 2	1.9	1.7	2.2	2.3
[mm]	TriLight	2.1	2.1	2.4	1.9

Clearfil APX, Pertac II, Prodigy, and Spectrum TPH were evaluated according to ISO 4049.

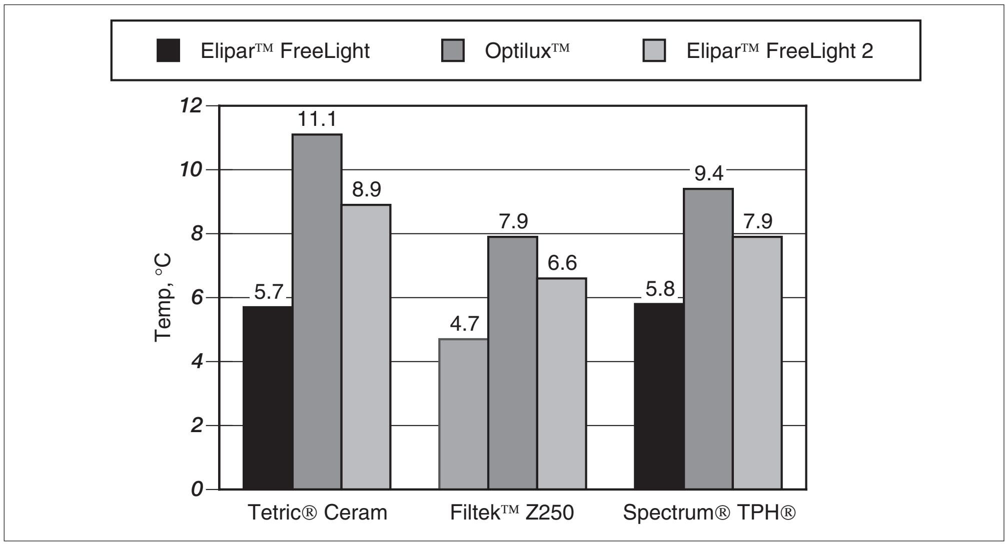
The Development of Temperature During Use of the Elipar™ FreeLight, Elipar™ FreeLight 2 LED Curing Lights and a Halogen Lamp.

Data on polymerization-related temperature development within restorative composites is of practical interest, though experimental design and data interpretation are demanding. In principle, two different "heat sources" may contribute to a rise in temperature of composite restorations:

- Irradiated light of the polymerization lamp (dT_{rad})
- Heat generated by the polymerization reaction (dT_{poly}).

The peak temperature development of in-vitro samples cured with various lights is shown in Figure 2 (Clinical Research Lab, 3M ESPE). The peak temperature rise of samples cured with the Elipar FreeLight 2 LED curing light is statistically lower than samples cured with the high intensity light (Optilux™ 501).

Figure 2. Peak temperature development comparisons of Elipar FreeLight, Elipar FreeLight 2 LED curing light and Optilux 501 during light polymerization



A Comparison of the Depth of Polymerization Achieved with Elipar™ FreeLight, Elipar™ FreeLight 2 LED Curing Light and a Halogen Lamp.

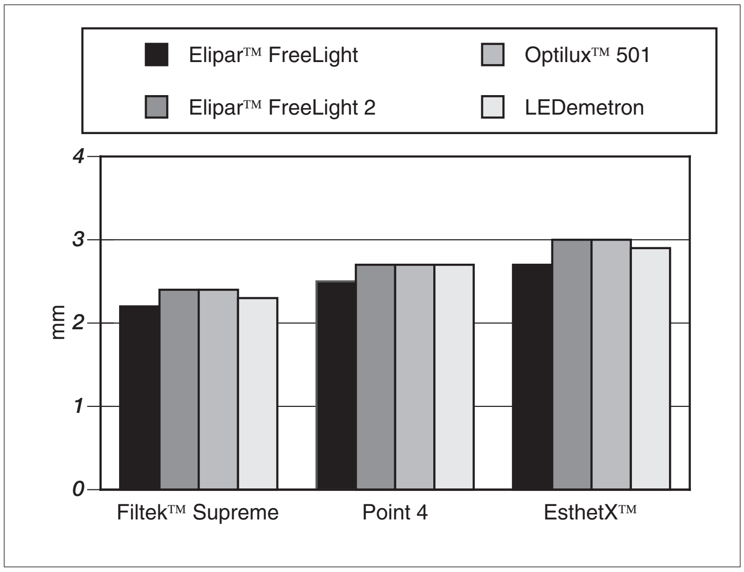
3M ESPE R&D

The following standardized procedure describes the protocol to establish the depth of cure (ISO 4049). A composite is packed into a metal cylinder. The top surface is exposed to a visible light source for the recommended length of time. After exposure, the composite is removed from the mold and uncured material is scraped away using a plastic instrument. The value recorded is half the height of the cylinder of cured material after it is scraped back.

Figure 3 shows the cure depth of 3M ESPE Filtek™ Supreme, EsthetX™, and Point 4™ restoratives polymerized according to manufacturers' recommendations with the Elipar FreeLight curing light. Also shown are the cure depths at a 50% reduction in the recommended cure times with the Elipar FreeLight 2 LED curing light, the L.E. Demetron I curing light and Kerr's Optilux™ 501 operated in "Boost" mode and using the turbo and light guide.

With all three composites, the Elipar FreeLight 2 LED curing light achieved equivalent depths of cure compared to the results of the Optilux 501 with the same cure time.

Figure 3. Depth of Cure of Filtek Supreme universal restorative, EsthetX and Point 4 restoratives.



The Emission Spectra of the Elipar™ FreeLight, Elipar™ FreeLight 2 LED Curing Light and Optilux™ 501 and Their Respective Compatibility with Camphorquinone.

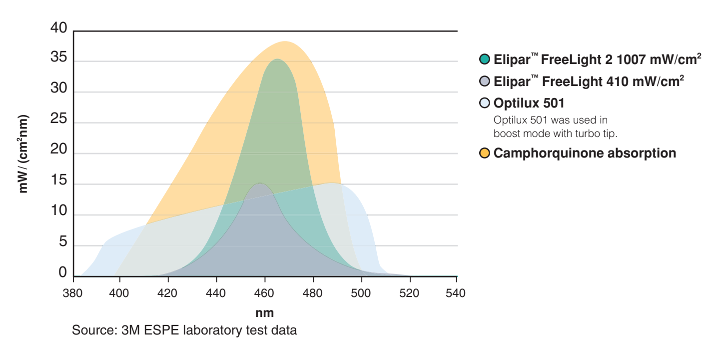
(3M ESPE R&D)

Information about the spectral composition of the emitted light from a polymerization lamp can advance understanding about the improved efficiency of the LED technology. Absorption curves are commonly used for the characterization of photoinitiators and the overlap between them and light source emission spectra predict reaction efficiencies.

The absorption spectrum of camphorquinone is shown in Figure 4. As indicated by the spectrum, camphorquinone has the capacity to absorb light ranging from 380 to 500 nanometers. Since camphorquinone in the presence of amine-based coinitiators can start polymerization, the camphorquinone absorption curve constitutes the total range of light that can initiate a polymerization reaction. For example, light in the range 380-430 nm could be absorbed by camphorquinone but the probability is lower than wavelengths at its absorption maximum of 465 nm. Light of 465 nm wavelength is much more likely to start a photopolymerization reaction and therefore is more efficient than light of other wavelengths.

As shown in Figure 4, the emission spectrum of the Elipar FreeLight curing light, the Elipar FreeLight 2 LED curing light, and the absorption spectrum of camphorquinone are very similar. Both the Elipar FreeLight and Elipar FreeLight 2 LED curing lights exhibit nearly identical efficiencies of light polymerization of composites while the latter offers a higher total light intensity (equivalent to the area under the emission curve).

Figure 4. Absorption spectrum of camphorquinone and emission spectra of the Elipar FreeLight Curing Light, the Elipar FreeLight 2 LED Curing Light, the Elipar FreeLight, and the Optilux 501 Curing Light.



Source: 3M ESPE laboratory test data

Technique Guide

3M ESPE **USAGE TIPS**

Elipar™ FreeLight 2 LED Curing Light

Removing the Battery Cap:

- Rotate the cap at the bottom of the handpiece counter-clockwise until it stops, and then remove the cap.

1

Inserting the Battery:

- Insert the rechargeable battery in a fluent motion as directed by the arrow until you hear or feel the battery **SNAP** into place.
- Replace the cap and rotate clockwise until it locks into place.
- Malfunction of the light will result if the battery has not been seated fully and secured into the handpiece.
- In the event of malfunction, remove the battery from the handpiece as instructed below.

2

Removing the Battery:

- Push a small spatula or similar aid between the cylinders of the battery until the snap-lock releases the battery.

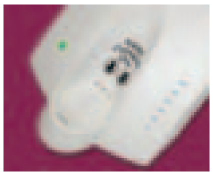
3

- Remove the battery as illustrated in figure 4. Reinsert the battery or insert a new battery and replace the cap as described and illustrated in figure 2 above.

4

Charging Steps:

- Place the charger base on a level surface. Do not obstruct the vent slots on the bottom of the unit.
- Plug in the charger base. The green LED on the left side of the device should illuminate indicating the unit is ready for operation.
- Prior to the first use, place the handpiece in the charger base to charge the new battery.
- The yellow LED on the left side of the charger base will illuminate after approximately 2 seconds. The battery is charged once the yellow LED turns off.
- **Note: it will take 3 TO 4 charging cycles (completely discharged and recharged) before the battery reaches maximum charging capacity.**



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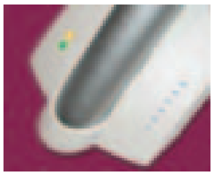

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Cleaning/Disinfecting the Charger Base and Handpiece:

- **Wipe handpiece and charger base for disinfection. Do not spray. Disinfecting agents must not enter openings on unit.**
- Apply disinfecting agent with a soft cloth and allow disinfectant to remain on surface for the amount of time recommended by the manufacturer. Follow precautions for use.
- Perform a final wipe with a clean cloth to remove any residual deposits of the disinfectant solution.
- **Wet charge contacts will shut down the charging process and will be signaled by ongoing beeps and a flashing yellow light on the charging base**. If this occurs, simply remove handpiece from charging base and thoroughly dry contacts on charging base and handpiece as described above.
- Do not use solvents or abrasive cleaning agents as these may damage plastic parts.

7

8

Cleaning/Sterilizing the Light Guide:

- Cured composite on the tip of the light guide should be removed with alcohol. A plastic spatula may help in removing the material. Do not use any sharp or pointed instruments.
- The light guide can be steam autoclaved. Do not sterilize with dry heat or chemicals.
- Water spots should be wiped off both ends of the light guide before and after steam sterilization.

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3M ESPE Customer Hotline 1-800-634-2249
Please refer to Instructions for Use for more detailed information as well as precautionary and warranty information.

Instructions for Use

Product Description

Elipar™ FreeLight 2, manufactured by 3M ESPE, is a high-performance light unit for intraoral polymerization of dental materials. The unit consists of a charger and a cordless handpiece powered by a rechargeable battery. The unit is designed for use on a table and cannot be wall-mounted.

The unit uses a high-performance Light Emitting Diode (LED) as the light source. In contrast to halogen light units, the unit emits light mainly in the wavelength range of 430 to 480 nm, e.g. the relevant range for camphorquinone-containing products.

The optimal match of the wavelength range to the intended purpose ensures that the polymerization performance is similar to that of halogen light-emitting units, albeit at lower light intensity. The polymerization performance of this light unit is so high, that the exposure times can be reduced by 50%, compared to a conventional halogen light unit.

Exposure time options: 5, 10, 15, or 20 seconds.

The charger is equipped with an integral light intensity testing area.

The device is shipped with a turbo light guide with an 8 mm diameter light exit. It is not permissible to use the light guides of other units.

The “maxi fiber rod” with a diameter of 13 mm for larger areas (e.g. for fissure sealing), and the “proxi fiber rod” with a point-shaped light exit (e.g. for use in interproximal areas), are available as accessories. **Both the maxi fiber rod and the proxi fiber rod may only be used for the mentioned purposes and not for the polymerization of usual fillings, as otherwise complete polymerization can not be guaranteed.**

The handpiece is equipped with a “power-down” function to minimize the unit’s energy consumption. The handpiece switches to “power-down” mode once it is placed in the charger or if left unused for approximately 10 minutes outside the charger.

In stand-by mode, the charger consumes maximally 0.75 W. Starting in 2003, this value will be recommended for the stand-by mode by the EU according to the “Code of Conduct” on efficiency of external power supplies.

Fields of Application

Polymerization of light-curing dental materials with photoinitiator for the wavelength range 430-480 nm. Though the majority of light-curing dental materials are responsive in this range of wavelengths, you may wish to contact the manufacturer of the material in question to confirm the wavelength range.

Installation of the Unit

Factory Settings

The factory settings of the unit are 20 seconds operation time.

Initial Steps

Charging

1. Please ensure first that the voltage stated on the rating plate corresponds to the existing main supply voltage. The rating plate is attached to the bottom of the unit.
2. Place the charger on a level surface.
   - To protect the device from over-heating, do not obstruct the vent slots on the bottom of the unit.
3. Plug in the charger base.
4. Connect the power cable of the charger to the power supply of the Charger.
   - The green LED on the left side of the device is illuminated. This shows that the unit is ready for operation; please refer to the section, "LED display of the charger."

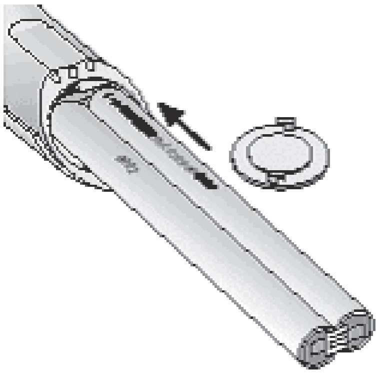
Light Guide/Handpiece

Never insert the handpiece in the charger unless the battery is inserted in the handpiece first!

- Steam Autoclave the light guide prior to first use.
- Then insert the light guide in the handpiece until it snaps into place.
- Place the enclosed glare shield on the light guide.

Inserting the Battery

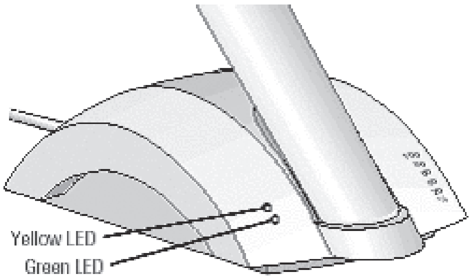
- Rotate the lid at the lower end of the handpiece counterclockwise until it hits the stop, and then remove the lid.
- To avoid malfunction, make sure the battery is properly inserted. Lay the handpiece upside down and insert the rechargeable battery in a fluent motion as directed by the arrow until you hear the battery snap into place.
- Replace the lid and rotate clockwise until it locks into place.



- In the event of malfunction, remove the rechargeable battery from the device and re-insert as described above.

Battery Charging

- Prior to the first use, place the handpiece in the charger to fully load the new rechargeable battery.
  - The yellow LED of the charger illuminates after approximately 2 seconds; please see also section, “LED Display of the Charger.” The battery is fully charged once the yellow LED is turned off.
  - Note: Several cycles of charging and discharging may be necessary before the optimum cure time per charge is obtained.



LED Display of the Charger

Green LED	Yellow LED	Acoustical signal	Handpiece inserted in charger?	Indicates
On	Off	–	No	Charger is ready for operation
On	Off	–	Yes	Charging has been completed
On	On	–	Yes	Rechargeable battery is being charged
On	Flashing	–	Yes is defective	Rechargeable battery
On	Flashing	Ongoing Beeps	Yes are wet	Charging contacts

Table Holder for the Handpiece

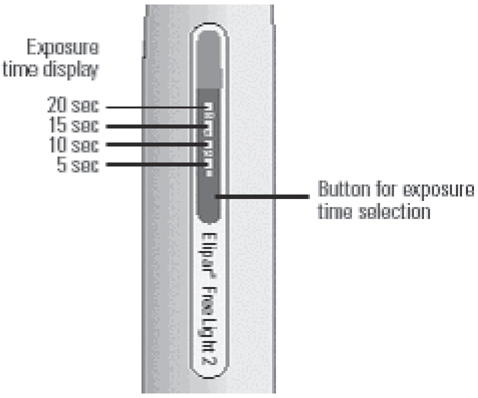
While performing a procedure, the handpiece can be placed in a table holder.

Operation

Selection of Exposure Time

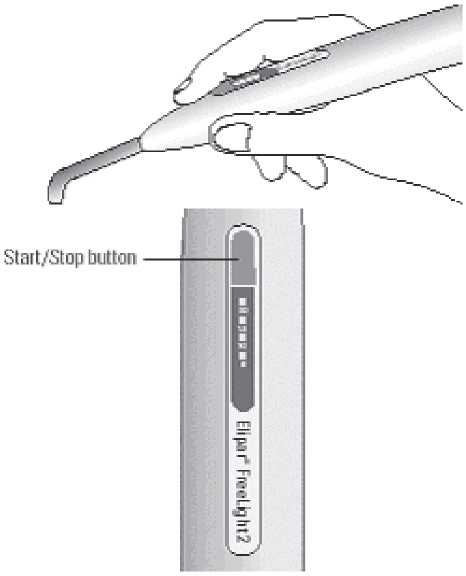
Exposure times of 5, 10, 15, and 20 seconds are available.

- For the compatible product at hand, use the exposure time as stated in the product’s Instructions for Use and reduce to half.
- Select the exposure time by pressing the “sec” button.
  - The selected exposure time is indicated by the 4 green LEDs.



  - Each time the button is pressed, the setting advances to the next (higher) value; after 20 seconds the exposure time setting returns to 5 seconds. Keep the button depressed to scroll through the available settings.
  - The button for selection of the exposure time is deactivated during light activation.

Activating and Deactivating the Light



- Activate the light by briefly pressing the green Start button.
  - Initially, the LEDs show the preset exposure time: 4 illuminated LEDs represent 20 seconds of exposure time. After every 5 seconds of exposure, one of the LEDs is turned off (e.g., 3 LEDs correspond to 15 seconds of exposure time remaining, 2 LEDs to 10 seconds of exposure time remaining, etc.).
- If it is desired to turn off the light before the preset exposure time has completely elapsed, press the green Start button again.

Positioning the Light Guide

- Rotate the light guide into the optimal position for polymerization.
- To make full use of the light intensity provided, place the light guide as close to the filling as possible. Avoid directly contacting the filling material.
  - Keep the light guide clean at all times to obtain full light intensity.
  - **Damaged light guides substantially reduce the light power and must be replaced immediately. Sharp edges may cause serious injury.**

Removing and Inserting the Light Guide from/into the Handpiece

- To remove the light guide from the handpiece pull towards the front of the device.
- To put the light guide into the handpiece, push the light guide in until it snaps into position.

Measurement of Light Intensity

The light intensity can be reliably determined only with the charger of the Elipar™ FreeLight 2 unit. The light testing area is situated on the charger base. Testing the light intensity with any other unit produces erroneous results because of differences in the light sources used and arrangement of the components.

Caution: Measure the light intensity with the 8 mm turbo light guide only.

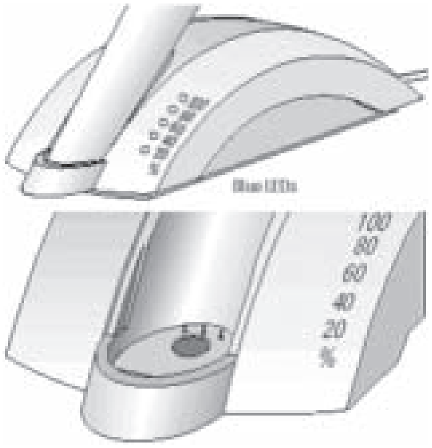
- If required, clean the test area with a wet cloth. Take care not to bend or damage the charging contacts.
- Without applying pressure, place the exit tip of the light guide level with the test area.

- Activate the lamp by pressing the green Start button.
  - All 5 blue LEDs come ON for approximately 1 second.
  - After this period of time, the number of illuminated LEDs is indicative of the measured light intensity: 5 LEDs = 100%, 4 LEDs = 80%, 3 LEDs = 60%, 2 LEDs = 40%, 1 LED = 20%.
- If the light intensity is below 80% (fewer than 4 LEDs are ON), check the light guide for contamination or defects.
- Proceed as follows:

1. Clean the light guide if contaminated; please refer to the section on “Care.”
2. Replace the light guide if defective.
3. If (1) and (2) fail to improve the situation, please contact 3M ESPE Customer Service or your retailer.

Low Battery Charge Display

After frequent use the battery charge of the device may drop to below approximately 10%, so that only a few more exposures can be performed without re-charging. Low battery charge is shown by several means:



- A short audible alarm is emitted 5× at the completion of an exposure, and repeated thereafter whenever any button is touched.
- The 5-second-LED of the handpiece begins to flash.
- The handpiece should be placed in the charger as soon as possible to re-charge the battery.

Power-Down Mode

Once the handpiece is placed in the charger, all internal functions and LEDs are automatically turned off as the handpiece switches to power-down mode. This reduces the power consumption of the rechargeable battery to a minimal level. Outside the charger, the handpiece is also switched to power-down mode if left unused for approximately 10 minutes.

- To terminate the power-down mode press one of the two buttons.
  - The power-down termination signal (two short audible signals) is emitted indicating that the handpiece is ready for operation: the handpiece displays show the latest selected exposure mode and time settings.

Acoustic Signals - Handpiece

An acoustical signal is emitted:

- Every time a button is pressed.
- Every time the light is turned ON or OFF.

- After 5 seconds of exposure time have elapsed (1 alarm signal), 2× after 10 seconds, 3× after 15 seconds.

Two acoustic signals are emitted:

- Every time the power-down mode is terminated by pressing any of the buttons.

A 2 second-error signal is emitted if:

- The temperature control is activated.
- The rechargeable battery is discharged to an extent that reliable polymerization is no longer ensured.

Acoustical Signals - Charger

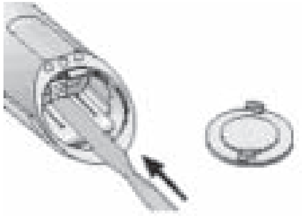
- Ongoing beeps are emitted when the handpiece is in the charger and the charge contacts are wet.

Operating Errors

Error	Cause *Solution*
The 5 second-LED flashes and a short signal is emitted 5× whenever a button is touched or the light is turned off.	The residual battery charge has dropped below 10%. *Solution: Place the handpiece in the charger and re-charge the battery.*
The ongoing exposure is interrupted (light off signal is emitted) followed by a 2 second-error signal; the device switches to power-down mode and resists further activation.	The battery lacks sufficient charge. *Solution: Place the handpiece in the charger and re-charge the battery.*
A 2 second-error signal is emitted upon pressing of the Start button.	The temperature control is activated to protect the handpiece from overheating. The handpiece can be used again once it has cooled down. *Solution: Allow the handpiece to cool down. The light may be successfully activated once the handpiece has cooled down.*
Ongoing beeps are emitted and the yellow LED is flashing when the handpiece is put into the charger.	The charge contacts are wet. *Solution: Dry the charge contacts. Do not bend the pins during drying.*
The yellow LED of the charger flashes.	The battery is defective. *Solution: Replace the battery.*
The green LED of the charger fails to light up, even though the power cable is connected to a power outlet.	Power outlet carries no voltage. *Solution: Use a different power outlet.* OR Charger is defective. *Solution: Have the charger repaired.*

Maintenance and Care

Replacement of the Battery



Never place the handpiece in the charger without the battery inserted in the handpiece. Use 3M ESPE batteries only. The use of other manufacturer batteries or non-rechargeable or primary batteries is a potential hazard and may damage the device.

- Rotate the lid at the lower end of the handpiece counterclockwise until it hits the stop, and then remove the lid.
- Push a small spatula or similar aid between the cylinders of the battery until the snap-lock releases so that the battery protrudes slightly from the handpiece body.
- Remove the battery from the handpiece.
- Push the (replacement) battery into the handpiece proceeding along the direction shown by the arrow until the battery locks into place.
- Replace the lid and close by rotating clockwise.
- Insert the handpiece into the unit to completely charge the new battery for its first use.
  - – The yellow LED of the charger illuminates after approximately 2 seconds; please see also “LED Display of the Charger.” The battery charging process is complete once the yellow LED is turned off.
  - – Note: Several cycles of charging and discharging may be necessary before the optimum cure time per charge is obtained.

Handpiece/Battery Care

- Do not use any other chargers as this may damage the battery.
- The battery must not be immersed in water or thrown into open fires. Please see also “Disposal.”

Cleaning the Light Guide

The light guide can be steam autoclaved. Do not sterilize by chemical means or hot-air.

- The light guide should be regularly wiped clean with a soft cloth. The spots of dried liquid should be wiped off the ends of the device especially before and after steam sterilization.
- Adhering polymerized composite should be removed with alcohol. A plastic spatula may help in removing the material.
  - – To protect the surface of the device from scratching, do not use any sharp or pointed tools.

Cleaning the Charger and Handpiece

- For disinfection of all components of the device, spray the disinfection agent onto a 4×4 gauze and proceed to disinfect the device. Improper disinfection can cause material defects.

  - **To avoid internal damage, do not spray disinfectant directly on handpiece or charger surface.** Disinfection agents must not enter the device. Apply surface disinfectant on the cool surface of the handpiece or charger.

- Perform a final wipe with a clean, moist cloth to remove residual surface disinfectant.
  - Do not use solvents or abrasive cleaning agents as these may damage plastic parts of the device.
  - Cleaning agents must not enter the devices.

- Make sure that charge contact pins remain dry and are not contacted by metallic or greasy parts. Do not bend the charge contacts during drying. Wet charge contacts will cause an operating error (ongoing beeps and flashing yellow LED).

Storage of the Handpiece during Extended Periods of Non-use

- If the handpiece is not to be used for an extended period of time (e.g., during vacation), fully charge the battery prior to departure or keep the handpiece inserted in the operational charger.
  - Otherwise, nearly discharged batteries may become excessively discharged due to the low degree of power consumption ongoing even in Power Down mode. This may damage the battery.
- Fully or nearly discharged batteries must be recharged as soon as possible.

Disposal

Your new device is equipped with a Nickel-metal hydride battery. This kind of battery is classified by the federal government as a non-hazardous waste. It is recyclable and safe for disposal in the normal municipal waste stream.

- Recycle or dispose of defective batteries and units in accordance with local legal regulations.

Questions and Answers

Occasionally, upon placing the handpiece in the charging base after disinfection, a continuous beeping signal is heard and the yellow LED flashes. Why does this occur and how can I reduce or eliminate this from happening?

The continuous audible and visual signals are a warning that the charging contacts are wet. After the disinfection procedure, carefully dry the contacts on the handpiece and the charging base prior to placing the handpiece in the charger. Alternatively, allow the light to air dry completely on the table holder prior to placing in the charger. For additional information, please refer to the section entitled, "Maintenance and Care" of the instructions for use.

What kind of measurements will I get with other LED curing lights?

The following LED curing light measurements provide examples of results obtained with the same handheld light meters. Individual light meters and measurements can vary.

Radiometer	Kerr L.E. Demetron I (mW/cm^2)	Ultradent UltraLume™ 2 (mW/cm^2)	Discus Dental Flash-lite™ (mW/cm^2)
Demetron Model 100 Curing Radiometer	950	430	430
Caulk™/Dentsply Cure Rite Visible Light Meter	1330	890	670

Are there light-cured materials that are incompatible with the Elipar™ FreeLight 2 LED curing light?

Most commercial products are compatible with the Elipar FreeLight 2 LED curing light. Photoinitiators other than camphorquinone that have an absorption maximum outside the 430-480 nm wavelength range, are not compatible with the Elipar FreeLight 2 LED curing light. Some materials like Tetric™ Bleach, are incompatible with the Elipar FreeLight 2 LED curing light. Compatible and incompatible products are listed in Table 4, page 11.

Does the rechargeable battery used in the Elipar FreeLight 2 LED curing light have a "memory effect"?

The specific charging technology and the nickel-metal hydride storage battery of the Elipar FreeLight 2 LED curing light has no memory effect. The storage battery can be recharged at any time.

How long will the Elipar FreeLight 2 LED curing light operate and how do I know when the storage battery is almost empty?

Completely charged storage batteries allow a total exposure time of approximately 20 minutes. A residual operating time of 10% is indicated by optic and acoustic signals (see Instructions for Use and page 21: "Low Battery Charge Display").

Does the charge state of the storage battery have an impact on the light intensity of Elipar™ FreeLight 2 LED curing light?

There is no significant reduction of light intensity over the total operation time of the curing light.

Does using more LEDs automatically mean an increase in light intensity?

The number of LEDs in a curing light does not necessarily have any bearing on the spectral output of the unit, regardless of the number of LED involved. Different LEDs have different intensities, so a curing light with one high intensity LED could be more powerful than a curing light with many standard LEDs. Curing light output depends on three things: spectral output of the LED wavelength, intensity of the LED, and optical light delivery.

Is the Elipar FreeLight 2 LED curing light suitable for bleaching teeth?

When bleaching agents are exposed to light, the thermal energy of the exposure can accelerate the bleaching reaction. Heat generation of the Elipar FreeLight 2 LED curing light is greatly reduced because of the LED technology. For this reason, the Elipar FreeLight 2 LED curing light is not indicated for bleaching procedures.

Summary

With its innovative LED technology, the Elipar FreeLight 2 LED curing light represents the newest development in light polymerization devices. LEDs are characterized by an exceptionally high light production efficiency. Cooling by means of a ventilating fan is not necessary. For this reason, the Elipar FreeLight 2 LED curing light has no ventilation slots, simplifying disinfection.

The low power requirements of the Elipar FreeLight 2 LED curing light allow battery-operation. The rechargeable nickel-metal hydride battery supports 20 minutes of exposure time without recharging and does not exhibit “memory effects.”

Research studies on material characteristics demonstrate the Elipar FreeLight 2 LED curing light is an excellent curing device for dental materials. Temperature development during photopolymerization is positively affected. In addition, the mechanical properties and depths of polymerization achieved with this instrument are comparable to conventional halogen lamps but require only half the exposure time.

The Elipar FreeLight 2 LED Curing Light is available with two different polymerization modes: the standard and the softstart=exponential option. Both modes result in identical mechanical properties of the cured materials.

References

Mills R.W., Jandt K.D., Ashworth S.H. “Dental composite depth of cure with halogen and blue light emitting diode technology”, Br. Dent. J. 186, 388-391 (1999).

Note: With an LED curing light emitting only 64% of the light intensity of a halogen lamp, significantly greater polymerization depths were obtained. Besides the light intensity, the emission spectrum provides important additional information on the efficiency of a curing light. With further improvement of the LED technology, LED curing lights have the potential to be an interesting alternative to halogen devices.

Jandt K.D., Mills R.W., Blackwell G.B., Ashworth S.H. “Depth of cure and compressive strength of dental composites cured with blue light emitting diodes (LEDs)”, Dent. Mater. 16, 41-47 (2000).

Note: With regard to compressive strength, no statistically significant differences were found between an LED curing light with a light intensity of 350 mW/cm^2 and a commercially available 755 mW/cm^2 halogen lamp (Spectrum®, Dentsply). The depths of polymerization attained with the LED curing unit were lower than those achieved with the halogen lamp, but significantly exceeded the minimum requirements of ISO 4049.

Stahl F., Ashworth S.H., Jandt K.D. Mills R.W. “Light-emitting diode (LED) polymerization of dental composites: flexural properties and polymerization potential”, Biomaterials 21, 1379-1385 (2000).

Note: Flexural strengths and moduli of elasticity of dental composites showed no statistically significant differences when cured with a LED curing unit or a commercially available halogen curing light with twice as high light intensity. This was not true for the restorative composite Solitaire®. However, the respective values are of limited relevance as the flexural strength of Solitaire does not meet state-of-the-art requirements even when cured with halogen lamps. Because of this shortcoming, Solitaire was superceded by an alternative product. In this study, theoretical calculations demonstrated that light intensity is not the only quality parameter of a curing device. When the emission spectrum was included into the evaluation, the LED curing light achieved 92% of the efficiency of a halogen lamp.

Tarle Z., Knezevic A., Meniga A., Sutalo J., Pichler G. “Temperature Rise in Composite Samples Cured by Blue Superbright Light Emitting Diodes”, IADR-Meeting Nizza, Abstract #433 (1998).

Note: When compared to the Elipar™ Highlight, an LED curing lamp of 12 mW/cm^2 light intensity produced a 7% lower conversion rate. This study demonstrated that temperature development in composite materials was reduced using an LED lamp.

Meniga A., Knezevic A., Tarle Z., Sutalo J., Pichler G. “Blue Superbright LEDs as an Alternative to Soft-Start Halogen Curing Unit”, IADR-Meeting Nizza, Abstract #432 (1998).

Note: Using the same LED curing light as in Tarle et al., (see above) there were no statistically significant differences in the mechanical properties of the composites compared to the Elipar Highlight. The conversion rates for the LED device as measured with FTIR (fourier transform infra red spectroscopy) were 10% lower than obtained with the Elipar Highlight.

Tarle Z., Knezevic A., Meniga A., Sutalo J., Pichler G. “Polymerization Kinetics of Composites Cured by Low Intensity Blue Superbright LEDs”, IADR-Meeting Vancouver, Abstract# 2319 (1999).

> Note: A significant reduction of temperature development during polymerization was achieved with an LED lamp of 12 mW/cm^2 light intensity. However, the conversion rates were lower than those obtained with commercially available curing units. Combining more than 16 conventional LEDs improved polymerization.

Hartung M., Kürschner R. “Surface Hardness and Polymerization Heat of Halogen/LED-Cured Composites”, AADR-Meeting Chicago, Abstract#1745 (2001).

> Note: No differences were noted in mechanical composite properties using an LED curing light (3M ESPE) and Elipar™ TriLight. Temperature development with the LED lamp was up to 5 K lower than with the halogen lamp.

Technical Data

Charger

Operating voltage:	120 V
Power input:	max 10 VA max. 0.75 W in stand-by mode
Dimensions:	Depth: 210 mm (8.3 in.) Width: 95 mm (3.7 in.) Height: 60 mm (2.4 in.)
Weight:	555 g (1.2 lb.)

Handpiece

Power supply:	Nickel-metal hydride rechargeable battery, 4.8 V
Wavelength range:	430 - 480 nm
Light intensity:	Approx. 1000 mW/cm^2
Duration of continuous use:	4 min (dependent on the ambient temperature before activation of temperature control)
Total operation time with new, fully charged storage battery:	typically 20 minutes
Dimensions:	Diameter: 30 mm (1.2 in.) Length: 285 mm (11.2 in.)
Weight:	220 (0.5 lb.)

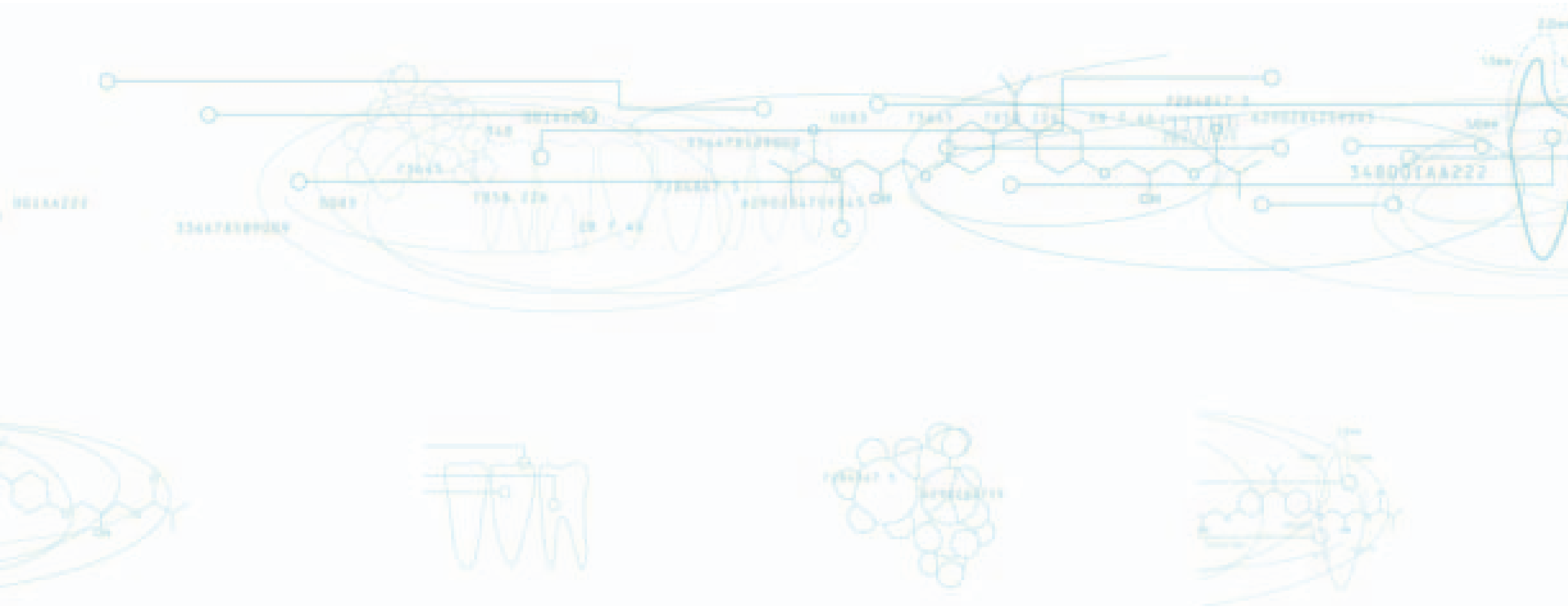
Charger and Handpiece

Time to charge empty battery:	Approx. 2 hours
Operating temperature:	10°C…40°C/59°F…104°F
Relative humidity:	30% ...75% Atmospheric pressure at 700hPa to spr1060hPa
Total height with handpiece inserted in charger:	190 mm

Transport and Storage Conditions

Ambient temperature range:	-20°C to +40°C
Relative Humidity:	10% to 80% excluding condensation
Atmospheric pressure:	500hPa to 1060 hPa

Subject to technical modification without prior notice.



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