

LEDEX™ WL-070+

LED DENTAL CURING LIGHT



Wireless Charging Stand



Dear Customer,

Thank you for choosing DENTMATE LEDEX™ WL-070+ Dental Curing Light.

A lot of researches & developments have gone into the manufacturing of this product. We sincerely hope that it will give you many years of trouble-free use. Please read and understand all the instructions before using this equipment, and save this manual for your reference.

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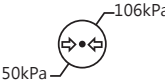
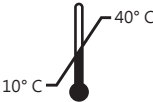
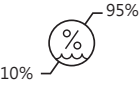


1. Symbols Used

1.1. In these instructions for use



If the instructions are not followed properly, operation may lead to hazards for the product or the user/patient.

1.2. On the product/packaging

 <p>Serial number</p>	 <p>Catalogue number</p>
 <p>Manufacturer</p>	 <p>Date of manufacture</p>
 <p>Class II (AC Adapter)</p>	 <p>Consult the Instructions for use</p>
 <p>This shows the Type B applied part.</p>	 <p>Do not dispose of with normal household waste</p>
 <p>Recycling</p>	<p>IPX0 Ordinary equipment</p>
 <p>EU-representative</p>	 <p>Atmospheric pressure for storage</p>
 <p>Temperature limits</p>	 <p>Storage humidity range</p>
 <p>CE marking</p>	 <p>Store in a dry place</p>

2. Product Information

The light has been manufactured with a super-high luminosity LED. The light wavelength is between 440 and 480 nm, and the intensity is up to 1200mW/cm². These characteristics enable the light to polymerize almost all photosensitive composite resins.

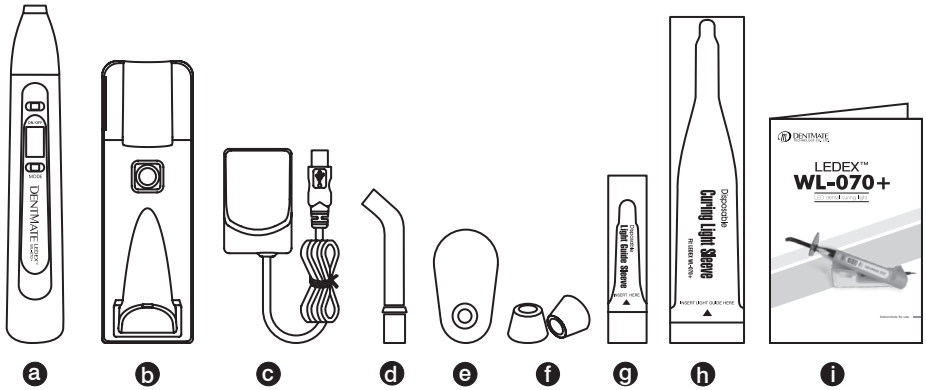
LEDEX™ WL-070+ is characterized by :

- Wireless charging stand & built-in intensity indicator
No need to plug in the cable; no pogo pin required. Easy to interpret due to the built-in intensity indicator.
- The light guide rod is made from genuine optical fiber and not inferior acrylic that optimizes light conduction and minimizes loss of light from source to tip thereby ensuring the highest possible intensity of light at the light guide tip.
- Advanced and high efficient cooling heat sink designed accompanied with over temperature protection. A thermal protection circuit and safety mode accord to protect the light from overheating.
- The automatic memorization of the last operation chosen is another unique feature of the light.
- Including standard mode and ramp mode. It has auto sleep function for saving the energy of battery.

2.1. Indication for use

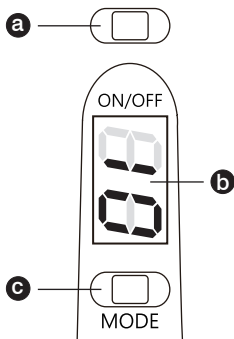
LEDEX WL-070+ is a visible curing unit programmed for polymerization of dental light cured materials by dental professionals.

2.2. System components



Item	Description	Quantity
a	LEDEX™ WL-070+ handpiece	1
b	Wireless charging stand	1
c	Power supply (input AC100~240 V , 50-60 Hz, output DC 5 V/ 2A)	1
d	Optical fiber light guide rod (Ø8 mm)	1
e	Filter	1
f	Anti-glare shield	2
g	Disposable Light Guide Sleeve	20
h	Disposable Curing Light Sleeve	10
i	Instructions for use	1

2.3. Features



a ON-OFF : Pressing this button initiates the selected curing cycles. Pressing this button during the curing cycle will interrupt or end the cycle. If the unit is in the sleep mode, pressing this button will awaken the unit of the curing mode which is last used.

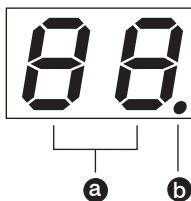
b Display

c MODE :

Push the MODE button, in one second the time can be changed 5 → 10 → 15 → 20 → 25 → 30 → 5 secs.

Push the MODE button, in three seconds the function can be changed standard → ramp → standard → ramp.

2.4. Display



Different modes and output power would be displayed on the screen as below :

a Display : Seconds display · troubleshooting status · battery status.

b Indicator light on : Ramp Mode

2.5. Battery status and charging the battery

Check the status of Charging the battery:



a). Press and hold the MODE button more than 6 seconds. And hear two beeps.



b). Read the numerical code that shows on the Display.

Battery Status	Numerical
Fully charged	≥ 4.2
General	4.1~3.5
Low	≤ 3.4



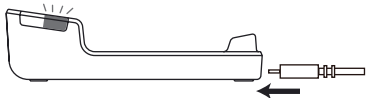
When the battery is in low status, the Display will glow and show the sign of "LO".



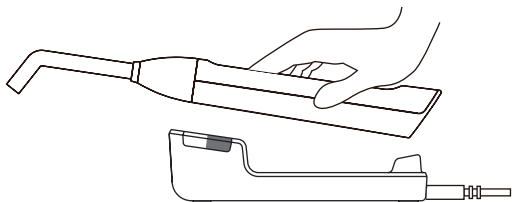
When the battery has malfunctioned and can't be charged, the Display will glow and show the sign of "E2." Please call your qualified technician to replace a new battery.

Charging the Battery:

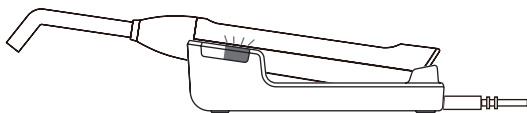
The battery is only charged to about 60% prior to the shipment. Each time, charge it fully before using it. The time for charging is around 2 hours.



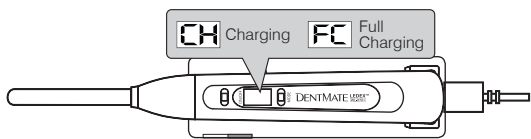
Connect the power supply to AC 100-240 V electronic socket and plug in the connector to LEDEX™ WL-070+ handpiece. Indicator signal will display green light after connect.



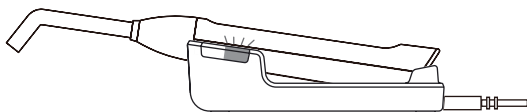
Put LEDEX™ WL-070+ on the wireless charging stand correctly after two beeps.



The indicator signal will start to flash when LEDEX™ WL-070+ put on the wireless charging stand. If the indicator signal does not flash, please take the handpiece up and put on the wireless charging stand again.



When battery is charged, the display will show CH signal. When battery is full charging, the display will show FC signal.



When battery is full charging, the indicator signal will change to green light.

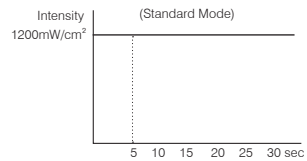
2.6. Operation modes & setting the seconds



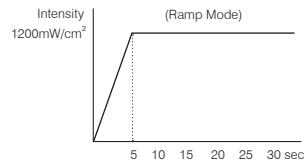
Press and hold the mode button for three seconds. Start to revise the modes after one beep.



After entering operation modes, operation panel will display the last record. Example: **5.0**



Press the mode button, it will switch to ramp mode, operation panel will display **r.0**



After check the mode, release the mode button and start to revise seconds.



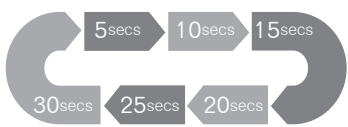
Dot light up : Ramp Mode



Dot light off : Standard Mode

Revise the seconds

Press the MODE button, the time would be changed as followed 5 secs → 10 secs → 15 secs → 20 secs → 25 secs → 30 secs → 5 secs



2.7. Output/Interrupt the light



When the status of LEDEX™ WL-070+ hand piece is turning on, push the ON/OFF button again to output the light. Then the display will be showed final countdown.



During the exposure time, the specialist can push ON/OFF button to interrupt the light. Then the system will generate one beep and reset the time automatically.

2.8 Sleep mode automatically

LEDEX™ WL-070+ sleeps automatically if no operations are performed for three minutes, and the Display will be turned off.

2.9 Safety status

After the LEDEX™ WL-070+ is operated for long periods of time, however the temperature may become too high, so the safety mode function will then be activated automatically to protect the light.

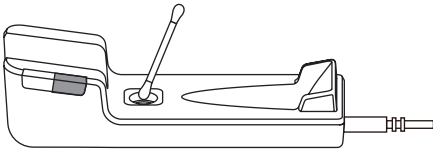
2.7. Maintenance

Prevention of cross infection, cleaning, disinfection and storage.

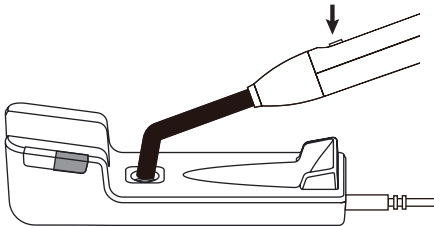
The use of the sleeve is an additional precautionary measure against contamination and does not substitute disinfection of the device.

After use, remove sleeve. Clean and disinfect LED Tip and handpiece with commercial alcohol based surface disinfecting solution. Keep other solvents or flammable liquids as well as intense sources of heat away from the unit as they may damage its plastic housing.

Always safeguard charger, handpiece and LED Tip against moisture as this may cause electrical short-circuit or dangerous malfunction.

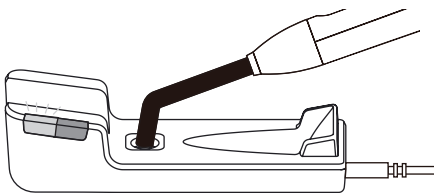


Verify that the radiometer sensor is free of debris that could impact the accuracy of the measurement. If the radiometer sensor requires cleaning.

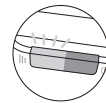


Test the light guide attachment with the Built-in intensity indicator.

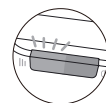
Carefully hold the unit and optical fiber light guide must be horizontal alignment in the middle of the sensor area, then press the on/off button.



A few seconds later, the test results will show orange or blue light.



orange light $\leq 700 \text{ mW/cm}^2$



blue light $> 700 \text{ mW/cm}^2$

3. Contraindications

For patients who are prone to photobiological reactions :

Do not use the LEDEX™ WL-070+ Dental Curing Light for patients with a history of photobiological reactions (including patients with Urticaria solaris or erythropoietic protoporphyria) or those who currently have treatments with photosensitising pharmaceuticals.

4. Warnings



4.1. User

The handpiece is intended for the polymerization of light-cured materials and is used by trained and qualified professionals, such as dentists.



4.2. Ambient conditions

Do not place the device in humid surroundings or any places which are close to any liquids.

Do not expose the device to any heat sources. Store the device in a safe environment.

- The device could be operated up to a maximum temperature of 35 °C and up to an altitude of 2,000 m above sea level.
- Do not use the device in the presence of free oxygen, anesthetics or flammable substances.
- The device may interfere or be interfered with the radio or the operation of the equipment nearby. If this happens, reduce the interference by reorienting and repositioning the device or screening off the immediate environment. The electromagnetic radiation emitted from this device is below the recommended limits specified by the applicable relevant provisions (EN 60601-1-2:2007 & EN 60601-1:2006).

- The device requires special precautions with regard to electromagnetic compatibility (EMC) and it must be installed and operated in strict compliance with the EMC information. Especially, do not use the device in the vicinity of fluorescent lamps, radio transmitters, remote controls, portable or mobile RF communication devices, even if they meet CISPR 8 requirements.
 - Do not charge, operate or store the device at high temperatures. Comply it with the specified operating and storage conditions.
-



4.3. To avoid electric shock(Shock hazard)

The WL-070+ Dental Curing Light is an electric device designed to meet the worldwide electrical safety standards, which includes U.S.A and Europe, so it's safe and effective for all dental applications.

To avoid electric shock:

- Do not attempt to open or alter the unit in any way. Only the service centers authorized by DENTMATE can open the unit housing and repair the device.
 - Do not put any foreign objects into the housing of the unit.
 - Use only the WL-070+ wireless charging stand when recharging this product. Never attempt to use any other devices for recharging.
 - Connect the power plug into a suitably grounded and approved outlet. When you use an extend cable, make sure the grounded line is not interrupted.
 - Always unplug the charging dock before disinfecting.
 - Never use the power supply if the cord has been damaged.
-



4.4. Heat development (burn hazard)

As it is the case with all high-performance lights, the high light intensity results in a certain heat development. Prolonged exposure near the pulp and soft tissues may result in irreversible or reversible damage. Therefore, this high-performance curing light must be operated by trained professionals.



4.5. Battery

Use only original spare parts, particularly DENTMATE batteries and charging bases. Do not short circuit battery. Do not store at temperatures above 40 °C / 104 °F (or 60 °C / 140 °F for a short period). Always store batteries charged. The storage period must not exceed 6 months. It may explode if it's disposed of in fire.



4.6. Accessories

Only use original DENTMATE components/accessories and spare parts :

original DENTMATE accessories	DENTMATE REF
LEDEX™ WL-070+ Handpiece	1105-0001-00
Wireless charging stand	2000-0069-00
Power supply (input AC100~240 V, 50-60 Hz, output DC5 V/2 A)	2000-0093-00
Filter	2000-0018-00
Optical fiber light guide rod(Ø8 mm)	2000-0009-00
Anti-glare shield	2000-0019-00
Disposable Light guide Sleeve	2000-0014-00
Disposable Handpiece Sleeve	2000-0016-00

Using other makes of accessories/spare parts can lead to increased emission of electromagnetic interference or to reduced electromagnetic interference immunity.



4.7. Repairs and defects

Do not use the device if you suspect its damage or defect.



4.8. Transport

Intact devices can be transported by land freight or air freight in the original packaging. The applicable requirements must be met. Defective devices can also be transported by air freight or land freight in the original packaging. If the battery is defective, the device won't be able to be transported by air freight under any circumstances.

5. Precaution

5.1. During operation, the light should be aimed straightly on the resin to ensure solidification effectively.

5.2. Never aim the light directly at unprotected soft tissues because this may lead to injury or irritation. Do not aim the light at eyes. Light reflected from the tooth surface may also injure eyes. Use the protective shield supplied with the unit or suitable, light filtering safety glasses.

6. Troubleshooting

Problem	Resolution
	Please call your qualified technician.
	When the battery has malfunctioned and can't be charged. Please call your qualified technician to replace it with a new battery.
	The temperature rises up to high really. Please wait a moment and then use it again.
The intensity is too low	If result of intensity test in Standard mode is under 700 mW/cm ² , the output is too low, please contact with your dealer.

7. Cleaning, Disinfection and Sterilization

This product must be disinfected as normal preparation for each patient. Read this entire section before cleaning the unit. Failing to follow these cleaning guidelines could cause damage.

The plastic of the handpiece, cradle and filter should be cleaned with a wet cloth, while the optical light guide rod should be cleaned with alcohol or put it in autoclave for disinfection. Remember to use autoclave 134°C/75 psi for maximum result. The disinfection time at 134°C should be 5 minutes. A disposable curing sleeve available from your dealer may be used as protection over the optical light guide rod without loss of light intensity. The applicant will validate the sterilization procedure according to ISO 17665-1.

8. Disposal

Comply with your national regulations, guidelines and requirements for the disposal of end-of-life electrical equipment and batteries. Specialized dental dealers will be pleased to provide you with country-specific information concerning disposal.

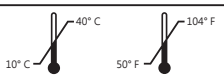

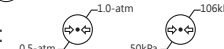
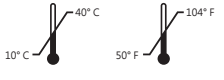

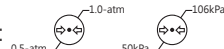
This device is provided with a Li-ion battery. For environmental reasons, please dispose of the device according to local environmental guidelines or regulations. Make sure the product or the battery is not mixed with other types of waste when it is disposed of. Prior to disassembly and disposal, your device has to be completely reprocessed and must not be contaminated.

9. Warranty

DENTMATE TECHNOLOGY Co., Ltd. warrants the product to be free of manufacturing defects for a period of one year from the date of purchase; this is deemed as the date of the invoice. It could be repaired or replaced at its own discretion all equipment failures due to manufacturing defects. However, the followings are expressly excluded from the warranty:

1. Damage and/or failure of the equipment caused by falling and/or jolting during transportation after purchase and/or during the normal use.
2. Damage and/or failure of the equipment caused by natural disasters, such as earthquakes, floods, lightning, pollution, incorrect electrical voltage and voltage spikes.
3. Any attempts to open the hand piece will invalidate the warranty.

10. Product Specifications

Type of Information	Specifications
Dental Curing Light	Medical equipment
Device Name	LEDEX™
Model Number	WL-070+
Power supply	Input: AC100~240 V, 50-60 Hz Output: DC 5 V/2 A
Light source	High power dental blue 5 W LED
The range of wavelength	440 to 480 nanometers
Radiant intensity	up to 1200 mW/cm ²
Hand piece dimensions	Ø26 (max) x L156 mm
Hand piece weight	120 g (with battery & light guide rod)
Wireless charging stand dimensions	W45 x L135 x H40 mm
Wireless charging stand weight	85 g
Equipment class(AC Adapter)	Class II
Safety	IEC 60601-1
EMC(Electro-Magnetic Compliance)	IEC 60601-1-2
Protection from electric shock	Type B applied part
Protection from ingress of liquids	IPX0
Operation	Continuous operation patient application, duty cycle 50 seconds ON /1 minute OFF.
Operating environment	<p>Ambient temperature: </p> <p>Relative humidity: </p> <p>Atmospheric pressure: </p>
Storage and Transport environment	<p>Ambient temperature: </p> <p>Relative humidity: </p> <p>Atmospheric pressure: </p>

11. EMC Declaration of conformity

Important information regarding Electro Magnetic Compatibility (EMC) with the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation. Medical devices should not interfere with other devices, too.

In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the EN60601-1-2:2007 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.

This medical device manufactured by DENTMATE conforms to this EN60601-1-2:2007 standard for both immunity and emissions. Nevertheless, special precautions are needed to be observed:

- Do not use mobile (cellular) telephones and other devices which generate strong electrical or electromagnetic fields near the medical device. This may result in incorrect operation of the unit and create a potentially unsafe situation. Keep a minimum distance of 7 m. Verify correct operation of the device in case the distance is shorter.

Further documentation in accordance with EN60601-1-2:2007 is available within this manual referring to section "Manufacturer's Declaration".

12. Manufacturer's Declaration


The WL-070+ is intended for use in the electromagnetic environment specified below. The customer or the user of the WL-070+ should assure that it is used in such an environment.

Electromagnetic Emissions: (IEC60601-1-2)

Emission Test	Compliance	Electromagnetic Environment
RF emission CISPR 11	Group 1	The WL-070+ uses RF energy only for internal functions. Therefore, this RF emission is extremely weak and there is little chance of it creating any kind of interference whatsoever with nearby electronic equipment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class B	The WL-070+ 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 IEC 61000-3-3	Complies	

(IEC60601-1-2)Electromagnetic Immunity:

Immunity test	IEC60601-1-2 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electric fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines ±1kV 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 % UT for 0.5 cycle	<5 % UT for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the WL-070+ requires continued operation during power mains interruptions, it is recommended that the WL-070+ be powered from an uninterruptible power supply or a battery.
	40% UT for 0.5 cycle	40% UT for 0.5 cycle	
	70% UT for 0.5 cycle	70% UT for 0.5 cycle	
	<5 % UT for 5 sec.	<5 % UT for 5 sec.	
Power frequency (50/60Hz) 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: UT is the a.c. mains voltage prior to application of the test level.			

Immunity test	IEC60601-1-2 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80MHz 80%AM(2Hz)	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the WL-070+, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommend separation distance $d = 1.2 \sqrt{P}$ 150 kHz to 80 MHz $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 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).</p>
Radiated RF IEC 61000-4-3	3V/m 80MHz to 2.5GHz 80%AM(2Hz)	3 V/m	<p>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.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol </p>
<p>Note1 : At 80MHz and 800MHz, the higher frequency range applies.</p> <p>Note2 : These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p>			
<ol style="list-style-type: none"> 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 WL-070+ is used exceeds the applicable RF compliance level above, the WL-070+ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the WL-070+. Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m. 			

Recommended Separation Distances:

Recommended separation distance between portable and mobile RF communications equipment and the WL-070+

The WL-070+ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the WL-070+ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the WL-070+ 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 $d = 1.2 \sqrt{P}$	80MHz to 800MHz $d = 1.2 \sqrt{P}$	800kHz to 2.5GHz $d = 1.2 \sqrt{P}$
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 metres (m) can be determined 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.


Note1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies

Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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