

spot-on®cordfree

Instructions for Use





1. DEAR CUSTOMER

1.1. Prologue

With **spot-on** on base you have acquired a product that represents the latest state of the art and has been manufactured according to strict quality criteria. As we continue to develop our products, it is possible that the images and drawings in this document may differ slightly from the product you have acquired.

This manual contains a detailed description and instructions for use. If you have any further questions or suggestions, please do not hesitate to contact us by telephone or e-mail.

These instructions for use are part of **spot-on** **Cordfree**. Please keep them to hand for future reference. If you pass this product on to third parties, please also include this document as it contains important information on commissioning and handling the product.

Use this manual to familiarize yourself with the product before using it during part of any treatment.

1.1.1. Responsibility of the Manufacturer

The **spoton** ©cordfree has been manufactured in accordance with the state of the art and recognised safety regulations.

orangedental GmbH & Co. KG [hereinafter referred to as orangedental] only considers itself responsible for the effects on safety, reliability and performance of the device if:

- >> Assembly, add-ons, readjustments, alterations or repairs are carried out by persons authorised by orangedental.
- >> the device is used in accordance with the instructions for use.



1.1.2. Responsibility of the Operator

The operator is among other things responsible for:

- >> compliance with accident prevention regulations and the Ordinance on the Installation, Operation and Use of Medical Devices (German regulation MPBetreibV).
- >> the operation.
- >> maintenance.
- >> the proper and safe condition of the product and the availability of this manual at the place of use.
- >> following the safety instructions contained in this manual (cf. section 1.3 Conventions, Symbols used).



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1.3. Conventions, Symbols used

In these instructions, the conventions stated below indicate important information:

WARNING: This symbol is used if deviating from the procedure described

may result in physical injury or death.



CAUTION: This symbol is used if deviating from the procedure described

may result in damage to the product or loss of data.



IMPORTANT: The use of the term **IMPORTANT**, formatted in bold capitals,

indicates advice for the use of the device or for the

application of a certain procedure.

Note: Notes are used to highlight important or unusual points.

Symbols used on the product, its packaging or in these instructions have the following meanings.

CHECK INSTRUCTIONS

This symbol indicates that this user manual contains important, mandatory instructions which must be followed to comply with the safety standards for the medical product.



ATTENTION

This symbol indicates that there are warnings or regulations concerning the product which are not specified on the label. It advises the reader to consult the accompanying documents



MANUFACTURER

This symbol is used in order to display the name and address of the manufacturer of the medical device.





ORDER NUMBER

This symbol indicates the order number.

REF

SERIAL NUMBER

This symbol is used to indicate the serial number.



CE MARKING

This symbol, attached by the manufacturer, indicates that the medical device is in conformity with and fulfills all requirements of the medical device directive 93/42/EEC.



DISPOSAL

This symbol means that the device labelled must not be discarded with normal household waste.





2. ABOUT THE PRODUCT

The **spot**—on ^{®cordfree} is characterised by the fact that the battery is attached directly to the lighting unit and therefore no cable is required.

Another special feature of **spot-on** sensor and the associated automatic switch-off. The motion sensor determines the current orientation of the lighting unit. If this corresponds to the usual working position, the lamp is activated and the oral cavity can be illuminated. When it is nearly horizontal, the lighting unit is deactivated. This prevents, for example, your assistant from being blinded.

2.1. Intended Use

The **spot**—on **cordfree* is used for illumination of the oral cavity of a patient using a binocular loupe system of the practitioner. The **spot**—on **cordfree* is designed for use by dentists or qualified dental personnel within a dental workspace.



Scope of delivery 2.2.



Lighting unit

The magnetic adapter is already mounted on it.



2 battery units



Power supply for charging the battery unit



Charging cable for connection between power supply unit and charging unit



Charging unit



Allen key

2.3. **Accessories**

The following parts below can be reordered from orangedental GmbH & Co KG via your depot under the article number indicated.



1 battery unit

ArtNr. zublup0499500



1 Orangefilter

ArtNr. zublup0499440



3. INSTALLATION

Before using the **spot-on** **coordfree* for the first time, you should charge the battery unit completely. After approx. one hour the battery is 80% charged; after two hours it is fully charged.

In order to charge, connect the charging cable with the supplied power supply unit and plug it into a suitable mains socket. Now plug the Micro-USB plug of the charging cable into the socket of the charging unit. Insert either one or both battery units into the recesses provided in the charging unit. The magnets in the charging unit ensure correct positioning. As long as the battery unit is charging, the respective LED lights up orange. When it turns off completely, the corresponding battery is fully charged. Now remove the battery unit from the charging unit by pulling out the battery unit while holding the charging station with your other hand.

CAUTION:

If one of the LEDs lights up permanently without a battery being inserted, please disconnect the charging unit from the mains plug and no longer use the charging unit. Get in touch with orangedental.

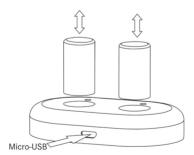


Figure 1: charging batteries

Note:

Do not use a USB port on your PC for charging. This cannot provide the required power.



Now you can insert the battery unit into the lighting unit. The magnetic system ensures correct positioning.

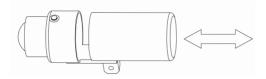


Figure 2: Inserting the battery

Note:

If no adapter is attached to the magnifying glasses yet, please use the supplied Allen key or contact orangedental if necessary.

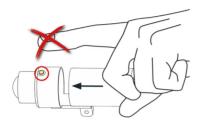
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4. USAGE

Switching on

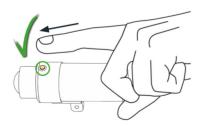
Insert a battery into the lighting unit (see 3: Installation). The LED now lights up for one second. During this time, the touch sensor is calibrated and should therefore not be touched.



The LED then turns off automatically. The **spot** on ^{®cordfree} is now ready for use.

The **spot** on **coordfree* is operated by a touch sensor located in the centre of the lighting unit. It is possible to feel a minimal elevation of the sensor.

Note: If you have difficulty feeling the touch sensor, swipe your finger forward from the battery unit.



If you touch the sensor with your finger briefly (less than one second), the light switches on. This is always the case, regardless of the orientation of the **spot** on **Goordfree*; the automatic switch-off function is still deactivated here (see 4.1.2: Automatic switch-off). It is activated once the value has fallen below the switch-off angle, unless the automatic switch-off function is turned off (see section 4.1.2).



Look through the magnifying glasses onto a flat surface. You can optimally adjust the illumination of your field of vision by pressing up or down the lamp which is mounted on the glasses.

Switching off

With another short touch of the touch sensor, you switch off the light again.

If the light is currently deactivated due to the automatic switch-off function. a short flash acknowledges the successful switch-off.

Note: If the spot-on^{®cordfree} is no longer needed, remove the

battery to prevent it from deep discharging.

Charging

To charge the batteries, connect the charging cable to the supplied charging unit and plug it into a suitable mains socket. Now plug the Micro-USB plug of the charging cable into the socket of the charging unit. Then insert either one or both battery units into the recesses provided in the charging unit. The magnets in the charging unit ensure correct positioning. As long as the battery unit is charging, the respective LED lights up orange. When it turns off completely, the corresponding battery is fully charged. Now remove the battery unit from the charging unit by pulling out the battery unit while holding the charging station with your other hand.

CAUTION: If one of the LEDs lights up permanently without a battery

> being inserted, please disconnect the charging unit from the mains plug and no longer use the charging unit. Contact

orangedental.

Note: Do not use a USB port on your PC for charging. The USB port

> cannot provide the required power. Normally the USB interface in the computer switches off due to overload. If, contrary to expectations, it does supply power, the charging process would take three to four times as long as with the

supplied USB power supply unit.

The charging process is completed when the respective orange LED goes out completely. After approx. one hour, the battery is 80% charged. The battery is fully charged after about two hours.

Power saving mode

If the light is not moved within approx, two minutes, the energy-saving mode is automatically activated and the light switches off by itself off. If the lamp is moved again, it is automatically switched on.

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4.1. Settings

4.1.1. Adjusting the brightness

The factory setting is a luminous intensity of 10,000 lux. To change the light intensity, press the touch sensor six times when it is switched on (the light is switched off and on again three times). Then each time you press the touch sensor, the light intensity of the light changes from the lowest level, through the middle level to the highest and from the highest to the lowest.

Note:

If the touch button is not pressed for three seconds, you leave the setting mode. Pressing the touch button again switches the **spot—on** **coordfree* off (see 4: Switching off).

Three different light intensities are possible:

normal light intensity approx. 10.000 Lux¹ increased light intensity approx. 15.000 Lux¹ maximum light intensity approx. 20.000 Lux¹

¹ measured at a working distance of 25 cm

The selected value is saved and is active again after the next switch-on.

Note:

If the touch button is pressed more than 20 times, pressing the button again also exits the setting mode and switches off the **spot—on**^{@cordfree}.



4.1.2. Automatic switch-off

The spot-on @cordfree has a function that ensures that the lighting unit is automatically switched on or off depending on its orientation. This allows you to illuminate your working area in your working position with your head slightly bent forward, while for an angle greater than α the lighting unit is automatically deactivated and therefore, for example, your assistant is not dazzled. Another positive side effect is the extension of the battery life.

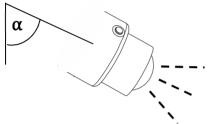




Figure 3: Switch-off angle undercut → the spot-on®cordfree lights up

Figure 4: Switch-off angle exceeded → the spot-on®cordfree is not lit

In order to satisfy an individual working posture, one can choose between three different angles α (small, medium and large).

It is also possible to deactivate the automatic switch-off function. In the delivery state, it is activated and triggers at the medium angle. The selected setting is saved and is active again after the next switch-on.

Note: The automatic switch-off triggers with a short time delay.

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Changing the switch-off angle or deactivating the automatic switch-off function

If you want to change the switch-off angle, put on the **spot-on** **cordfree* and switch it on. Within the next 15 seconds, tap twice from the side on one of the temples with your index finger and middle finger ("double tap"). A successful double-tap is acknowledged with a short blink.

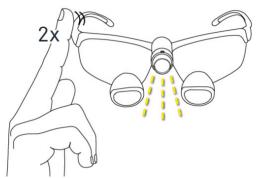


Figure 5: Douple tap on temples

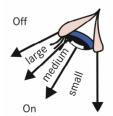
Immediately afterwards, press the touch sensor six times (the light is switched off and on again three times). Now you are in the mode to change the angle. Each time the touch button is pressed again, the angle is increased and indicated by a short flashing signal from the lamp. After the angle setting "large", the setting "automatic switch-off deactivated" follows.

Note:

If the touch button is not pressed withing six seconds, you leave the setting mode. Pressing the touch button again switches the **spot-on**®cordfree off.

Settings

Angle small	1x blinking
Angle medium	2x blinking
Angle large	3x blinking
Deactivated	4x blinking



The selected setting is saved and is active again after the next switch-on.



Note:

If the double tap has not been registered by the motion sensor, the <code>spot-on</code> explains may switch to the setting mode "brightness". Set the desired brightness and then follow the instructions again as described in Section 4.1.2: Changing the switch-off angle.

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5. ASSEMBLY OF SPARE PARTS AND ACCESSORIES

5.1. Mounting the orange filter

1. Make sure that the pre-assembled grub screw does not protrude into the inside of the orange filter.



2. Place the orange filter on the **spot-on**®cordfree and screw in the grub screw using the Allen wrench.



3. If you do not need the orange filter, lift it all the way to the top.





SAFETY, HANDLING AND MAINTENANCE

6.1. General

Keep in mind that the spot-on shines very brightly and warms up during operation. When using the spot-on scordfree, make sure that you do not shine into the eyes of the patient or your staff. Although the light output is so low that the evelid closure reaction prevents damage to the retina, the glare effect of the lamp is very strong as soon as you enter the light field with your eyes.

WARNING:

The spot-on @cordfree lighting unit corresponds to risk group 2 according to DIN EN 6247 1-1. Danger of glare! Do not look directly into the light beam.



The light beam must not be directed towards the eyes. Do not use the spot-on®cordfree for eye examinations (examination of pupils).

Increased risk of glare. Note that the reaction of the eyes decreases under the influence of drugs, medications or alcohol.

Risk of injury to the retina.

The product emits blue light (400-780 nm). Do not look directly into the light beam.

CAUTION:

Danger of heat accumulation, please do not cover during operation.



WARNING:

The battery unit is a lithium-ion battery. Please observe the following application instructions to avoid hazards:



- Do not use a defective or damaged battery.
- Do not short-circuit it. The lithium-ion batteries can easily be short-circuited if they are placed on a conductive surface. Also be careful when storing (do not store in a drawer or similar with other metallic objects).
- Avoid subjecting the batteries to heat and mechanical stress. Do not store them in direct sunlight.

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Do not open the batteries.



- Only use the supplied battery units and charging unit to charge the batteries.
- Keep small cells and batteries that could be swallowed out of the reach of children.

Ingestion may result in burns, perforation of soft tissue and death. Severe burns may occur within two hours of swallowing.

If a cell or battery is swallowed, seek immediate medical attention.

- Store batteries clean and dry. If connections are dirty, clean with a dry, clean cloth.
- Do not charge batteries for long periods of time when they are not needed.
- After prolonged storage it may be necessary to charge and discharge the cells or batteries several times to achieve full performance.
- As far as possible, batteries should be removed from the device when they are not in use

6.2. Hygiene

CAUTION: The light, battery and charging unit are not autoclavable. The

resulting temperatures would destroy the electronics.

Note: The spot-on ecordfree is appropriately sealed for cleaning / disinfection with moist media / wipes.

Cleaning should be done immediately after using **spot-on**®cordfree to prevent blood or protein residues from solidifying.

6.2.1. Cleaning

Remove the **spot-on**^{®cordfree} from the magnifying glasses.

IMPORTANT: Carry out the cleaning on the assembled **spot-on** ^{®cordfree}. No

cleaning agent must enter the interior of the light or battery

unit.





First, remove any residue by wiping with a mild detergent.

Now remove any residues of the cleaning agent with moist, lint-free disposable cloths.

6.2.2. Disinfection

The subsequent disinfection of the spot-on^{®cordfree} is carried out as wipe disinfection on the assembled spot-on @cordfree.

IMPORTANT: No disinfectant must enter the inside of the light or battery unit.

Use a cloth moistened (not wet) with the disinfectant for this purpose.

The products listed in section 6.2.3 below have been tested Note: positive for compatibility with spot-on ®cordfree. It cannot be guaranteed that other agents will not attack the surfaces.

Wipe the **spot-on** ®cordfree several times with the disinfectant wipe.

Allow the disinfectant to work long enough according to its instructions.

Now remove any residues of the disinfectant with sterile, moist, lint-free disposable wipes.

Now rub the spot-on economic dry with a sterile, lint-free disposable cloth and allow to dry thoroughly. Make sure that the glass lens of the lamp is clean. Dirt on the lens affects the light intensity.

When cleaning, please ensure that the disinfection or CAUTION: cleaning fluids used do not run into the interior of the light, battery or charging unit or behind the lens of the light unit.

Use only soft cloths for cleaning and disinfection and do not use sharp or scratching objects.

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6.2.3. Disinfectants for spot-on ®cordfree

The following products have been tested for disinfection of **spot**on **on on on**

Innocid DW-i disinfecting tissues

PRISMAN Pharma International AG; Am Stalden 16; CH-4622 Egerkingen

Omnizid Spray and wipe disinfection

OMNIDENT Dental-Handelsgesellschaft mbH; Gutenbergring 7-9; D-63110 Rodgau

Bacillol® Tissues

BODE Chemie GmbH; Melanchthonstraße 27; D-22525 Hamburg



Maintenance and servicing 6.3.

Repairs to the device should only be carried out by a service centre authorised by orangedental.

WARNING:

Take the device out of operation immediately if it shows visible damage or malfunctions. In this case, please contact your orangedental GmbH & Co. KG service centre.



Disposal 6.4.

The spot-on®cordfree and accessories contain a lithium-ion battery and other components that are not suitable for disposal in normal household waste.



Please contact your dental dealer or enretec GmbH (www.enretec.de) to arrange a return of the device. Please contact orangedental GmbH & Co. KG if you have any questions in this regard.



7. SPEZIFICATONS, CONFORMITY



orangedental GmbH & Co. KG Aspachstraße 11 | 88400 Biberach / Riß



7.1. Requirements for the practical environment

IMPORTANT: The spot-on®cordfree may only be operated by qualified and

trained persons.

Place the device so that it is not exposed to direct sunlight.

WARNING: The charging station must not be within reach of the patient.

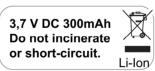


7.2. Product labelling

Lighting unit



Battery unit



Charging unit





7.3. Technical data

7.3.1. Dimensions

	data	unit
Housing battery unit	27 x 16 Ø	mm
Housing lighting unit	32 x 17 ø	mm
Housing charging unit	80 x 46 x 15	mm
Weight battery unit	11	g
Weight lighting unit	7	g
Weight charging unit	90	g

7.3.2. Electrical characteristics

	data	unit
Supply voltage Battery unit	3,7	V DC
max. current consumption	300	mA
battery Li-lon	1,2	Wh

7.3.3. Optische Eigenschaften

	data	unit
Light intensity normal/amplified/maximum approx.	10 / 15 / 20	x1000 Lux
measured at a working distance of 25 cm		

7.3.4. Service life

	data	unit
Service life	3	years
(battery excluded)		

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7.3.5. EMC Classification

	Data
EN 60601-1-2	uses HF energy exclusively for its internal function
Group 1	
EN 60601-1-2	is suitable for use in all establishments, including
Class B	residential areas and those directly connected to a public supply network which also supplies buildings used for residential purposes.

7.3.6. Compliance with standards

Protection class IP20

Classification according to 93/42/EEC

Electrical safety, standard fulfilled EN 60601-1

Photobiological safety of lamps DIN EN 62471

and systems

7.3.7. Environmental conditions

Operating conditions

Use only in normal climates

temperature: +10 °C to +40 °C rel. humidity: 35 % to 85 %

air pressure: 800 hPa to 1060 hPa

Transport conditions

temperature: -20°C to $+60^{\circ}\text{C}$ rel. humidity: 10% to 90%

air pressure: 700 hPa to 1060 hPa

Storage conditions

temperature: 0 $^{\circ}$ C to +40 $^{\circ}$ C rel. humidity: 35 % to 85 %

air pressure: 700 hPa to 1060 hPa



7.3.8. Electromagnetic compatibility

Guidance and manufacturer's declaration – electromagnetic emissions

The **spot**—on^{®cordfree} is intended for use in an environment as described below. The customer or the user of the **spot**—on^{®cordfree} should assure that it is used in such an environment.

te to doca in odon an environment.				
Interference emission measurements	Compliance	Electromagnetic environment – guidance		
RF-emissions as per CISPR 11	Group 1	The spot—on scordfree 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 as per CISPR 11	Class B	The spot-on coordfree is suitable for use in all establishments including		
Harmonic emissions as per IEC 61000-3-2	Not applicable	domestic premises and those directly connected to the public power supply		
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	network that supplies buildings used for domestic purposes.		

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Guidance and manufacturer's declaration – electromagnetic immunity

The **spot-on**^{®cordfree} is intended for use in the electromagnetic environment specified below. The customer or the user of **spot-on**^{®cordfree} should assure that it is used in such an environment.

should assure that it is used in such an environment.			
Immunity test	IEC 60601	Compli-	Electromagnetic
	test level	ance	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%.
	± 2 kV for	Not	Mains power quality
Electrical fast transient/burst IEC 61000-4-4	power supply lines ± 1 kV for input / output lines	applicable	should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2kV line(s) to line(s)	Not applicable	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 (>95 % dip in U _T) for ½ cycle 40 % UT (60 % dip in U _T) for 5 cycles 70 % UT (30 % dip in U _T) for 25 cycles 5 % UT (>95 % dip in U _T) for 5 s	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
ANMERKUNG U_T is the a.c. mains voltage prior to application of the test.			

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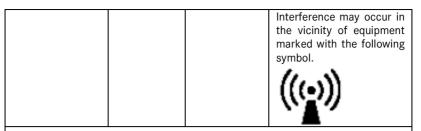


Guidance and manufacturer's declaration – electromagnetic immunity

The **spot**—on ^{®cordfree} is intended for use in an environment as described below. The customer or the user of the **spot**—on ^{®cordfree} should assure that it is used in such an environment

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 V _{eff} 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 V _{eff}	Portable and mobile RF communications equipment should be used no closer to any part of the spot —on ®cordfree including cables, then the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1.17 √P d= 1.17 √P for 80 MHz to 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 b		





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.

^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 access 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 spot-on®cordfree is used exceeds the applicable RF compliance level above, the **spot** on **®**cordfree should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the spot-on®cordfree.

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

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Recommended separation distances between portable and mobile RF communications equipment and the spot—on ®cordfree

The <code>spot-on®cordfree</code> is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the <code>spot-on®cordfree</code> can help prevent the electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the <code>spot-on®cordfree</code> – as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of			
Rated	transmitter [m]			
maximum	150 kHz to 80	80 MHz to	800 MHz to	
output	MHz	800 MHz	2.5 GHz	
power of	in the ISM bands	d= 1.17 √P	d= 2.3 √P	
transmitter	d = 1.17 √P			
in Watt				
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) according 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.

