beurer

TL 30

EN Daylight therapy lamp
Instructions for use

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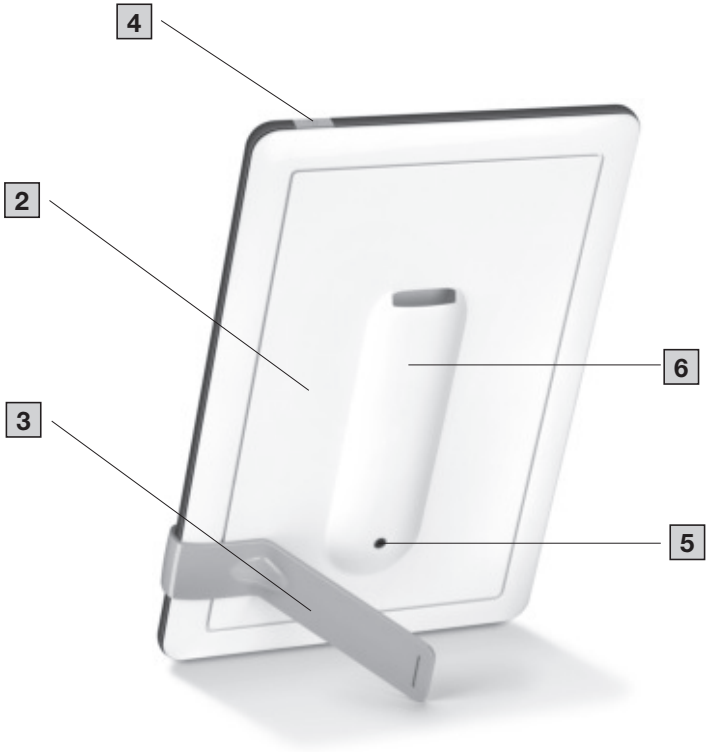
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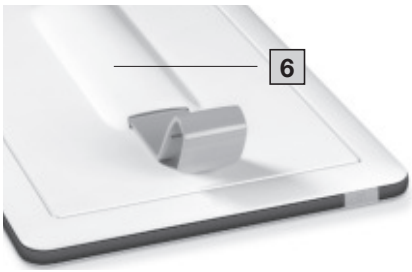
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ENGLISH

Read these instructions for use carefully. Observe the warnings and safety notes. Keep these instructions for use for future reference. Make the instructions for use accessible to other users. If the device is passed on, provide the instructions for use to the next user as well.

1. INCLUDED IN DELIVERY

Check that the exterior of the cardboard delivery packaging is intact and make sure that all contents are present. Before use, ensure that there is no visible damage to the device or applied parts and that all packaging material has been removed. If you have any doubts, do not use the device and contact your retailer or the specified Customer Services address.

- 1 daylight therapy lamp
- 1 stand
- 1 mains adapter
- 1 felt bag

2. SIGNS AND SYMBOLS

The following symbols are used on the device, in these instructions for use, on the packaging and on the type plate for the device:

⚠ DANGER Indicates an imminent danger. If it is not avoided, it will result in death or serious injury.
⚠ WARNING Indicates a potentially impending danger. If it is not avoided, there is a risk of death or serious injury.
⚠ CAUTION Indicates a potentially impending danger. If it is not avoided, slight or minor injuries may result.
NOTICE Indicates a potentially harmful situation. If it is not avoided, the system or something in its vicinity may be damaged.

	Product information Note on important information
	The electronic device must not be disposed of with household waste.
	Manufacturer
B A	Marking to identify the packaging material. A = material abbreviation, B = material number: 1–7 = plastics, 20–22 = paper and cardboard
	On/Off
MD	Medical device
REF	Article number
IP21	Protected against solid foreign objects 12.5 mm in diameter and larger, and against vertically falling drops of water
	Atmospheric pressure limitation
	Polarity of d.c. power connector
LOT	Batch designation
EU REP	Authorised representative in the European Community
	Importer symbol
	Observe the instructions Read the instructions before starting work and/or operating devices or machines
CE	**CE labelling** This product satisfies the requirements of the applicable European and national directives.
UDI	Unique device identifier (UDI) Identifier for unique product identification
RECYCLE	Separate the product and packaging elements and dispose of them in accordance with local regulations.
	Protection class II device
Storage/Transport	Permissible storage and transport temperature and humidity
Operating	Permissible operating temperature and humidity
	Date of manufacture
	For indoor use only
SN	Serial number
	Direct current
CH REP	Swiss Authorised Representative
#	Type number
	Manufacturer in accordance with the Packaging Regulation (PPWR)

3. INTENDED USE

Purpose

The daylight therapy lamp is intended to compensate the effects of lack of light, particularly sunlight, and provide relief from winter-seasonal affective disorders, mood disorders and circadian phase sleep disorders.

Patient population

For adults and children over the age of 3 years.

Intended users

The use of the device does not require a specific knowledge or professional ability. The patient is the intended operator, except for patients who require special assistance.

Indication

The device simulates daylight to provide relief from seasonal or mood disorders.

Contraindication
Do not use in case of people insensitive to heat, people with skin lesions due to illness, people with a condition that might render his or her eyes more vulnerable to phototoxicity, people with a photosensitive skin condition, patient is taking a photosensitizing medication or herb.

Clinical Benefits
Prevent or relieve the depression symptoms such as depressed mood, profound lack of energy, hypersomnia for patients suffering from winter seasonal affective disorders.

Why use a daylight therapy lamp?
When the hours of daylight are noticeably shorter in autumn and people increasingly stay inside in winter, the effects of a lack of light may become apparent. This is often described as “winter depression”. The symptoms can present themselves in a number of ways:

- Imbalance
- Subdued mood
- Lack of energy and listlessness
- Generally feeling under the weather
- Need for more sleep
- Loss of appetite
- Difficulty concentrating

The cause of these symptoms is the fact that light – particularly sunlight – is essential for life and has a direct effect upon the human body. Sunlight indirectly controls the production of melatonin, which is passed to the blood only in darkness. This hormone shows your body that it’s time to sleep. That’s why more melatonin is produced in months with less sunshine, making it difficult to get up in the mornings because your body functions are powered down. Use the daylight therapy lamp immediately after waking up (i.e. as early as possible) to end the production of melatonin and to brighten your mood.
Lack of light also prevents the production of the happy hormone serotonin, which is said to significantly influence our well-being. The application of light thus yields quantitative changes to hormones and neurotransmitters in the brain that have an effect on our activity levels, our feelings and our well-being. To compensate for such a hormonal imbalance, daylight therapy lamps can create a suitable replacement for natural sunlight.
In the medical field, daylight therapy lamps are used to combat the effects of a lack of light. Daylight therapy lamps simulate daylight over 10,000 lux. This light can influence the human body and be used as a treatment or as a preventative measure. Normal electric light, however, is not sufficient to influence the hormonal balance. This is because in a well-lit office, the light intensity is just 500 lux, for example.

4. WARNINGS AND SAFETY NOTES

⚠ WARNING

- The daylight therapy lamp is only intended for the use on the human body.
- Before use, ensure that all packaging materials are removed and that there is no visible damage to the device or applied parts . When in doubt, do not use the device and contact your retailer or the specified Customer Service address.
- This equipment is not intended for use by children and persons with reduced physical, sensory and mental capabilities, or lack of experience and knowledge, unless they have been given supervision or instruction concerning use of the equipment to ensure that they do not play with the equipment and to avoid the risk of fire and burns.
- Ensure that the daylight therapy lamp has a firm footing.
- Connect the device only to the mains voltage listed on the type plate.
- Check if the voltage indicated on the equipment corresponds to the local mains voltage before you connect the equipment to avoid risk of electrocution or permanent damage to the equipment.
- Do not dip the device into water and do not use it in wet rooms.
- Keep children away from packaging materials (risk of suffocation!).
- Do not cover up or pack away the device while it is warm.
- Always unplug the mains adapter and allow the device to cool down before touching it.
- Always unplug the appliance after use and in case of a power failure to avoid risk of damage to the equipment.
- Do not touch the device with wet hands while it is plugged in and do not allow any water to be sprayed onto the device. The device must be operated only when it is completely dry.
- Ensure that you only insert and remove the mains adapter with dry hands and that you only press the ON/OFF button with dry hands.
- Keep the mains cable away from hot objects and naked flames.
- Protect the device from strong impacts.
- Do not pull the mains adapter out of the socket using the mains cable.
- Do not use the device if it shows signs of damage or does not function properly. In these cases, contact Customer Services.
- If the mains connection cable of this device is damaged, it must be disposed of. If it cannot be removed, the device must be disposed of.
- Disconnection from the power supply network is only guaranteed when the mains adapter is unplugged.
- Do not use the device in the presence of flammable anaesthetic gas connections with air, oxygen or nitrogen oxide.
- Do not leave the device unattended when it is switched on to avoid the risk of fire or burns.
- If the wall socket used to power the device has poor connections, the plug of the device becomes hot. Make sure you plug the device into a properly installed wall socket to avoid the risk of fire and burns.
- Do not subject the device to heavy shocks to avoid risk of damage to the lamp.
- Water and electricity are a dangerous combination! To avoid risk of electrocution:
  - Do not use this equipment in wet surroundings (e.g. in the bathroom or near a shower or swimming pool);
  - Do not let water run into the appliance.
- No calibration and no preventive checks or maintenance need to be carried out on this device.
- You cannot repair the device. The device contains no parts that you can repair.
- Do not make any changes to the device without the manufacturer’s permission.
- If the device has been changed, thorough tests and checks must be carried out to ensure the continued safety of the device for any future use.
- To avoid strangulation and entanglement, keep cable out of reach of young children.
- The patient is an intended operator. The patient can use the device and its applied parts according to this manual.

General notes

⚠ IMPORTANT

- Always consult a doctor before using the daylight therapy lamp if you are taking medication such as pain relief medication, medication to reduce high blood pressure or antidepressant medication.

- Diabetics and people who suffer from retinal diseases must be examined by an optician before using the daylight therapy lamp.
- Do not use the device if you suffer from an eye disease such as cataracts, glaucoma, diseases of the optic nerve or inflammation of the vitreous body.
- Always consult a doctor before using the daylight therapy lamp if you have a strong sensitivity to light, your skin is sensitive to light or you are prone to migraine attacks.
- If you have health concerns of any kind, consult your general practitioner!
- Remove all packaging material before using the device.
- Light sources are excluded from the warranty.
- If the device has been in storage or recently transported, allow it to rest for at least two hours at room temperature before using it.
- The mains adapter is part of the ME equipment.
- Check whether light flashes, dark areas/shadows and other abnormalities occur after power-on. If there is any abnormality, please contact Customer Services or an authorised retailer.
- The patient cannot undergo an MRI scan while using this device.
- Report any serious incident that has occurred in relation to the device to the local competent authority and the manufacturer or European Authorised Representative (EU REP) Vigilance Contact Point: https://EC.europa.eu/growth/sectors/medical-devices/contacts.
- PRC is the abbreviation for the People's Republic of China.

Instructions for repairs

⚠ IMPORTANT

- Do not open the device. Do not attempt to repair the device yourself. This could result in serious injury. Failure to comply will invalidate the warranty.
- For repairs, please contact Customer Services or an authorised retailer.

5. DEVICE DESCRIPTION

The associated drawings are shown on page 3.

1	Fluorescent screen	4	ON / OFF button
2	Rear of the device housing	5	Mains adapter connector
3	Stand	6	Storage slot for holder

6. INITIAL USE

Take the device out of the plastic wrapping. Check the device for damage or faults. If you notice any damage or faults on the device, do not use it and contact Customer Services or your supplier.

Setting up the device

Place the device on a level surface. The position should be chosen to ensure a distance of between 10 cm and 30 cm between the user and the device. The lamp is most effective at this distance.

Mains adapter connector

- To prevent possible damage to the device, the daylight therapy lamp must only be used with the mains adapter described here.
- Insert the mains adapter into the connector provided for this purpose on the rear of the daylight therapy lamp. The mains adapter must only be connected to the mains voltage that is specified on the type plate.
- After using the daylight therapy lamp, unplug the mains adapter from the mains socket first and then disconnect it from the daylight therapy lamp.

⚠ IMPORTANT

- Ensure that there is a mains socket close to the set-up area.
- Arrange the mains cable so that no-one will trip over it.

7. USAGE

1 Remove the holder from the storage slot on the rear of the device.

2 Clip on the holder at the side. The orientation/angle of the TL 30 changes depending on where you attach the holder to the device. This allows you to tailor the angle as desired. The holder can be attached on both the long and short sides, which enables you to use the TL 30 both horizontally and vertically.

3 Switching on the lamp
▶ Press the On/Off button.

4 Enjoying the light
Sit as close as possible to the lamp, between 10 cm and 30 cm. You can go about your normal activities while using it. You can read, write, make telephone calls, etc.
- Every so often, briefly look directly into the light, since the effect results from the eyes/ retina receiving the light.
- Use the daylight therapy lamp as often as you want. However, the treatment is at its most effective if you carry out the light therapy according to the prescribed time period of at least 7 successive days.
- The most effective time of day for the treatment is between 6am and 8pm
  and we recommend that it is used for 2 hours per day.
- Do not look directly into the light the whole time you are using it, however, since that could lead to overstimulation of the retina.
- Start with shorter periods of illumination, which you increase over the course of a week.

Note:
Eye aches and headaches may arise after the first times using the lamp. These will go
away in later sessions, as the nervous system will become accustomed to the new stimulation.

5 Important instructions
When using the lamp, maintain the recommended distance of 10 - 30 cm between your face and the lamp. The duration of the application depends on the distance:

Lux	Distance	Application duration
10.000	approx. 10 cm	0,5 hour
5.000	approx. 20 cm	1 hour
2.500	approx. 30 cm	2 hours

Basically, the closer you are to the source of light, the less time you should use it.

6 Enjoying light over longer periods
Repeat your use of the lamp in the dark seasons for at least 7 successive days, or even longer, depending on your individual needs. If possible, conduct the treatment in the morning hours.

7 Switching off the lamp

▶ Press the On/Off button. The LEDs switch off. Unplug the mains part from the mains socket.

CAUTION!

The light remains hot after use. Let the lamp cool off first long enough before you put it away and/or pack it up!

8. CLEANING AND MAINTENANCE

The device should be cleaned from time to time.

⚠ IMPORTANT

- Ensure that no water gets inside the device! The device must be switched off, disconnected from the mains and allowed to cool down each time before cleaning.
- Do not clean the device in the dishwasher. Use a slightly damp cloth to clean the device.
- Do not use any abrasive cleaning products and never submerge the device in water. Do not touch the device with wet hands when it is plugged in and do not allow water to spray on the device. Only operate the device if it is completely dry.

Storage

If you are not going to use the device for an extended period of time, disconnect it and store it in a dry place, out of the reach of children.

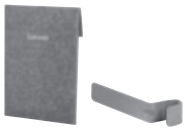
Follow the storage instructions provided in the "Technical specifications" chapter.

9. WHAT IF THERE ARE PROBLEMS?

Problem	Possible cause	Solution
Device does not light up	Device is switched off.	Touch the ON / OFF button 4
	No power	Connect the mains adapter correctly to a suitable socket.
	No power	The mains adapter is faulty. Contact Customer Services or your retailer
	LEDs have reached the end of their service life. LEDs faulty	For repairs, please contact Customer Services or an authorised retailer.

10. DISPOSAL

For environmental reasons, do not dispose of the device in household waste at the end of its service life. Dispose of the device at a suitable local collection or recycling point in your country. Observe the local regulations for material disposal. Dispose of the device in accordance with EC Directive Waste Electrical and Electronic Equipment (WEEE). If you have any questions, please contact the local authorities responsible for waste disposal. You can obtain the location of collection points for old devices from the local or municipal authorities, local waste disposal companies or your retailer, for example.

Component	Disposal	Photo
Device	The component mainly includes plastic and electronic components. All components comply with RoHS and REACH directives and can be disposed of safely.	
Applied parts (holder, feltbag)	The component are PC and cotton. All components comply with RoHS and REACH directives and can be disposed of safely.	
Mains adapter	The adapter mainly contains plastic and electronic components. All components comply with RoHS and REACH directives and can be disposed of safely.	

11. TECHNICAL SPECIFICATIONS

Type	GCE501
Model no.	TL 30 G
Dimensions (LWH)	156 x 20 x 236 mm
Weight	approx. 315 g +/- 15 g
Light wavelength Peak wavelength	380-780 nm 450+/- 5 nm
Lighting elements	LED
Power	7,8 watts
Light intensity	10,000 lux (Distance: approx. 10 cm)
Radiation	Output of radiation beyond the visible spectrum (infrared and UV) is so low that it is harmless to eyes and skin.
Operating conditions	0°C to +35°C, 15 - 90% relative humidity, 700 - 1060 hPa ambient pressure
Transport and storage conditions	-20°C to +60°C, 15 - 90% relative humidity, 700 - 1060 hPa ambient pressure
Product classification	External power supply, Protection class II, IP21
Color temperature of LEDs	6,500 kelvin

Included in delivery	Daylight therapy lamp, holder, storage pouch, mains part, these operating instructions
Limit short wavelength	432-467 nm
Expected life of the device	10,000 hours

Mains adapter

Model no.	LXCP12S-120065BWS LXCP12-012650CEH
Input	100–240 V ~ 50/60 Hz
Output	12 V DC, 650 mA
Protection	The device is double protected and therefore corresponds to protection class 2.
	Polarity of the the DC voltage connection
Classification	Protection class II

Maximum radiance output of the TL 30

Radiance output	Risk group classified in accordance with IEC 60601-2-83	Maximum value
Euva: Eye UV-A	Exempt Group	$5375x10^5$ W·m^{-2}
ES: Actinic UV skin & eye	Exempt Group	0
EIR: Infrared radiation hazard exposure limits for the eyes	Exempt Group	0
LIR: Retinal thermal	Exempt Group	0
LB: Blue light	Exempt Group	8,854 W·m^{-2}·sr^{-1}
LR: Retinal thermal	Exempt Group	112,3 W·m^{-2}·sr^{-1}

Subject to technical changes.
The serial number is located on the device.

Brightness: 10,000 lux (this point about the light intensity is merely for information purposes. With regard to the standard 60601-2-83, this light source is classified as an Exempt Group).

Notes on electromagnetic compatibility

The device complies with the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as well as the European standard EN 60601-1-2 (in accordance with CISPR 11, IEC61000-3-2, IEC61000-3-3, IEC 61000-4-2, IEC 61000-4-3, IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-6, IEC 61000-4-11, IEC 61000-4-8) and is subject to particular precautions with regard to electromagnetic compatibility.

- The device is suitable for use in all environments listed in these instructions for use, including domestic environments.
- The device may not be fully usable in the presence of electromagnetic disturbances. This could result in issues such as error messages or the failure of the display/device.
- Avoid using this device directly next to other devices or stacked on top of other devices, as this could lead to faulty operation. If, however, it is necessary to use the device in the manner stated, this device as well as the other devices must be monitored to ensure they are working properly.
- The use of applied parts other than those specified or provided by the manufacturer of this device can lead to an increase in electromagnetic emissions or a decrease in the device's electromagnetic immunity; this can result in faulty operation.
- Failure to comply with the above could impair the performance of the device.

12. WARRANTY

Further information on the warranty and warranty conditions can be found in the warranty leaflet supplied.

Notification of incidents
For users/patients in the European Union and identical regulation systems, the following applies: If a major incident occurs during or through use of the product, notify the manufacturer and/or their representative of this as well as the respective national authority of the member state in which the user/patient is located.

Electromagnetic compatibility

Table 1:

Guidance and manufacturer's declaration – electromagnetic emissions for all EQUIPMENT and SYSTEMS		
The Therapy lamp is intended for use in the electromagnetic environment specified below. The customer of the user of the Therapy lamp should assure that it is used in such and environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Therapy lamp 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	The Therapy lamp 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.

Table 2:

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS			
The Therapy lamp is intended for use in the electromagnetic environment specified below. The customer of the user of the Therapy lamp should assure that it is used in such and environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 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 %
Power frequency (50Hz) magnetic Field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic fields (IEC 61000-4-39)	30kHz, CW, 8A/m 134.2kHz, PM 2.1kHz, 65A/m 13.56MHz, PM 50kHz, 7.5A/m	N/A	The EUT does not contain magnetically sensitive components or circuitry, so this test does not need to be evaluated.

Table 3:

Guidance and manufacturer's declaration – electromagnetic immunity for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING			
The Therapy lamp is intended for use in the electromagnetic environment specified below. The customer or the user of Therapy lamp should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conduced RF IEC61000-4-6	150KHz to 80MHz 3Vrms	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the Therapy lamp, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d=1.2\sqrt{P}$; $d=1,2\sqrt{P}$

Radiated RF IEC61000-4-3	10V/m	10V/m	d=1.2√p 80 MHz to 1000 MHz d=2.3√p 1000 MHz to 2700 MHz	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 metres (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 1 At 80 MHz and 1000 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and re -flection 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 Therapy lamp is used exceeds the applicable RF compliance level above, the Therapy lamp should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Therapy lamp.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Table 4:

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFESUPPORTING

The Therapy lamp is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Therapy lamp can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Therapy lamp 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 (out ISM and amateur radio bands) $d=1.2\sqrt{P}$	**150 kHz to 80 MHz (in ISM and amateur radio bands)** $d=2\sqrt{P}$	**80 MHz to 1 GHz**	**1 GHz to 2.7 GHz**
0.01	0.12	0.2	0.12	0.23
0.1	0.38	0.632	0.38	0.73
1	1.2	2	1.2	2.3
10	3.8	6.32	3.8	7.3
100	12	20	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) 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.

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