

# **3M** Unitek

## **Ortholux™ Luminous Curing Light**

ENGLISH



**Fast Curing Cordless LED Light**



Instructions For Use

# Ortholux™ Luminous Curing Light

## Fast-Curing Cordless LED Light

### Safety

#### PLEASE NOTE!

Prior to installation and start-up of the unit, please read these instructions carefully!

As with all electrical devices, the proper function and safe operation of this unit depend on the user's compliance with the standard safety procedures as well as the specific safety recommendations presented in these Instructions for Use.

1. The unit must be used in strict accordance with the following Instructions for Use. The manufacturer assumes no liability for any damage resulting from the use of this unit for any other purpose.
2. Prior to start-up of the unit, ensure that the operating voltage stated on the rating plate is compatible with the available main voltage. Operation of the unit at a different voltage may damage the unit.
3. Position the unit so that the power plug is accessible at all times. The power plug is used to turn the unit on and off. To disconnect the charger from the main voltage, remove the power plug from the electrical outlet.
4. Use supplied 3M Unitek charger. The use of any other charger can result in damage to the battery.
5. The Ortholux™ Luminous Curing Light must be aimed away from the eyes in order to avoid serious health consequences due to irradiation of the eyes. **Use the eye shield.** Exposure must be restricted to the area of the oral cavity in which clinical treatment is intended.
6. **CAUTION!** In cases where the Ortholux Luminous Curing Light will be used outside of the oral cavity additional eye protection may be needed. The reflected light from curing surfaces when not confined to the oral cavity may be more intense than intra-orally. It is recommended that protective orange glasses be worn by everyone in close proximity of the extraoral curing in addition to the use of the eye-shield on the light.
7. **CAUTION!** The Ortholux Luminous Curing Light generates high intensity light. High intensity light always involves the production of heat. The light emitted should be aimed directly above the material to be cured - exposure of the soft tissues (gingiva, oral mucosa, and skin) to high-intensity light should be avoided as such exposure may cause damage or irritation. If applicable, cover such areas. If exposure of soft tissues cannot be avoided, adjust the polymerization process to the light level, e.g., by shortening the polymerization times or increasing the distance between the light guide exit and the material to be cured. When utilizing the light in Extended Mode (15s), do not keep the light in one position. Longer exposure in the region of the pulp can lead to injury or irritation of the pulp, which is why the specified exposure times must not be exceeded.

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8. Ortholux Luminous Curing Light may be operated only with the supplied light guide or 3M Unitek replacement light guide. The use of other light guides may result in a reduction or increase in the light intensity. The product's warranty does not cover any damage resulting from the use of third-party light guides.
9. Condensation resulting from the unit being transferred from a cold to a warm environment may be a potential risk. Hence, the unit should be turned on only after it is completely equilibrated to ambient temperature.
10. In order to avoid electric shock do not introduce any objects into the unit with the exception of replacement parts handled in accordance with the Instructions for Use.
11. Use only genuine 3M Unitek parts when replacing defective components as directed in these Instructions for Use. The product's warranty does not cover any damage resulting from the use of third-party replacement parts.
12. Should you have any reason to suspect the safety of the unit to be compromised, the unit must be taken out of operation and labeled accordingly to prevent third parties from inadvertently using a possibly defective unit. Safety may be compromised, e.g., if the unit malfunctions or is noticeably damaged.
13. Keep solvents, flammable liquids, and sources of intense heat away from the unit as they may damage the plastic housing of the charger, the seals, or the cover on the operating buttons.
14. Do not operate the unit in the proximity of flammable mixtures.
15. Do not allow cleaning agents to enter the unit as this may short-circuit the unit or cause potentially dangerous malfunction.
16. Only service centers authorized by 3M Unitek may open the unit housing and repair the device.
17. Ortholux Luminous Curing Light must not be used for patients, or by users, with heart pacemaker implants who have been advised to be cautious with regard to their exposure to small electrical devices.
18. Do not use Ortholux Luminous Curing Light for patients with a history of photobiological reactions (including individuals with urticaria solaris or erythropoietic protoporphyria) or who are currently on photosensitizing medication (including 8-methoxypsoralen or dimethylchlorotetracycline).
19. Individuals with a history of cataract surgery may be particularly sensitive to the exposure to light and should be discouraged from exposure to the Ortholux Luminous Curing Light unless adequate safety measures, such as the use of protective goggles to filter blue light, are undertaken.
20. Individuals with a history of retinal disease should seek advice from their ophthalmologist prior to operating the unit. In operating the Ortholux Luminous Curing Light, this group of individuals must take extreme care and comply with any and all safety precautions (including the use of suitable light-filtering safety goggles).
21. This unit has been developed and tested in accordance with the relevant EMC regulations and standards. It is in conformity with legal requirements. Since various factors such as power supply, wiring, and the ambient conditions at the place of operation can affect the EMC properties of the unit, the possibility that, under unfavorable conditions, there will be EMC disruptions cannot be completely excluded. If you should notice problems in the operation of this or other units, move the unit to a different location.
22. Prior to each use of the unit ensure that the emitted light intensity is sufficient to safely guarantee polymerization. Use the light testing area integrated into the charger for this purpose.

## Glossary of Symbols



Attention, Consult Accompanying Documents



Type B Equipment - Protection against electric shock



Class II Equipment - double insulated



Establishes that the product conforms to all applicable legal requirements



**NRTL approval applies only to USA version PN 704-460**



Battery power level



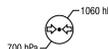
Icon to identify electric and electronic devices. The unit must be collected and disposed of separately.



Temperature limitation



Humidity limitation



Atmospheric pressure limitation



## Product Description

Ortholux Luminous Curing Light, is a high-performance light source for intraoral polymerization of orthodontic adhesives. It consists of a charger and a cordless handpiece powered by a rechargeable battery. The charger is designed for use on a table and cannot be wall-mounted.

The light source is a high-performance light-emitting diode (LED). The emitted light covers the light wavelengths between 430 and 480 nm.

Settable exposure times:

- 3, 6, 9, or 12 seconds.
- Extended mode (15 seconds)
- Tack cure mode (1 second)

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

The unit is shipped with an 8 mm diameter light guide. It is not permissible to use light guides from other manufacturers.

The handpiece is equipped with a sleep mode to minimize the unit's energy consumption. The handpiece switches to sleep mode once it is placed in the charger or if left unused for approximately 5 minutes outside the charger.

NOTE: Do not discard these Instructions for the duration of product use.

## Fields of Application

- Polymerization of light-curing orthodontic adhesives with photoinitiators in the wavelength range of 430-480 nm.

The high intensity light output of the Ortholux Luminous Curing Light allows for faster curing times than other available curing lights. Refer to the table under Recommended Cure Techniques with 3M Unitek Adhesives.

- Though the majority of light-curing orthodontic adhesives are responsive in this range of wavelengths, you may wish to contact the manufacturer of the material in question.

## Technical Data

### Charger

Operating voltage:	100 - 127 V 50/60 Hz 230 V 50/60 Hz (see rating plate for factory-set voltage)
Power input:	Nominal consumption 0.045 A (230 V) 0.1 A (100-127 V)
Dimensions:	Length: 170 mm Width: 95 mm Height: 50 mm Weight: 650 g

Classification: Protection class II, 

## Handpiece

Power supply: lithium-ion battery, nominal voltage 3.7 V

Utilizable wavelength range: 430-480 nm

Wavelength peak: 455 nm +/- 10 nm

Light intensity (between 400 and 515 nm): 1600 mW/cm<sup>2</sup> (independent of battery power level)

Light emission area: typically 42 mm<sup>2</sup> (optically active)

Intermittent operation: 1 minute on, 15 minutes off (ambient temperature of 40°C)  
typically 7 minutes operating time at ambient temperature (23°C)

Total exposure time with new, fully charged battery: typically 60 minutes

Dimensions: Diameter: 28 mm  
Length: 270 mm

Weight: 250 g (including light guide)



## Charger and Handpiece

Time to charge empty battery: approximately 2.0 hours

Operating temperature: 10°C to 40°C (59°F to 104°F)

Relative humidity: 30% to 75%

Atmospheric pressure: 700 hPa to 1060 hPa

Total height with handpiece inserted in the charger: 180 mm

## Transport and Storage Conditions:

Ambient temperature range: -20°C to +40°C /  
-4°F to +104°F

Relative humidity: 30% to 75%

Atmospheric pressure: 700 hPa to 1060 hPa

*Subject to technical modification without prior notice.*

## Installation of the Unit

### Factory Settings

The factory settings of the unit are as follows:

- When first turned on the unit is in Extended Mode, i.e. only the Power level LED is lit on the hand piece.

### Initial Steps

#### Charger

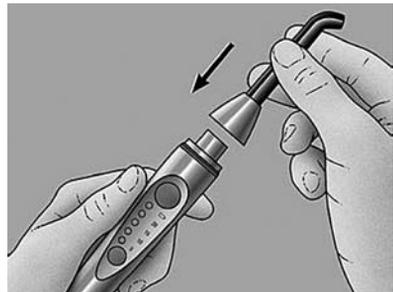
- Please ensure first that the voltage stated on the rating plate corresponds to the existing main supply voltage. The rating plate is attached to the bottom of the charger.
- Place the charger on a level surface.
- Connect the power cable of the charger to the power supply.
  - The green LED on the charger showing that the unit is ready for operation comes on. This shows that the unit is ready for operation; please refer to the section "Operating Status Display of the Charger."

#### Light Guide/Handpiece

- Never place the handpiece in the charger without the battery inserted in the handpiece!
- Place the eye shield on the front of the unit.
- Autoclave the light guide prior to first use.
- Insert the light guide firmly into the handpiece.

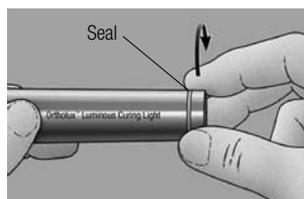
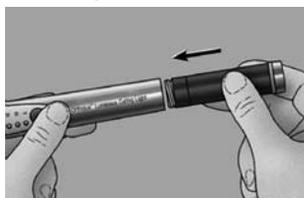
#### Removing and Inserting the Light Guide from/into the Handpiece

- The light guide has a magnetic holder. Remove the light guide from the handpiece by pulling it towards the front.
- Attach the light guide to the handpiece until it is firmly in place.



## Insert the battery:

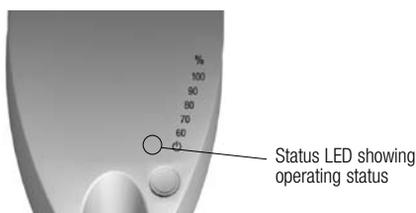
- **Remove the protective cap from the battery and keep with the unit packaging.**
- Slowly insert the battery with the thread side towards the metal housing into the handpiece until it stops. Screw the battery clockwise by hand until the seal is pressed firmly against the metal housing. The unit will not function properly if the battery is not screwed in completely!
- **If the unit does not function properly, remove the battery and reinsert it as described above.**



## Battery Charging

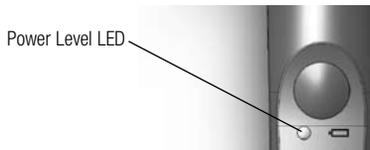
- The unit contains a powerful lithium-ion rechargeable battery. The battery does not have any memory effect and can therefore be recharged at any time by placing it in the charger (see “Power Level Display of the Handpiece” below).
- Alternatively, the battery in the unit can be replaced by a spare battery (available separately) which has been charged.
- Place the handpiece on the charger for approximately 1.5 hours before the first use, in order to charge the new battery completely for the first time.
  - The status LED showing the operating status of the charger flashes green during the charging operation; see below “Operating Status Display of the Charger.”

## Operating Status Display of the Charger



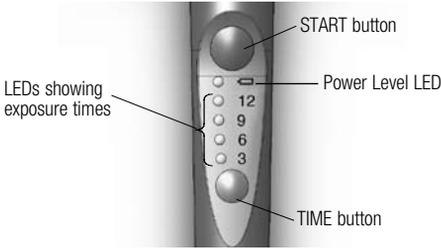
Status LED	Operating status	
	Handpiece/battery outside the charger	Handpiece/battery in the charger
Steady green light	Charger ready for operation	Charging has been completed
Flashes green	n/a	Battery is being charged
Steady red light	Charge contact pins are wet	Charge contact pins are wet
Flashes alternately red and green	Malfunction in the charger	Problem during charging

## Power Level Display of the Handpiece



Power Level LED	Operating status	
	Handpiece outside the charger	Handpiece in the charger
Steady green light	Battery is charged, handpiece ready for operation	Not possible, handpiece is in sleep mode
Steady red light	Warning for low battery capacity, remaining capacity adequate typically for 20 3-second cycles	Not possible, handpiece is in sleep mode
Flashes red	Battery fully discharged, exposure cycle will be completed or, if in extended mode, stopped	Problem in charging, battery is defective or cannot be charged

## Operation



## Activating the Handpiece

If the Power Level LED is off, briefly press the START button to activate the hand piece. The Power Level LED will come on and a short audible signal is emitted. The hand piece is now ready for operation; the handpiece displays the latest set exposure time setting.

## Selection of Exposure Time

Press the TIME button to cycle through the following settings from left to right. Press the TIME button again to go back to 3s settings from the Extended Mode.

3s	6s	9s	12s	Extended Mode (15s)
●	●	●	●	●
○	○	○	○	○
○	○	○	○	○
○	○	○	○	○
○	○	○	○	○

**Caution!** High intensity light always involves the production of heat. When utilizing the light in Extended Mode (15s), do not keep the light in one position. Longer exposure in the region of the pulp can lead to injury or irritation of the pulp, which is why the specified exposure times must not be exceeded.

## Activating and Deactivating the Light Emission

Briefly press the START button to activate the light emission for the Exposure Time set as described above.

- Once the emission has begun, the active Exposure Time LEDs will count down every 3s with an acoustical signal indicating the elapsed time, except for the Extended Mode. When the emission is completed, the Exposure Time LEDs will return as set before.
- Example with 12s Exposure Time setting:

Beginning of Emission	3 sec Elapsed	6 sec Elapsed	9 sec Elapsed	End of Emission
●	●	●	●	●
○	○	○	○	○
○	○	○	○	○
○	○	○	○	○
○	○	○	○	○
ON Signal	1 beep	2 beeps	3 beeps	OFF Signal

- For Extended Mode, an acoustical signal is emitted every 3 seconds for a total of 15 seconds.
- If desired, press the START button to stop the light emission before the set time is over.

## Tack Cure Function

Hold down the START button to activate the Tack Cure function regardless of the set Exposure Time. The unit emits a single one-second light pulse which allows for a short exposure to tack cure brackets. The light will return to standard operation when the START button is no longer depressed.

## Recommended Cure Techniques with 3M Unitek Adhesives

- Rotate the light guide into the desired position for polymerization.
- For most 3M Unitek adhesives, reference the table below for recommended cure technique.

Appliance	Adhesive	Ortholux™ Luminous Curing Light
Metal Brackets	Transbond™ XT Adhesive,	3 seconds mesial x
	Transbond™ PLUS Color	3 seconds distal
Ceramic Brackets	Change Adhesive,	3 seconds through the bracket
	APC™ II Adhesive	
Buccal Tubes (direct bond)	Coated Brackets,	6 seconds mesial x 6 seconds occlusal
	APC™ PLUS Adhesive Coated Brackets	
Lingual Retainers	Transbond™ LR Adhesive	3 seconds mesial x 3 seconds distal
Molar Bands	Transbond™ Plus Band Adhesive	12 seconds (3 seconds per cusp)
	Unitek™ Multi-Cure Glass Ionomer Band Cement	
Indirect Trays (Metal Brackets)	Transbond™ Supreme LV Adhesive	6 seconds mesial x 6 seconds distal through the tray
Indirect Trays (Ceramic Brackets)		6 seconds through the bracket and tray

- For other 3M Unitek adhesives not specifically mentioned, please refer to the adhesive Instructions for Use.
- If using other light cure adhesive systems, consult the adhesive manufacturer's instructions.
- The light guide tip should be placed approximately 1-2 mm above the appliance and pointed perpendicular towards the tooth surface.

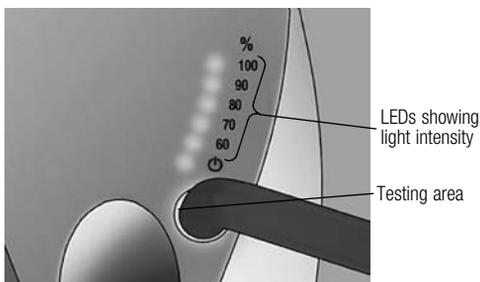
- The recommendations are applicable with 100% light output intensity, measured at the intensity test area on the charging base.
- A technique tip for faster light curing of metal brackets is to position the light guide interproximal to two brackets. In order for the bracket to fully cure, both sides of the bracket must be exposed to the light.
  - **Keep the light guide clean at all times to obtain full light intensity.** Cured primer/adhesive on the light guide will reduce the intensity resulting in incomplete cure.
  - **Damaged light guides substantially reduce the light intensity and must be replaced immediately, sharp edges may cause serious injury!**

NOTE: Holding the light away from the tooth, moving the light guide and turning the light guide tip at an angle may cause incomplete cure of the material.

### Sleep Mode

Once the handpiece is placed in the charger, all internal functions and LEDs are automatically turned off as the handpiece switches to sleep mode. This reduces the power consumption of the battery to a minimal level. Outside the charger, the handpiece is also switched to sleep mode if it is not used for approximately 5 minutes. See “Activating the Handpiece” to wake up the unit.

### Measurement of Light Intensity



The light intensity of the Ortholux Luminous Curing Light handpiece can only be reliably determined using the light intensity testing area on the Ortholux Luminous Curing Light charger! The circular testing area is located below the Status LED on the charger. Measurements carried out using other units will produce incorrect results due to the different light sources and the varying arrangement of the components of the units.

### NOTE: The light intensity is independent of the battery charge level.

Caution!

- Clean the testing area with a damp cloth.
- Without applying pressure, place the light guide on the testing area such that the light-emitting opening of the light guide is flush with the testing area.
- Activate the lamp by pressing the START button.
  - The number of illuminated LEDs on the charger is indicative of the measured light intensity: 5 LEDs = 100%, 4 LEDs = 90%, 3 LEDs = 80%, 2 LEDs = 70%, 1 LED = 60%.
- **If the light intensity is below 80% (fewer than 3 LEDs are ON), check the light guide and handpiece for contamination or defects.**
- Remove and clean the light guide of any contamination. Replace a defective light guide with a new light guide. If the measures described above do not result in any improvement, call 3M Unitek Customer Service.

### Acoustical Signals - Handpiece

An acoustical signal is emitted

- every time a button is pressed
- every time the light is turned ON or OFF
- 1 time after 3 seconds exposure time, 2 times after 6 seconds, 3 times after 9 seconds  
Exception: in Extended Mode; an acoustical signal is emitted every 3 seconds
- every time the sleep mode is terminated by pressing the START button.

A 2 second-error signal is emitted, if

- the handpiece overheats
- the battery lacks sufficient charge

The acoustical signals from the handpiece can be turned off (except for the 2-second error signal). Put the handpiece in sleep, e.g., by setting it in the charger. Take the device from the charger; press the TIME button, then press the START button. This changes the sleep mode of the handpiece back to active and the status “Acoustical signals activated” to “Acoustical signals deactivated”. The acoustical signals can be reactivated by following the same procedure.

## Troubleshooting

Error	Cause	Error	Cause
The charge level display on the handpiece glows red steadily.	<p>The remaining battery charge is adequate only for typically 20 3-second exposure cycles.</p> <ul style="list-style-type: none"> <li>Place the handpiece in the charger and re-charge the battery.</li> </ul>	During light emission in extended mode, an error signal sounds for 2 seconds, the emission is stopped, and the handpiece changes to sleep mode.	<p>The handpiece has become overheated in the course of use. The handpiece can be used again once it has cooled down.</p> <ul style="list-style-type: none"> <li>Allow the handpiece to cool down.</li> </ul>
The power level display of the handpiece flashes red. The ongoing exposure is interrupted (light off signal is emitted) followed by a 2 second-error signal; the handpiece switches to "sleep" mode and resists further activation.	<p>The battery lacks sufficient charge.</p> <ul style="list-style-type: none"> <li>Place the handpiece in the charger and re-charge the battery.</li> </ul>		<ul style="list-style-type: none"> <li>Immediately after the temperature control has turned off the handpiece, it must cool down a minimum of 1.5 minutes in the air before a new light emission can be started.</li> <li>The handpiece can be used again, once pressing the START button successfully activates the light.</li> </ul>
The power level display of the handpiece flashes red while the handpiece is in the charger.	<p>Charging problem. The battery is defective or at the end of its useful life.</p> <ul style="list-style-type: none"> <li>Remove and re-insert the battery to reset the unit.</li> <li>Replace the battery.</li> </ul>		<ul style="list-style-type: none"> <li>During the cooling-off period immediately after the acoustical signal has gone off, 2 minute cooling-off time in the air typically corresponds to 1 minute operating time.</li> </ul>
The handpiece has not been used for a long time and now it cannot be turned on.	<p>There is not enough charge in the battery to turn on the handpiece.</p> <ul style="list-style-type: none"> <li>Place the handpiece in the charger and re-charge the battery.</li> </ul>	The LED showing the operating status in the charger flashes alternately red and green. The handpiece is not in the charger.	<p>Charger is defective.</p> <ul style="list-style-type: none"> <li>Unplug and plug in the charger to reset.</li> <li>Have the charger repaired.</li> </ul>
The light emission does not start when the START button is pressed; an error signal sounds for 2 seconds.	<p>The handpiece has become overheated in the course of use. The handpiece can be used again once it has cooled down briefly.</p> <ul style="list-style-type: none"> <li>Allow the handpiece to cool down.</li> </ul>	The LED showing the operating status in the charger flashes alternately red and green. The handpiece is in the charger.	<p>Malfunction during charging.</p> <ul style="list-style-type: none"> <li>Remove and re-insert the battery to reset the unit.</li> <li>The battery is damaged.</li> <li>Replace the battery.</li> </ul>
	<ul style="list-style-type: none"> <li>The handpiece can be used again, once pressing the START button successfully activates the light.</li> <li>During the cooling-off period immediately after the acoustical signal has gone off, 2 minute cooling-off time in the air typically corresponds to 1 minute operating time.</li> </ul>	The LED showing the operating status in the charger does not come on although the plug has been connected to an electrical outlet.	<p>Power outlet carries no voltage.</p> <ul style="list-style-type: none"> <li>Use a different power outlet.</li> </ul> <p>Charger is defective.</p> <ul style="list-style-type: none"> <li>Have the charger repaired.</li> </ul>
		The light intensity is too low.	<ul style="list-style-type: none"> <li>Clean the light guide and the protecting glass in the light guide mounting hole (please refer to "Cleaning the Light Guide").</li> </ul>

**Error****Cause**

- Solution

The LED showing the operating status in the charger glows red steadily.

The charge contact pins in the handpiece or the charger are wet.

- Dry the charge contact pins. Be careful not to bend the flexible charge contact pins in the charger.

**Maintenance and Care**

The Ortholux Luminous Curing Light is maintenance-free with the exception of cleaning the light guide and replacing batteries as needed. The light output should be checked on a regular basis, i.e. daily, using the integrated light intensity testing area on the charging base. See the information contained in this chapter to secure problem-free operation. There are no user serviceable parts on the unit. If the unit malfunctions and the trouble shooting steps above do not remedy the situation, call 3M Unitek Customer Service.

**Inserting/Removing the Battery**

Never place the handpiece in the charger without the battery inserted in the handpiece!

Use 3M Unitek batteries only! The use of other manufacturer batteries or non-rechargeable batteries/primary batteries is a potential hazard and may damage the unit.

- Remove the battery from the handpiece by turning it counter-clockwise as shown. (Page 6)
- Insert the (new) battery into the handpiece and turn it clockwise until the seal is firmly pressed against the metal housing.
- Place the handpiece in the charger for 1.5 hours in order to fully charge the new battery for the first time.
  - The LED showing the operating status on the charger flashes green; see also "Operating Status Display of the Charger."

**Handpiece/Battery Care**

- Use only the 3M Unitek charger which is provided with the unit; failure to do so could lead to damage to the battery!
- Do not immerse the battery in water or incinerate! Please also observe the chapter on "Safety."

**Cleaning the Light Guide**

The light guide can be autoclaved.

**Do not sterilize by chemical means or hot-air!**

- The light guide should be regularly wiped clean with a soft cloth. Especially before and after steam

sterilization, the spots of dried liquid should be wiped off the ends of the device.

- Adhering polymerized material should be removed with alcohol, a plastic spatula may help in removing the material.
  - Do not use any sharp or pointed tools for cleaning in order to protect the surface of the unit from scratching.
- The protective glass of the handpiece can be cleaned with a soft and fluff-free cloth.

**Cleaning the Charger, Handpiece, and Eye Shield**

- To disinfect all components, spray the disinfectant on a towel and use it to disinfect the unit. **Do not spray the disinfectant directly on the handpiece or the charger.**
  - Disinfection agents must not enter the unit!
- Dry residual disinfectants on the charger, the handpiece and the eye shield with a soft and fluff-free cloth, as they damage the plastic components.
- Clean the charger, the handpiece and the eye shield with a soft cloth and, if required, a mild cleaning agent.
  - Solvents or abrasive cleaners may not be used in any case, as they damage the plastic components!
  - Cleaning agents must not enter the unit!
  - Make sure that charge contact pins remain dry and are not contacted by metallic or greasy parts. Do not bend the charge contact pins during drying. Wet charge contact pins will cause an operating error (malfunction message: the LED showing the operating status of the charger flashes red).

**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. A safety switch within the battery prevents a total discharge.
- Discharged or nearly discharged batteries must be recharged as soon as possible.

**Disposal**

Your new unit contains a powerful lithium-ion rechargeable battery. Dispose of defective batteries and units in accordance with local legal regulations!

## **Customer Information**

No person is authorized to provide any information that deviates from the information provided in this instruction sheet.

## **Warranty**

3M Unitek warrants this product will be free from defects in material and manufacture for a period of two years from date of purchase. 3M UNITEK MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and 3M Unitek's sole obligation shall be repair or replacement of the 3M Unitek product.

## **Limitation of Liability**

Except where prohibited by law, 3M Unitek will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

Information valid as of March 2009

# 3M Unitek Service Centers

## Denta n.v.

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## Guidance and manufacturers declaration – electromagnetic emission

The Ortholux™ Luminous Curing Light unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Ortholux Luminous Curing Light unit should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Ortholux Luminous Curing Light unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A,	The Ortholux Luminous Curing Light unit is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

## Guidance and manufacturer's declaration – electromagnetic immunity

The Ortholux™ Luminous Curing Light unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Ortholux Luminous Curing Light unit should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic 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	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % $U_T$ (>95 % dip in $U_T$ ) for 0,5 cycle  40 % $U_T$ (60 % dip in $U_T$ ) for 5 cycles  70 % $U_T$ (30 % dip in $U_T$ ) for 25 cycles  < 5 % $U_T$ (>95 % dip in $U_T$ ) for 5 sec	< 5 % $U_T$ (>95 % dip in $U_T$ ) for 0,5 cycle  40 % $U_T$ (60 % dip in $U_T$ ) for 5 cycles  70 % $U_T$ (30 % dip in $U_T$ ) for 25 cycles  < 5 % $U_T$ (>95 % dip in $U_T$ ) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Ortholux Luminous Curing Light unit requires continued operation during power mains interruptions, it is recommended that the Ortholux Luminous Curing Light unit be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE  $U_T$  is the a. c. mains voltage prior to application of the test level.

## Guidance and manufacturer's declaration – electromagnetic immunity

The Ortholux™ Luminous Curing Light unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Ortholux Luminous Curing Light unit should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10 V	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Ortholux Luminous Curing Light unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance</b></p> $d = \left[ \frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[ \frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$
Conducted RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = \left[ \frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>where <math>p</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in metres (m).<sup>b</sup></p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

<sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Ortholux Luminous Curing Light unit is used exceeds the applicable RF compliance level above, the Ortholux Luminous Curing Light unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Ortholux Luminous Curing Light unit.

<sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

## Recommended separation distances between portable and mobile RF communications equipment and the Ortholux™ Luminous Curing Light unit

The [EQUIPMENT or SYSTEM] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Ortholux™ Luminous Curing Light unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Ortholux Luminous Curing Light unit as recommended below, according to the maximum output power of the communications equipment

<b>Separation distance according to frequency of transmitter</b>			
<b>m</b>			
<b>Rated maximum output of transmitter</b>	<b>150 kHz to 80 MHz</b>	<b>80 MHz to 800 MHz</b>	<b>800 MHz to 2,5 GHz</b>
W	$d = \left[ \frac{3,5}{V_1} \right] \sqrt{P}$	$d = \left[ \frac{3,5}{E_1} \right] \sqrt{P}$	$d = \left[ \frac{7}{E_1} \right] \sqrt{P}$
0,01	0,04	0,12	0,40
0,1	0,11	0,38	1,26
1	0,35	1,20	4,00
10	1,11	3,79	12,65
100	3,50	12,00	40,00

For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.