Visible light–curing unit

PRODUCT NAME (DATE OF ADA ACCEPTANCE)

Ortholux XT (Received ADA Seal of Acceptance in June 1993)

MANUFACTURER

3M Unitek, 2724 S. Peck Road, Monrovia, Calif. 91016-5097, 1-800-423-4588, "www.3M.com/unitek"

SUMMARY

Ortholux XT is a high-intensity light source emitting filtered visible blue light in the 400- to 500-nanometer range for polymerization of visible-light–cured resins. The Ortholux handpiece comes with a portable power supply, a light-intensity check in the power supply, a spare lamp, an eyeshield and a mounting kit. The handpiece consists of a pistol grip with a thermoplastic housing that contains the light source, cooling fan, light guide receptacle (8- or 13-millimeter–diameter fused quartz lightguide), optical filter, light switch and timer switch. The timer is operator-selectable with options of five, 10, 15 and 20 seconds and an XT option of up to 600 seconds. The push-button switch allows for timer disruption and reactivation.

3M Unitek reported (3M Unitek, unpublished data submitted to the ADA, date not known) that the cooling fan generates noise below 43 decibels when the internal handpiece temperature is below 100 C. At 120 C, the fan speed increases, generating 52 dBA. The U.S. Air Force Dental Investigative Service[1] reported that the cooling fan is extremely quiet.

The light shuts off when it reaches 140 C. The light source is a 75-watt tungsten/halogen lamp. The handpiece weighs less than one pound. The power supply contains the built-in intensity meter that illuminates a green light-emitting diode when the tested light exceeds 400 milliwatts per square centimeter. The power cord is six feet in length. A built-in voltage regulator ensures a steady voltage supply to the unit.

ADA ACCEPTED American Dental Association ®

CONSIDERATIONS FOR ACCEPTANCE

Ortholux XT was evaluated according to the ADA Guidelines for Submission of Visible Radiation–Emitting Resin Curing Devices and met all the requirements. Some of the following information is required:

- General description of the mechanical design that includes the following:
  - description of the operational portions of the device;
  - type of light source;
  - type of filter, means of filter protection against mechanical damage and transmission characteristics of the filter;
  - expected minimum light source life;
  - expected filter life;
  - electrical safety;
  - description of beam collimating and limiting devices;
  - description of protective eyewear for the operator;
  - appropriate tips that are capable of disinfection;
  - pertinent details of quality assurance and quality control.

Other information that is required:

- spectral characteristics of the device in terms of wavelengths and absolute intensities;
- comparison of the spectral characteristics of the device with the appropriate safety limits;
- absence of any hazard to operator or patient due to extensive heating of the devices;
- evidence of curing;
- biological data demonstrating safety.

DEVICE CHARACTERISTICS, SAFETY AND EFFICACY DATA

The average lamp life is at least 4,000 cycles (one cycle equals lamp on 20 seconds, lamp off 20 seconds, with minimum dwell every 10 cycles).

The expected unit life (including filter) is at least 10,000 average cycles.

Ortholux XT is listed by Underwriters Laboratories Inc., or UL. UL completed safety testing according to UL 544, UL Standard for Safety for Medical and Dental Equipment.[2]

The beam collimator is a fused glass fiber-optic rod that is available in two sizes (8 mm and 13 mm).

The handpiece surface temperature does not exceed 60 C during use. A malfunction of the fan will cause the light to shut off automatically.

Safety limits for light use were evaluated according to American National Standards Institute Standard Z 136, 1-1980, for the safe use of lasers. The conclusion was made that viewing the light reflected from a tooth while using the Ortholux light does not present a thermal injury hazard or a photochemical blue-light hazard with normal use (3M Unitek, unpublished data submitted to the ADA, date not known). The unit comes with an eyeshield that can be used to block reflected light below 500 nm.

Curing depth was evaluated using four composites (3M Unitek, unpublished data submitted to the ADA, date not known). The depth of cure was determined using light outputs ranging from 300 to 600 mW/cm^2 for 20, 30, 40 or 50 seconds (measured with the Curing Radiometer, Demetron Research, Orange, Calif.), all of which produced acceptable curing depths.

Ortholux XT was tested for mucosal irritation on guinea pigs by exposing the buccogingival regions to the light from a 2-cm distance for 2.5 minutes. No irritation was found one, two, three or 14 days postexposure.[3]

INDICATIONS AND PRECAUTIONS

The instructions state that although the light output is filtered to reduce the ultraviolet light, prolonged exposure may cause retinal damage to eyes and may heat oral tissues. People who have extreme brightness sensitivity caused by cataract surgery, photosensitizing drugs and so forth should avoid exposure. Prolonged viewing should be avoided and protective glasses should be worn.

- The light guide can be disinfected by autoclaving and by soaking in a bactericidal agent.
- Light transmission can be compromised if the light guide tip is dirty or scratched.
- Ortholux is not safe for use with flammable anesthetics or in other explosive environments.

1. U.S. Air Force Dental Investigation Service. 47-22 3M Curing Light XL3000 (project 95-23). Dent Items Significance 1996;47. Available at: "www.brooks.af.mil/DIS/DIS47/sec2b.htm#DIS47022". Accessed Sept. 4, 2002.
2. Underwriters Laboratories Inc. Report on medical and dental equipment, professional. Dental Products Division of 3M Co., St. Paul, Minn. File E97689. Project 92NK16598. Northbrook, Ill.: Underwriters Laboratories; 1992.
3. Hart GE, O'Malley KD. Mucosal irritation study with Visilux 3M curing light model 5510AA in guinea pigs. St. Paul, Minn.: Safety Evaluation Laboratory, Riker Laboratories Inc.; 1983.

Visible light curing

Curing lights are used to activate photoinitiators in restorative materials to initiate polymerization. Photoinitiators are activated by absorbing photons. The change in the molecular structure of the restorative material, or polymerization, occurs as monomers are incorporated into a polymer network.[1] The amount of activated photoinitiator depends on the concentration of photoinitiator in the material, the number of photons to which the material is exposed and the energy of the photons. The number of photons and energy of the photons (wavelength) depends on the curing light.[1] Photoinitiator activation occurs at specific wavelengths. The most common photoinitiator in dental materials is camphoroquinone, the activity of which peaks between 470 and 480 nanometers.[2]

Factors affecting polymerization include filler type (size and loading), the effectiveness of the light transmission (for example, light guide tips being free from debris and scratches), thickness and shade of restorative material, exposure time, distance of the light source from the restorative material and light intensity.[3] Several types of available curing units have different light intensities and light sources. Light-curing units use halogen-based; light-emitting diode, or LED; plasma-arc; or laser technology. The energy levels range from 300 to more than 1,000 milliwatts per square centimeter.[4]

Halogen bulbs generate light through the heating of tungsten filaments to high temperatures. A small percentage (< 1 percent) of the energy is given off as light, while most of the energy given off is in the form of heat.[1,4] A drawback of halogen bulbs is that this generation of heat causes a degradation of the components of the curing unit over time.[5,6] The result can be a decline in the irradiance, which compromises the curing ability of the unit. A study by Barghi and colleagues[7] found that 45 percent of light-curing units in 122 dental offices had outputs below 300 mW/cm^2. Even when light output is set to 300 mW/cm^2, a study by Fan and colleagues[8] found that only 62 percent of the resin-based composites tested were adequately cured, with a light intensity of 300 mW/cm^2 in the 400- to 515-nm–wavelength range, using the manufacturer's recommended irradiation times. Ninety percent of the composites