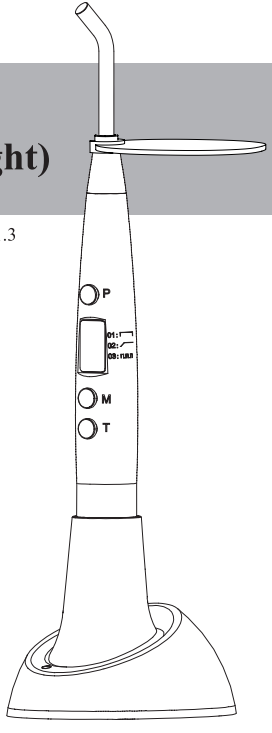
WOODPECKER®

Instruction Manual for LED.H (curing light)

Industrial design patent No.: CN 201130176281.3



CE

Please read this manual before operating

Guilin Woodpecker Medical Instrument Co., Ltd.

Content

1 Principle and usage

1.1 LED.H adopts the principle of ray radiation to solidify the light-sensitive resin by shooting at it in a short time.

1.2 This product is used to restore teeth.

2 Structure and component

LED.H (dental) is composed mainly of high power LED, optical fiber and main unit.

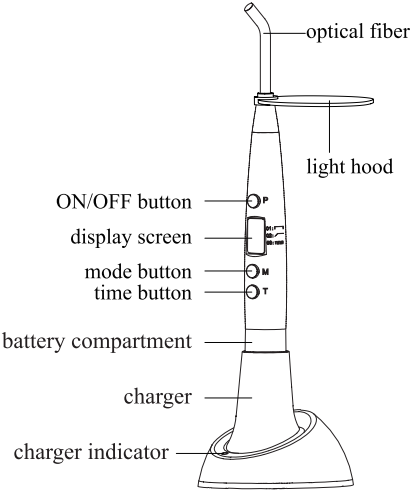


Figure 1- Ⅰ

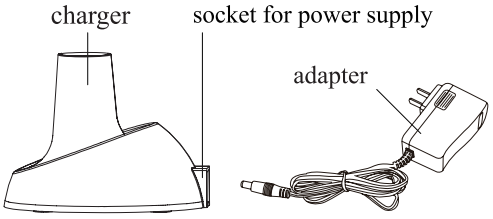


Figure 1－Ⅱ

3 Technical specifications

3.1 Power supply: rechargeable Lithium battery

Battery model: ICR18650

Battery voltage and capacity: 3.7V/2200mAh

Input of adapter: AC100V to 240V, 50Hz/60Hz

Output of adapter: DC5V/1A

3.2 Applied part: optical fiber

3.3 Light source:

a) 5W high power blue LED

b) Wave length: 385nm-515nm

c) Light intensity: 1000mW/cm^2~1200mW/cm^2

3.4 Working condition:

a) Environment temperature: 5℃ to 40℃

b) Relative humidity: 30%~75%

c) Atmosphere pressure: 70kPa to 106kPa

3.5 Dimensions: Φ25mm×252mm

3.6 Net weight: 178g

3.7 Consumption power: ≤8W

3.8 Protection type against electrical shock: class Ⅱ

3.9 Protection against electrical shock: type B

3.10 Protection against harmful ingress of water or particular matter: ordinary equipment (IPX0)

3.11 Safety in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide: not suitable under this condition.

4 Installment and dismantlement

4.1 Take off the red cap from the optical fiber and then insert the metal part into the front of LED.H, make sure to screw the fiber to the end.

4.2 To install the light hood on the top of the optical fiber.

4.3 For dismantlement, taking the instruction of istallment above reversely.

4.4 When finishing using or when the battery needs to be charged, plug the output port of the adapter into the charge port, than connect the adapter to the power supply. After that, place the device into the socket on the charger.

5 Operation

5.1 Lightly press the mode key. Following three modes are available.

5.1.1 Full power mode: screen shows 01, LED works in full power.

5.1.2 Ramping mode: screen shows 02, LED turns from weak to stronger, and reaches the highest power in 5 seconds.

5.1.3 Pulse mode: screen shows 03, LED works in the mode of pulse.

5.2 Lightly press the time button to choose the solidification time. 9 working time modes are available: 3,5,10,15,20,25,30,35,40 seconds.

5.3 During the operation, aim blue light at the position needing solidification. Press the ON/OFF switch, a “beep” sound will appear, the LED starts to work under the selected mode. Then it counts down to “0” second to end the solidification.

5.4 During operation, the blue light can be stopped by press the power button at any time.

5.5 Low power detect circuit is fixed inside of the main unit, when low power is detected, the indicator of the main unit will wink, please charge in time.

5.6 When the battery needs to be charged, connect the plug of the adapter into the AC100V~240V power supply. Then connect the output plug of the adapter to the input plug of the pedestal, and then the indicator turn to green, that means the pedestal is standby. Put the main unit to the charging point of the pedestal, the indicator turn to yellow, and the curing lights starts charging. When charging finished the indicator turn to green.

5.7 After the operation, please clean the fiber with calico in order not to

affect the light intensity.

5.8 This equipment will turn off automatically if no any action within 2 minutes, turn it on by press any button.

5.9 The depth of solidification of composite is no less than 4mm per 10 seconds.

5.10 The optical fiber should be sterilized for 4 minutes with 134℃ and 2.0bar~2.3bar (0.20MPa~0.23MPa) before each use.

5.11 The curing light is equipped with over-heat protection system. It can continuously work 200s, For example, continuously operate the curing light for 10 times under 20s working mode (even the curing light works less than 20s, it is counted as a full operation), then it will come into over-heat protection status. And only after 2-minute sleep, it can restart working 200s continuously.

6. Cleaning, Disinfection and Sterilization

The cleaning, disinfection and sterilization of optical fiber is as follow. Unless otherwise stated, they will be hereinafter referred to as “products”.

Warnings

The use of strong detergent and disinfectant (alkaline pH>9 or acid pH <5) will reduce the life span of products. And in such cases, the manufacturer takes no responsibility.

This device shall not be exposed to high temperature above 138℃.

Processing limit

The pro ducts have been designed for a large number of sterilization cycles.

The materials used in manufacture were selected accordingly. However with every renewed preparation for use, thermal and chemical stresses will result in ageing of the products. The maximum number of sterilizations for optical fiber is 500 times.

6.1 Initial processing

6.1.1 Processing principles

It is only possible to carry out effective sterilization after the completion of effective cleaning and disinfection. Please ensure that, as part of your responsibility for the sterility of products during use, only sufficiently validated equipment and product-specific procedures are used for cleaning/disinfection and sterilization, and that the validated parameters are adhered to during every cycle.

Please also observe the applicable legal requirements in your country as well as the hygiene regulations of the hospital or clinic,especially with regard to the additional requirements for the inactivation of prions.

6.1.2 Post-operative treatment

The post-operative treatment must be carried out immediately, no later than 30 minutes after the completion of the operation. The steps are as follows:

1. Remove the optical fiber from the Curing light Device,and rinse away the dirt on the surface of product with pure water (or distilled water/ deionized water);

2. Dry the product with a clean, soft cloth and place it in a clean tray.

Notes

a) The water used here must be pure water, distilled water or deionized water.

6.2 Preparation before cleaning

Steps

Tools: tray, soft brush, clean and dry soft cloth Remove optical fiber from main unit and put it into the clean tray.

Use a clean soft brush to carefully brush the optical fiber until the dirt on surface is not visible. Then use soft cloth to dry the optical fiber and put them into a clean tray. The cleaning agent can be pure water, distilled water or deionized water.

6.3 Cleaning

The cleaning should be performed no later than 24 hours after the operation.

The cleaning can be divided into automated cleaning and manual cleaning. Automated cleaning is preferred if conditions permit.

6.3.1 Automated cleaning

•The cleaner is proved to be valid by CE certificationin accordance with ENISO 15883.

▪There should be a flushing connector connected to the inner cavity of the product.

▪The cleaning procedure is suitable for the product, and the irrigating period is sufficient.

It is recommended to use a washer-disinfector in accordance with EN ISO15883. For the specific procedure, please refer to the automated disinfection section in the next section “Disinfection”.

Notes

a) The cleaning agent does not have to be pure water. It can be distilled water, deionized water or multi-enzyme. But please ensure that the selected cleaning agent is compatible with the product.

b) In washing stage, the water temperature should not exceed 45 °C, otherwise the protein will solidify and it would be difficult to remove.

c) After cleaning, the chemical residue should be less than 10mg / L.

6.4 Disinfection

Disinfection must be performed no later than 2 hours after the cleaning phase.

Automated disinfection is preferred if conditions permit.

6.4.1 Automated disinfection-Washer-disinfector

·The washer-disinfector is proved to be valid by CE certification in accordance with EN ISO 15883.

·Use high temperature disinfection function. The temperature does not exceed 134 ° C, and the disinfection under the temperature cannot exceed 20 minutes.

·The disinfection cycle is in accordance with the disinfection cycle in EN ISO 15883.

Cleaning and disinfecting steps by using Washer-disinfector

1. Carefully place the product into the disinfection basket. Fixation of

product is needed only when the product is removable in the device. The products are not allowed to contact each other.

2. Use a suitable rinsing adaptor, and connect the internal water lines to the rinsing connection of the washer-disinfector.

3. Start the program.

4. After the program is finished, remove the product from the washer-disinfector,

inspect (refer to section “Inspection and Maintenance”) and packaging (refer to chapter “Packaging”). Dry the product repeatedly if necessary (refer to section “Drying”).

Notes

a) Before use, you must carefully read the operating instructions provided by the equipment manufacturer to familiarize yourself with the disinfection process and precautions.

b) With this equipment, cleaning, disinfection and drying will be carried out together.

c) Cleaning: (c1) The cleaning procedure should be suitable for the product to be treated. The flushing period should be sufficient (5-10 minutes). Pre-wash for 3minutes, wash for another 5 minutes, and rinse it for twice with each rinse lasting for 1 minute. (c2) In the washing stage, the water temperature should not exceed 45 °C, otherwise the protein will solidify and it is difficult to remove. (c3) The solution used can be pure water, distilled water, deionized water or multi-enzyme solution, etc., and only freshly prepared solutions can be used. (c4)During the use

of cleaner, the concentration and time provided by manufacturer shall be obeyed.

The used cleaner is neodisher MediZym (Dr. Weigert).

d) Disinfection: (d1) Direct use after disinfection: temperature ≥ 90 ° C, time ≥ 5 min or A0 ≥ 3000.

(d2)Sterilize it after disinfection and use: temperature ≥ 90 ° C, time ≥ 1 min or A0 ≥ 600.

(d3) For the disinfection here, the temperature is 93 ° C, the time is 2.5 min, and A0>3000.

e) Only distilled or deionized water with a small amount of microorganisms (<10 cfu/ml) can be used for all rinsing steps. (For example, pure water that is in accordance with the European Pharmacopoeia or the United States Pharmacopoeia).

f) After cleaning, the chemical residue should be less than 10mg / L.

g)The air used for drying must be filtered by HEPA.

h) Regularly repair and inspect the disinfector.

6.5 Drying

If your cleaning and disinfection process does not have an automatic drying function, dry it after cleaning and disinfection.

Methods

1. Spread a clean white paper (white cloth) on the flat table, point the product against the white paper (white cloth), and then dry the product with filtered dry compressed air (maximum pressure 3 bar). Until no liquid is sprayed onto the white paper (white cloth), the product drying is

completed.

2. It can also be dried directly in a medical drying cabinet (or oven). The recommended drying temperature is 80℃~120℃ and the time should be 15~40 minutes.

Notes

a) The drying of product must be performed in a clean place.

b) The drying temperature should not exceed 138 °C;

c) The equipment used should be inspected and maintained regularly.

6.6 Inspection and maintenance

In this chapter, we only check the appearance of the product. After inspection, if there is no problem, the optical fiber can only be used.

6.6.1 Check the product. If there is still visible stain on the product after cleaning/disinfection, the entire cleaning/disinfection process must be repeated.

6.6.2 Check the product. If it is obviously damaged, smashed, detached, corroded or bent, it must be scrapped and not allowed to continue to be used.

6.6.3 Check the product. If the accessories are found to be damaged, please replace it before use. And the new accessories for replacement must be cleaned, disinfected and dried.

6.6.4 If the service time (number of times) of the product reaches the specified service life (number of times), please replace it in time.

6.7 Packaging

Install the disinfected and dried product and quickly package it in a

medical sterilization bag (or special holder, sterile box).

Notes

a) The package used conforms to ISO 11607;

b) It can withstand high temperature of 138 °C and has sufficient steam permeability;

c) The packaging environment and related tools must be cleaned regularly to ensure cleanliness and prevent the introduction of contaminants;

d) Avoid contact with parts of different metals when packaging.

6.8 Sterilization

Use only the following steam sterilization procedures (fractional pre-vacuum procedure*) for sterilization, and other sterilization procedures are prohibited:

1. The steam sterilizer complies with EN13060 or is certified according to EN 285 to comply with EN ISO 17665;

2. The highest sterilization temperature is 138 ° C;

3. The sterilization time is at least 4 minutes at a temperature of 132℃/134℃ and a pressure of 2.0 bar ~ 2.3 bars.

4. Allow a maximum sterilization time of 20 minutes at 134 °C.

Verification of the fundamental suitability of the products for effective steam sterilization was provided by a verified testing laboratory.

Notes

a) Only products that have been effectively cleaned and disinfected are allowed to be sterilized;

b) Before using the sterilizer for sterilization, read the Instruction Manual provided by the equipment manufacturer and follow the instructions.

c) Do not use hot air sterilization and radiation sterilization as this may result in damage to the product;

d) Please use the recommended sterilization procedures for sterilization. It is not recommended to sterilize with other sterilization procedures such as ethylene oxide, formaldehyde and low temperature plasma sterilization. The manufacturer assumes no responsibility for the procedures that have not been recommended.

If you use the sterilization procedures that have not been recommended, please adhere to related effective standards and verify the suitability and effectiveness.

* Fractional pre-vacuum procedure = steam sterilization with repetitive pre-vacuum. The procedure used here is to perform steam sterilization through three pre-vacuums.

6.9 Storage

6.9.1 Store in a clean, dry, ventilated, non-corrosive atmosphere with a relative humidity of 10% to 93%, an atmospheric pressure of 70KPa to 106KPa, and a temperature of -20 °C to +55 °C;

6.9.2 After sterilization,the product should be packaged in a medical sterilization bag or a clean sealing container, and stored in a special storage cabinet. The storage time should not exceed 7 days. If it is exceeded, it should be reprocessed before use.

Notes:

a) The storage environment should be clean and must be disinfected regularly;

b) Product storage must be batched and marked and recorded.

6.10 Transportation

1. Prevent excessive shock and vibration during transportation, and handle with care;

2. It should not be mixed with dangerous goodsduring transportation.

3. Avoid exposure to sun or rain or snow during transportation.

The cleaning and disinfection of main unit are as follows.

• Before each use, wipe the surface of the machine with a soft cloth or paper towel soaked in 75% medical alcohol. Repeat the wipe for at least 3 times.

• After each use, wipe the surface of the device with a soft cloth soaked in clean water (distilled or deionized water) or a clean disposable wipe. Repeat the wipe for at least 3 times.

7 Cautions

7.1 Please recharge the battery at least 4 hours before first time usage.

7.2 During the operation, the light should be aimed straightly at the composite resin to ensure the effect of solidification.

7.3 Avoid aiming at eyes directly.

7.4 Only the original pedestal charger, adapter and Lithium battery could be used, because other brand pedestal charger, adapter and Lithium battery are likely to damage the circuit.

7.5 It is forbidden to touch the charging connector with metal or other conductor, to avoiding damage the circuit of charge or the battery.

7.6 Please recharge the battery in cool and ventilated room.

7.7 It is forbidden to self-taking-apart the battery, in order not to result in short-circuit or leakage.

7.8 It is forbidden to extrude, shake or rock the battery. The Lithium battery is forbidden to be in short-circuit situation and it is forbidden to put the battery with metal or other conductors.

7.9 If you don't use this equipment for a long time, please take the battery out and preserve separately.

【WARNING】If the curing light works for 40s continously,the temperature of the top of optical fiber may reach 56℃.

【WARNING】Do not modify this equipment without authorization of the manufacturer.

8 Contraindication

The heart disease patient, pregnant woman and children should be cautious to use this equipment.

9 Maintenance

9.1 This equipment does not include the self-maintenance parts, so it should be performed by professional or special maintenance shop.

9.2 Only the optical fiber of this equipment can be autoclaved under high

temperature and high pressure, other parts should be cleaned by clean water or neutral sterilized liquid, but do not soak the equipment in the water. Do not clean by volatile or soluble liquid, otherwise the marks of the control panel will fade.

9.3 Please clean the optical fiber to avoid the remaining resin on the surface and infect the life-span and the effectiveness of solidification.

10 Troubleshooting

Faulty	Possible cause	Solutions
No indication, no response.	1. Battery is out of power. 2. Faulty of battery. 3. The main unit battery protection system works.	1. Charge the equipment/ Change a new batter. 2. Change a new battery. 3. Place the main unit into the socket on the charger for activation.
“Er” shown on the screen.	Faulty of main unit.	Send to after service for repair.
Wink shown on the screen.	Low battery.	Reconnect the charger, if "Er" show again after 15 minutes please change the battery.

Faulty	Possible cause	Solutions
Light intensity is weak.	1. The optical fiber is not installed well. 2. There is crevice on the optical fiber. 3. There is resin on the tip of the optical fiber.	1. Reinstall the optical fiber. 2. Change a new optical fiber. 3. Clear the resin.
The equipment is not charging when the adapter is connected.	1. The adapter is not connected well. 2. Faulty of adapter or incompatible. 3. The charging point is impurity.	1. Reconnect. 2. Change the adapter. 3. Cleaned by the alcohol.
Effective duration of the battery become short.	The capacity of the battery decreased.	Change a new battery.
The mode indicator twinkles when charging.	1. Low voltage. 2. Short-circuit of the battery.	1. Back to normal after 15 minuets charging. 2. Change a new battery.

If such handlings are completed, the equipment still cannot work normally, please contact with the special maintenance shop or our company.

11 After service

From the date this equipment has been sold, base on the warranty card, we will repair this equipment free of charge if it has quality problems,

please refer to the warranty card for the warranty period.

12 Storage and transportation

12.1 This equipment should be handled carefully, kept away from shaking point, installed or stored at shadowy, dry, cool and ventilated places.

12.2 Don't store it together with articles that are combustible, poisonous, caustic and explosive.

12.3 This equipment should be stored in the environment where the relative humidity is 10%~93%, the atmosphere pressure is 70kPa to 106kPa and the temperature is -20℃ to +55℃.

12.4 Excess impact or shake should be avoided during transportation.

12.5 Don't mix it with dangerous articles during transportation.

12.6 Keep it away from sun or snow or rain during transportation.

13 Environmental protection

Please dispose according to the local laws.

14 Representative in Europe

EC REP MedNet EC-Rep GmbH
Borkstrasse 10 · 48163 Muenster · Germany

15 Symbol instructions

Trademark

CE marked product

Type B applied part

Screw inside/ outside

Ordinary equipment

Class II equipment

Date of manufacture

Manufacturer

Recovery

Used indoor only

Keep dry

Handle with care

Sterilizable up to the temperature specified

Temperature limitation for storage

Humidity limitation for storage

Atmospheric pressure for storage

Appliance compliance WEEE directive

Follow Instructions for Use

EC REP Authorised Representative in the EUROPEAN COMMUNITY

16 Statement

All rights of modifying the product are reserved to the manufacturer without further notice. The pictures are only for reference. The final interpretation rights belong to GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD. The industrial design, inner structure, etc, have claimed for several patents by WOODPECKER, any copy or fake product must take legal responsibilities.

17 EMC - Declaration of conformity

The device has been tested and homologated in accordance with EN 60601-1-2 for EMC. This does not guarantee in any way that this device will not be effected by electromagnetic interference Avoid using the device in high electromagnetic environment.

Guidance and manufacturer's declaration - electromagnetic emissions		
The model LED.H is intended for use in the electromagnetic environment specified below. The customer or the user of the model LED.H should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The model LED.H 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 CISPR11	Class B	The model LED.H is suitable for used in domestic establishment and in establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Guidance & Declaration — electromagnetic immunity			
The model LED.H is intended for use in the electromagnetic environment specified below. The customer or the user of the model LED.H 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 %.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1 kV for Input/output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±2 kV line to earth	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 model LED.H requires continued operation during power mains interruptions, it is recommended that the model LED.H be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Not applicable
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance & Declaration - Electromagnetic immunity			
The model LED.H is intended for use in.the electromagnetic environment specified below. The customer or the user of the model LED.H 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	*3V* *3 V/m*	Portable and mobile RF communications equipment should be used no closer to any part of the model LED.H, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** 3V $d=1.2\times P^{1/2}$ 80 MHz to 800 MHz $d=2.3\times P^{1/2}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter In watts (W) according to the transmitter manufacturer and *d* Is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur In the vicinity of equipment marked with the following symbol: 

NOTE I At 80 MHz end 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.

[a] 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 model LED.H is used exceeds the applicable RF compliance level above, the model LED.H should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model LED.H.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the model LED.H

The model LED.H is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model LED.H can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model LED.H as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz to 80MHz $d=1.2\times P^{1/2}$	80MHz to 800MHz $d=1.2\times P^{1/2}$	800MHz to 2,5GHz $d=2.3\times P^{1/2}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (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) accordable to the transmitter manufacturer.

NOTE I 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.

Scan and Login website for more information

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