ORTHOMETRIC®
Helping the World Smile

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INSTRUCTIONS FOR USE

Merely illustrative images

LED CURING LIGHT

LEDX-PRO

CE

ORTHOMETRIC®
Helping the World Smile

LED CURING LIGHT

LEDX-PRO

Dear Customer,

Thank you for choosing Orthometric's LEDX-PRO 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 instruction for use for your reference.

The instruction for use is subject to change without further notice.

ORTHOMETRIC®
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LED CURING LIGHT

LEDX-PRO

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ORTHOMETRIC®
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1. SYMBOLS USED

1.1. In these instructions for use

WARNING

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

1.2. On the product/packaging

SN	Serial number	REF	Catalogue number
	Manufacturer		Date of manufacture
	Class II (AC Adapter)		Consult the Instructions for use
	This shows the Type B applied part.		Do not dispose it with normal household waste
	Recycling	IPX0	Ordinary equipment
	Do not use if package is damaged	106kPa / 50kPa	Atmospheric pressure for storage
10°C / 40°C	Temperature limits	75% / 30%	Storage humidity range
CE	CE marking		Keep dry
	Fragile Handle with care		Keep away from sunlight

2. PRODUCT INFORMATION

The light has been manufactured with a super-high luminosity 10 W LED. The light wavelength of LEDX-PRO is between 440 and 480 nm and the light intensity is up to 3200 mW/cm^2. It can cure the composite over 2 mm in 1 sec. These characteristics enable the light to polymerize almost all photosensitive composite resins.

LEDX dental curing light is characterized by :

- 7 powerful extensive modes including Low, Ramp, Standard, High, Fast Ortho, Turbo and Plasma modes.
- The light guide rod is made from genuine optical fiber minimizes loss of light from source to tip. It ensures the highest possible intensity of light at the light guide tip.
- Advanced and high efficient cooling heat sink are designed and accompanied with over-heating prevention. A thermal protection circuit and safety mode are also designed to prevent the light from overheating.
- The automatic memorization of the last operation is another unique feature of the light.
- There is a built-in radiometer displaying light indensity.
- Automatic sleep mode saves battery and extends usage time.

2.1. Indications for use

LEDX-PRO is a visible curing unit programmed for polymerization of dental light cured materials only by dental professionals.

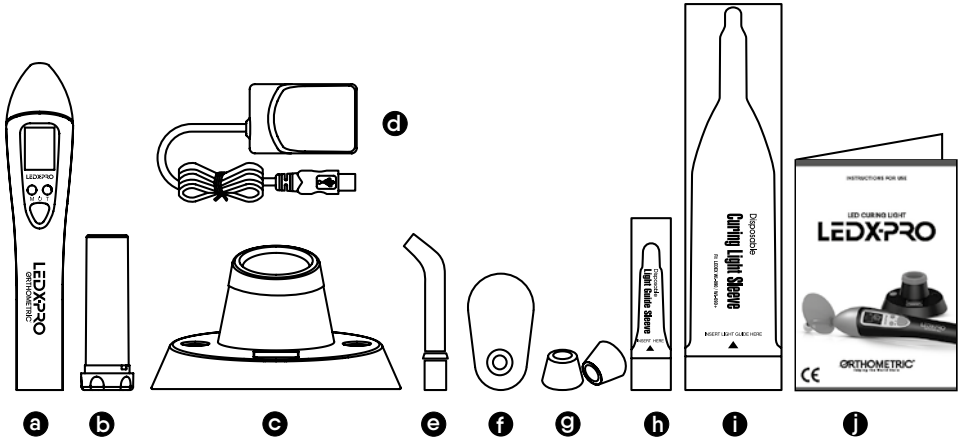
FOR DENTAL USE ONLY!

2.2. Procedure

Please follow the insturction before use. As for handpiece instuctions, please refer to 2.6-2.7. It is required to use the disposable sleeves to prevent cross infection. Put the sleeve and cover the handpiece before operation. After conducting a sugery on a patient, please take off the sleeve and throw away, as the sleeve is prohibited to reuse.

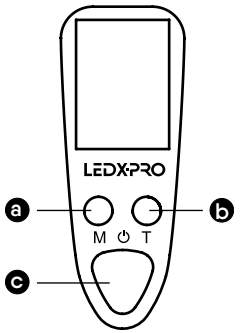
LEDX-PRO

2.3. System components



Item	Description	Quantity
a	LEDX-PRO Handpiece	1
b	Battery (3.7 V/2500 mAh)	1
c	Cradle	1
d	Power supply (Input AC100~240 V, 50-60 Hz, output DC5 V/2 A)	1
e	Optical fiber light guide rod (Ø 11>8 mm)	1
f	Filter	1
g	Anti-glare shield	2
h	Disposable light guide sleeves	20
i	Disposable curing light sleeves	10
j	Instructions for use	1

2.4. Features

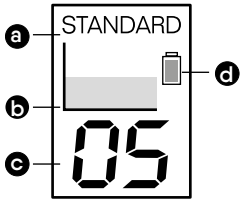


a MODE : Pressing this button sequentially toggles the unit through the 7 curing modes.

b TIME : Pressing this button sequentially toggles the unit through the serial curing time.

c ON-OFF : Press this button to start the handpiece. Press this button again to turn on the curing light. Pressing this button during the curing cycle will interrupt and end the cycle. If the unit is in sleep mode, press this button will wake the unit and it will display with the last mode choosen.

2.5. Display



The display shows different information to the user. As shown above, it comprises different zones identified from top to bottom as follows:

a A display of the curing mode selected.

b The output mode icons represent the type of light emission.

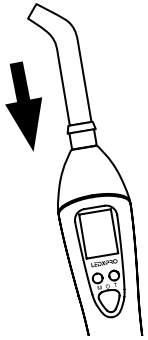
c This is the display of duration seconds of the selected curing cycle. During operation, this countdown display indicates the remaining activation time until the current cycle is completed.

d A battery charge level indicator is symbolized by a ladder with 0 to 5 levels and charging status.

2.6. Installation and charging

Startup

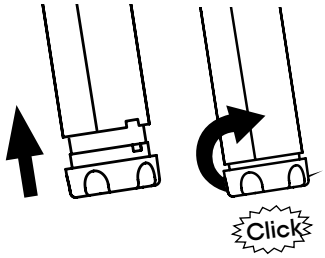
When receiving the unit, any damages may occur during transportation. If necessary, contact your supplier.



Handpiece

First of all, this product must be cleaned as normal preparation for each patient to prevent cross infection (see the chapter 7).

Remove the protective caps from the handpiece which should be kept whenever not in use to prevent liquid from damaging the LED. Next, insert the light guide into the handpiece and ensure the light guide is properly insert.

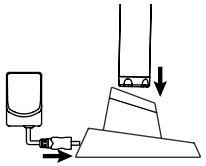


Battery

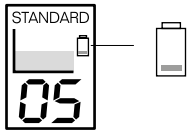
We recommend you to charge the battery fully before the first use.

Put the battery into the handpiece and rotate clockwise until you hear a “click” sound and feel the battery clicked into the right place.

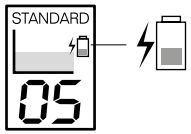
Ensure all the segments of the display are shown. The battery supplied is only charged to about 60% prior to shipment. Each time, charge it fully before using it.



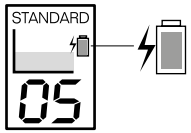
1. Connect the power supply to AC100~240 V electronic socket and plug-in the connector to the cradle. Put the handpiece into the cradle to charge the battery.



2. When the battery is low, the display of the handpiece will glow and show the of low battery sign.



3. When the battery is charging, the display of the handpiece will glow and show the sign of charging battery.



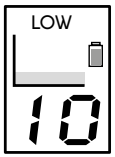
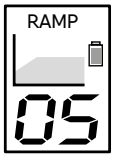
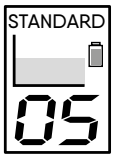
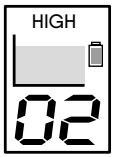
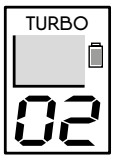
4. When the battery is fully charged, the display of the handpiece will be turn off to save power.

2.7. Operating modes

Select curing modes and curing time. The curing modes and the curing time can be individually set. LEDX-PRO is equipped with the following 7 curing modes for different indications. Use the mode selection button to choose the curing modes. The display will change accordingly (see Indicators on the handpiece). The device comes equipped with the following pre-set modes :

LEDX-PRO

Factory settings

Icon	Mode	Curing time duration (sec)	Intensity of light
	LOW	10,20,30,40	600 mW/cm²(+/-15%)
	RAMP	5,10,15,20,25,30,35,40	1000 mW/cm²(+/-10%)
	STANDARD	5,10,15,20,25,30,35,40	1000 mW/cm²(+/-10%)
	HIGH	2,4,6,8,10	1800 mW/cm²(+/-10%)
	FAST ORTHO	3,4,5 repeat 10 times	1800 mW/cm²(+/-10%)
	TURBO	2,3,4,5	2400 mW/cm²(+/-10%)

2.7. Operating modes

Light intensity

Recommended Curing Time (on STANDARD mode)

Fill Materials	Curing time
Universal composite (2 mm depth)	10 seconds
Universal composite (4 mm depth)	20 seconds

**Generally, these recommendations apply depends on situations. The emission window of the light probe is placed directly over the material in order to be polymerized. Extend the curing time accordingly to increase the distance between the light source and the material.

Recommended curing modes

Mode	Application
LOW	Tooth and composite resin.
RAMP	Wide area of composite resin, avoid shrinkage.
STANDARD	Most cases.
HIGH	For orthodontic or pediatric dentistry,
FAST ORTHO	For orthodontic, easy to bond materials.
TURBO	Dental cement, porcelain veneer,fiber post.
PLASMA	Dental cement, porcelain veneer,fiber post.

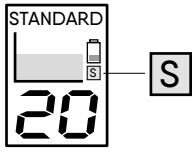
Sound mode

1. Press button M to switch to sound setting.
2. In sound setting, press button T to switch between Mute and Unmute.
3. Press button M to return to other mode.

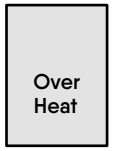
MUTE

LEDX-PRO

Safety status :

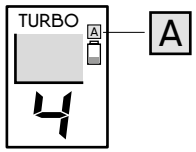


When LEDX-PRO is operated frequently for long period of time, the temperature may become too high. Therefore, the “Safety” mode function will then be activated automatically to prevent the light from overheating. The safety mode cuts the light intensity in approx. half and extends the irradiation time.



When the temperature becomes too high, the display of handpiece will glow and show the sign of “Over Heat”.

Adaptive Status :



While TURBO mode is selected, enough power of battery will be needed. If the battery power is not enough, the “Adaptive” mode function will then be activated automatically. It will cut the light intensity in approx. half and extend the irradiation time.

Auto sleep designed :

LEDX-PRO will sleeps automatically if no operations are performed for three minutes, the display will be turn off.

3. CONTRAINDICATIONS

For patients who are prone to photobiological reactions :

Do not use the LEDX-PRO 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 only 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 interference or interfere 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 LEDX-PRO 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.

LEDX-PRO

To avoid electric shock:

- Do not attempt to open or alter the unit in any way. Only the service centers authorized by ORTHOMETRIC can open the unit housing and repair the device.

- Do not put any foreign objects into the housing of the unit.

- Use only the LEDX-PRO cradle 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.

Note : At least 10 mm gap between soft tissues and optical fiber light guide rod.

4.5. Battery

Use only original spare parts, particularly ORTHOMETRIC 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 ORTHOMETRIC components/accessories and spare parts :

Original accessories	References
LEDX-PRO Handpiece	90.10.0019
Battery (3.7 V/2500 mAh)	90.10.0002
LEDX-PRO Cradle	90.10.0016
Power supply (Input AC100~240 V, 50-60 Hz, output DC5 V/2 A)	90.10.0011
Filter	90.10.0017
Optical fiber light guide rod(Ø 11>8 mm)	90.10.0012
Disposable curing light sleeves	90.10.0015

Using other accessories/spare parts may 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.

LEDX-PRO

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
Can not turn on the handpiece	Remove the battery and insert it again. If the error persists, please plug-in the power supply to cradle and charge the battery at least 10 mins. Then push the ON/OFF button again.
Can not charge the battery	Please clean battery contacts. If the error persists, please change a new battery
Display show "overheat" sign	If the temperature rises up too high, please wait a moment for cooling and then use it.
Display show "Error 1" sign	LED module is unnormal, please contact your qualified technician.
The intensity is too low	If the result of intensity test in Standard mode is under 700 mW/cm^2 and the output is too low, please contact with your dealer

7. DAILY MAINTENANCE

Read this entire section before cleaning the unit. This product must be cleaned as normal preparation for each patient to prevent cross infection.

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

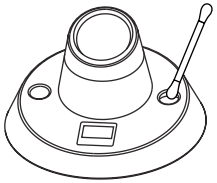
After using, remove the sleeve. Clean the optical light guide rods and the handpiece with a cloth moisture with alcohol or cleaner. Keep solvents or flammable liquids from the unit because they may damage its plastic housing.

Always keep the charger, handpiece and light guide well. Moisture may cause electrical short-circuit or dangerous malfunction.

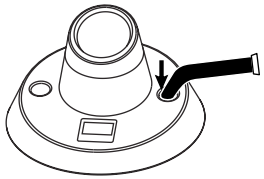
Test the Light Guide Attachment with the Radiometer

Verify the LEDX-PRO performance each time before using the radiometer which is built into the cradle.

1. The curing time interval should exceed 5 seconds for each cycle.



2. Verify the radiometer sensor which can impact the accuracy of the measurement. The surface of sensor area can be wiped with a cotton swab with alcohol.

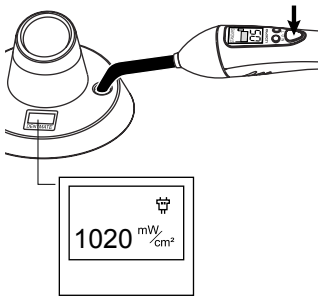


3. Carefully hold the unit, so the Light Guide Attachment is aligned with the radiometer sensor and centered within the white circle provided.

Tips:

Optical fiber light guide must be horizontal alignment in the middle of the sensor area.

LEDX-PRO



4. While holding the unit, press and release the ON-OFF Button. The radiometer will then provide a reading of the light intensity on the cradle display.

Notice:
The LEDX-PRO built-in radiometer is only suitable for measuring 8 mm optical fiber light guide rod. It will cause incorrect measurement if it uses in other sizes of optical light guide rod.

5. Wait till the light is off before moving the Light Guide Attachment away from the radiometer sensor.

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

ORTHOMETRIC - Industria e Comércio de Produtos Médicos e Odontológicos LTDA. 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	LEDX-PRO
Model number	90.10.2402
Power supply	Input: AC100~240 V, 50-60 Hz Output: DC 5 V/2 A
Battery	3.7 V, 2500 mAh, type: Li-ion
Light source	10 W LED
The range of wavelength	440 to 480 nm ; peak: 460 nm
Radiant intensity	Up to 3200 mW/cm²(± 10%)
Hand piece dimensions	Ø38 (max.) x L190 mm
Hand piece weight	180 g (with battery & light guide rod)
Cradle dimensions	Ø115 (max.) x H68 mm
Cradle weight	140 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 40 seconds ON / 120 seconds OFF on STANDARD mode.
Operating environment	Ambient temperature: 10° C 40° C 50° F 104° F Relative humidity: 30% 75% Atmospheric pressure: 0.5-atm 1.0-atm 50kPa 106kPa
Storage and transport environment	Ambient temperature: 10° C 40° C 50° F 104° F Relative humidity: 10% 95% Atmospheric pressure: 0.5-atm 1.0-atm 50kPa 106kPa

LEDX-PRO

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 ORTHOMETRIC 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 LEDX-PRO is intended for use in the electromagnetic environment specified below. The customer or the user of the LEDX-PRO 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 LEDX-PRO 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 LEDX-PRO 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	

LEDX-PRO

(IEC60601-1-2)Electromagnetic Immunity:

Immunity test	IEC60601-1-2 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge 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 %.
Electric fast transient/burst IEC 61000-4-4	± 2kV 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 % 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 LEDX-PRO requires continued operation during power mains interruptions, it is recommended that the LEDX-PRO 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 (50/60 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 atypical 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	3 Vrms 150 kHz to 80 MHz 80 %AM(2 Hz)	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the LEDX-PRO, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter Recommend separation distance d = 1.2 √P 150 kHz to 80 MHz d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √P 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to he transmitter manufacturer and d is the recommended separation distance in meters (m).
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz 80 %AM(2Hz)	3 V/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

Note1 : At 80 MHz and 800 MHz, 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.

1. 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 LEDX-PRO is used exceeds the applicable RF compliance level above, the LEDX-PRO should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the LEDX-PRO.
2. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

LEDX-PRO

Recommended Separation Distances:

Recommended separation distance between portable and mobile RF communications equipment and the LEDX-PRO

The LEDX-PRO is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the LEDX-PRO can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LEDX-PRO 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		
	150 kHz to 80 MHz d = 1.2 √P	80 MHz to 800 MHz d = 1.2 √P	800 kHz to 2.5 GHz d = 1.2 √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 80 MHz and 800 MHz, 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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