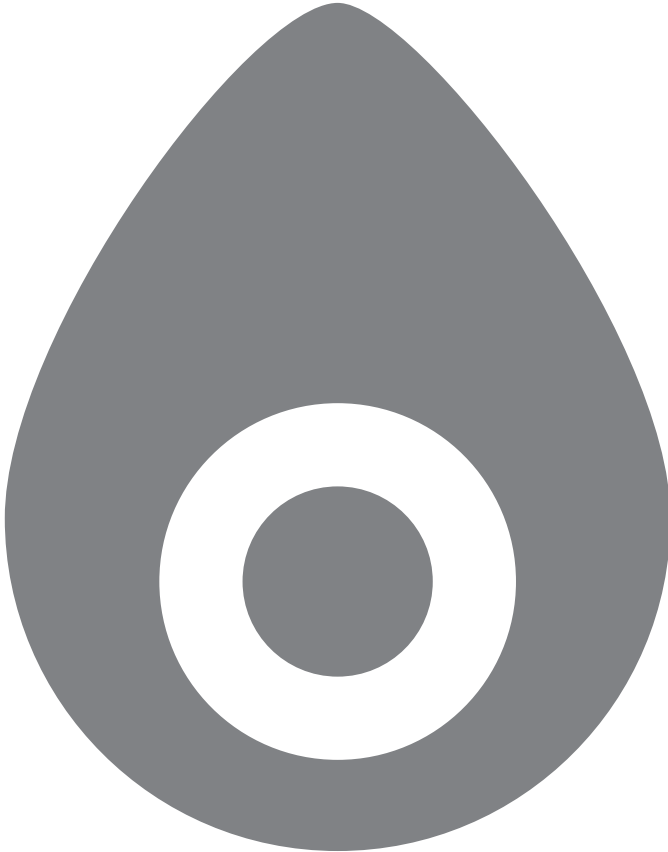




Instructions for use / Alarm unit, Fiber optic cable & Sensor patch

ENGLISH



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RM-1RM240




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Warnings and precautions

- Please refer to the hemodialysis equipment indication statement to confirm usage is consistent with its labeled indication.
- The Redsense device model RA-1-RA201 is designed to detect potential blood loss from the needle access site during hemodialysis.
- Read and follow all instructions carefully.
- This piece of equipment is only an alarm. It does not replace existing safety procedures.
- Redsense may only be used for its intended purpose and according to these instructions.
- The alarm unit may only be placed on the dialysis machine as shown in the instructions.
- The alarm unit shall only be used with the proper AC adapter.
- The alarm unit may only be used by persons who have received proper training from Redsense Medical or who have been approved by Redsense Medical. Use by untrained or improperly trained personnel may pose a danger to the patient.
- All use must be administrated under physician's prescription. and must be observed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.
- Before use, a test must be performed to make sure the observing person can clearly hear the alarm signal. The test is further described at page 4 under point 9.
- This device should not be relied upon as the sole monitor for blood loss at the blood access site.
- Redsense requires special precautions in terms of EMC and must be subsequently used in accordance with the EMC information in these instructions.
- Portable and mobile radio communication equipment may affect Redsense.
- Redsense is not intended to be used in a highly oxygenated environment.
- Modifying the equipment is not permitted. Modification of the equipment will void all guarantees and product liability on the part of the manufacturer.
- Servicing of the equipment may only be performed by Redsense Medical or by persons authorized by them.
- External equipment intended for connection to signal input, signal output or other connectors shall comply with the relevant product standard e.g. IEC 60950-1 for IT equipment and the IEC 60601-series for medical electrical equipment. In addition, all such combinations – systems – shall comply with the safety requirements stated in the collateral standard IEC 60601-1-1 or the general standard IEC 60601-1, edition 3, clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 shall be kept outside the patient environment i.e. at least 1.5 m from the patient support. Any person who connects external equipment to signal input, signal output or other connectors has formed a system and is therefore responsible for the system to comply with the requirements. If in doubt, contact Redsense Medical or your local representative.
- Redsense is a laser class I product. 

About Redsense alarm systems

Redsense is an alarm system for monitoring the blood access during hemodialysis. The Redsense system consists of the following and can be used in combination with:

- Alarm unit, RA-1-RA201
- AC adapter, RC-1-RC201
- Fiber optic extension, RE-1-RE201
- Sensor patch, RS-1-RS201

When the sensor patch is placed over the blood access, it detects any blood coming in contact with the sensor. This can occur if the needle is accidentally dislodged or if blood is leaking during dialysis.

Indications For Use

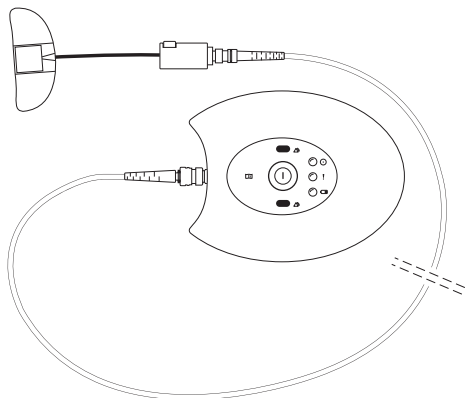
The Redsense device is intended to monitor for potential blood loss from the hemodialysis access site in hemodialysis patients undergoing hemodialysis treatment. The device includes a blood sensor incorporated into a sensor patch. The sensor monitors potential blood leakage from the venous needle blood access via a light signal and will alarm if blood leakage is detected by the device's sensor.

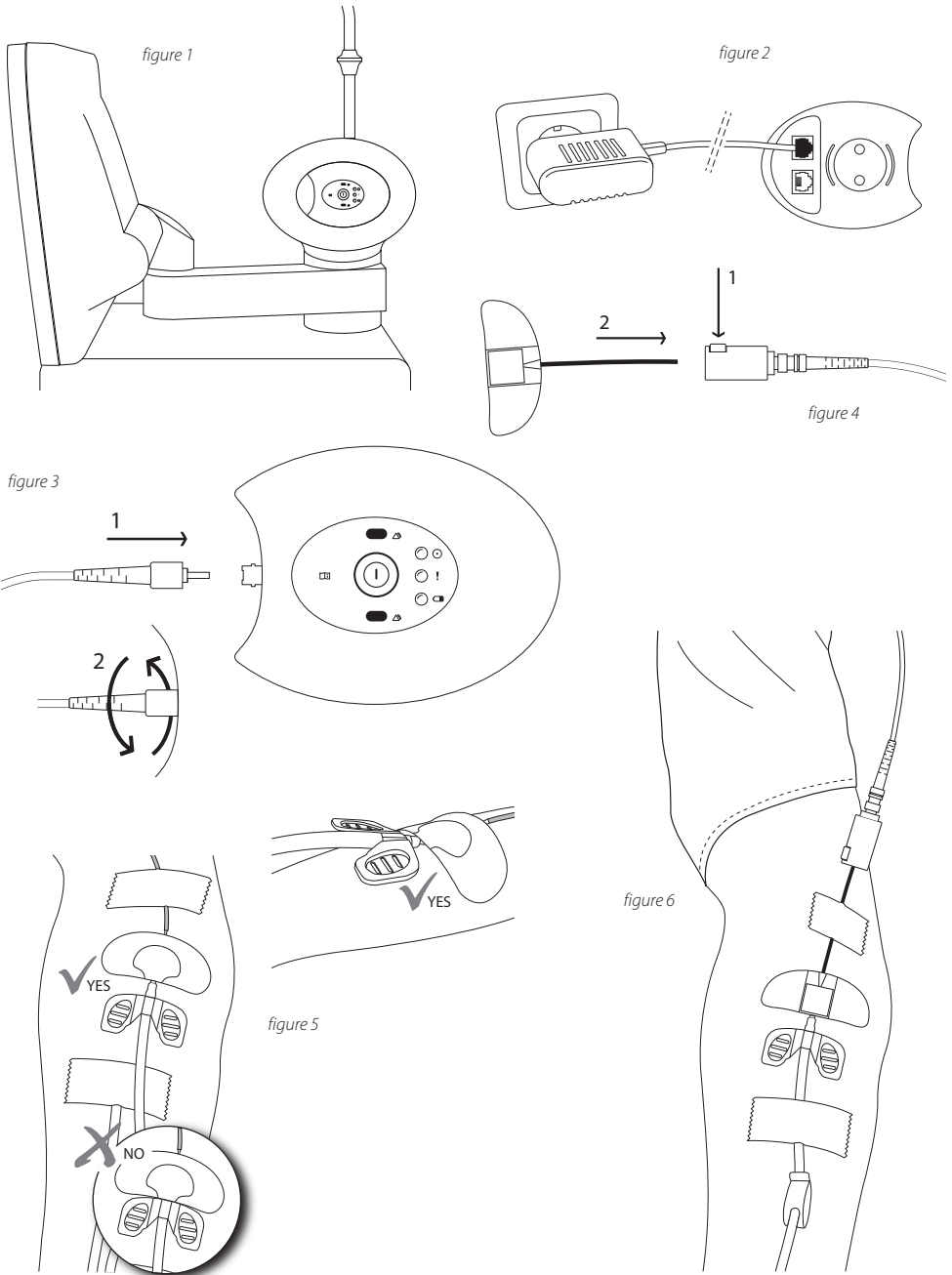
Mounting Redsense

The Redsense sensor should be placed on the patient after the needles have been inserted and before dialysis begins. Redsense must be turned on the entire time that dialysis is running.

1. Attach the alarm unit to the dialysis machine's IV pole / drip stand (see figure 1). If this isn't possible please contact Redsense Medical for consultation. Connect the AC adapter to a wall outlet and to the black-colored connector on the alarm unit. (Figure 2 shows the connector.)
2. The alarm unit indicates as follows whether the built-in battery is charged:
 - A flashing battery indicator light means that the battery is being charged. The unit cannot be started in this case. Wait until the charging is complete.
 - A solid battery indicator light indicates that charging is complete and monitoring can begin.
3. Connect the optical extension fiber to the alarm unit. Turn the coupling roughly a 1/3 turn to lock it. Check that the coupling is locked (see figure 3).
4. Check the date on the packaging for the sensor patch and be sure that the packaging has a Redsense label on it. Open and check that the sensor patch does not have any mechanical damage.
5. In order to start Redsense, push the on/off button and check that all the indicator lights are on and the speaker is functional. A short beep should be heard. If it is the first set-up or it is a new environment for the Redsense, please check that the patient's supervising staff or observing person can clearly hear the alarm sound at the correct distance. The alarm signal should be a continuous signal with three different levels/tones and can be initiated by starting Redsense and then provoking an alarm. The observing person must be sure that the alarm signal can be heard from other rooms or while there is noise. The observing person must be situated at places where the alarm signal can be heard during the entire dialysis treatment. If this isn't possible please consult Redsense Medical.
6. To stop testing the indicator lights and the alarm signal, push the on/off button again. The green indicator light starts to flash together with a intermittent signal.
7. Connect the fiber from the sensor patch to the optical extension fiber. Open the connector on the end of the optical extension fiber by holding in the locking button, inserting the sensor patch fiber from the sensor patch until it stops/resists, then releasing the lock button (see figure 4). When the green indicator light is solid, and the intermittent signal is turned off the monitoring function is working correctly.
8. Make sure the area around the needle is dry.
9. Apply the sensor patch to the skin over the needle with the absorbent part of the sticker centered directly over the insertion point. Be sure that the self-adhesive part of the patch does not cover the wings (see figure 5).
10. Secure the needles in place as usual using tape or similar material. Secure the needles in place according to the existing policy and procedure. Dressing material and or tape may be applied directly over the surface of the sensor patch according to the facility policy and procedure.

Figure 6 shows an example of how the sensor patch and the optical extension fiber can be attached to the patient's arm. Check that the sensor patch is clean and dry.





Mounting Redsense

A flashing green indicator light indicates that the alarm unit is performing a self-test. During this test, a number of parameters are checked that may eventually need to be adjusted. These are displayed when the following lights and symbols appear:

- The yellow indicator light, which is marked with a warning symbol, can indicate any of the following: Moisture has come in contact with the sensor. The sensor has come loose, is not connected or has been broken. The optical extension fiber is not connected correctly.
- If all of the indicator lights are flashing, an internal error has been detected. Contact Redsense Medical for additional support.

Any problems must be corrected before attempting to restart the alarm unit. If blood or moisture has come in contact with the sensor, it must be replaced with a new sensor. If some other technical problem occurs, do not use the alarm unit, rather switch to another Redsense alarm unit and contact Redsense Medical for additional support.

During dialysis

While the unit is running, the green indicator light will light up continuously, and in the event of an error the following alarm signals may be heard:

- The red indicator lights followed by a continuous alarm signal, indicate that blood has been detected by the sensor, either because the venous needle has been dislodged or leakage has occurred. First, deal with the leak and then turn off the alarm by holding in the button for at least 1 second.
- The yellow warning indicator light followed by an intermittent alarm signal indicates one of the following: Moisture has come in contact with the sensor. The sensor has come loose, is not connected or has been broken. The optical extension fiber is not connected correctly. Turn off the alarm by keeping the on/off button pressed, fix the cause of the alarm and then restart the alarm unit.
- The yellow warning indicator together with the battery indicator, followed by an intermittent alarm signal, means that the alarm unit is no longer receiving power from the AC adapter, which means that monitoring can no longer be performed correctly. In this case, turn off the alarm unit by keeping the button pressed in, then fix the cause of the AC power failure for the alarm unit.
- If all the indicator lights are flashing, followed by an intermittent alarm signal, this indicates an internal error. Turn off the alarm unit by holding in the button and continue running the dialysis without monitoring with Redsense. Contact Redsense Medical for additional support..

After completing dialysis

1. Press the on/off button for at least 1 second to turn off the alarm.
2. Disconnect the sensor patch from the optical extension fiber.
3. Clean the optical extension fiber.
4. Remove the sensor patch and dispose of it according to the clinic's procedures for handling dialysis waste.

Note: The alarm can also be turned off using the on/off button at any time during dialysis.

Maintenance

Cleaning

The actual sensor patch is made of disposable material and should not be cleaned or reused. The alarm unit and the optical extension fiber should be wiped off with disinfectant/alcohol and a moist cloth.

Charging the battery

The alarm unit contains a battery in order to issue an alarm in the event of a power failure from the AC adapter. When the alarm unit is connected to the AC adapter, the charging status for the built-in battery is displayed as:

- A flashing battery indicator light means that the battery is being charged. The unit cannot be started in this case. Wait until the charging is complete.

Maintenance

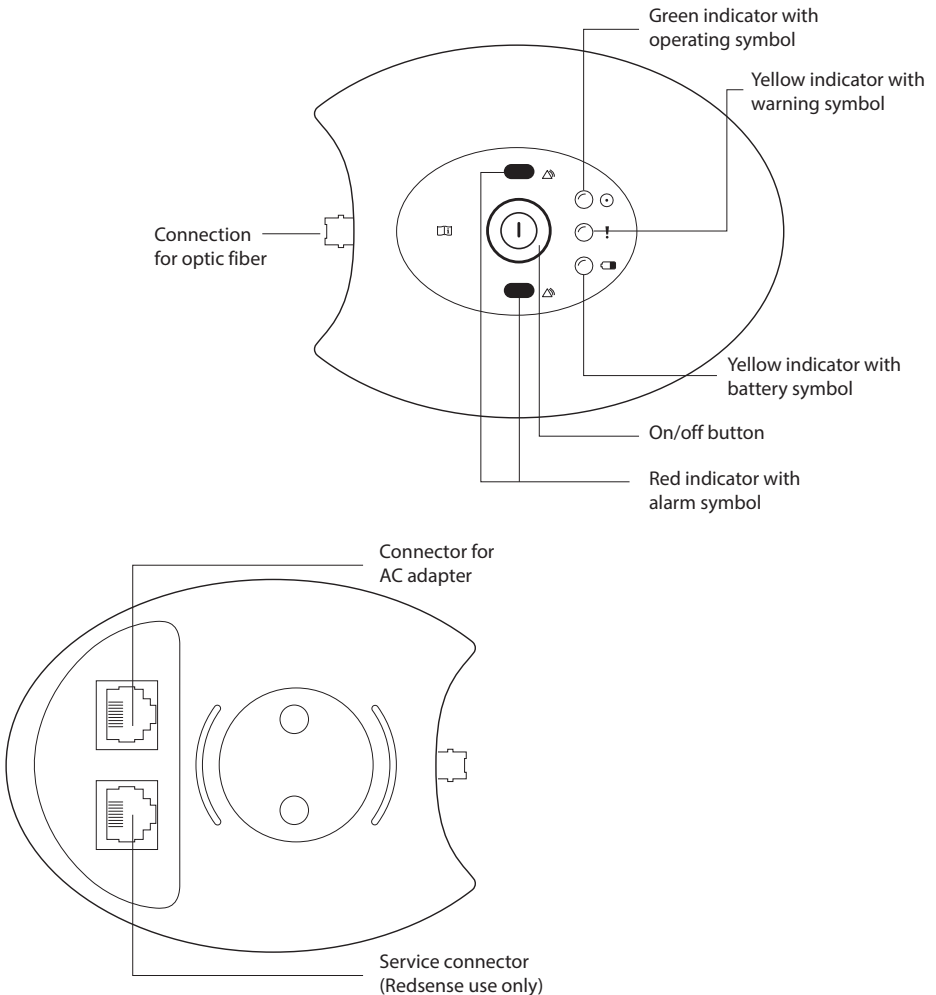
- A solid battery indicator light indicates that charging is complete and monitoring can begin.

Replacing the battery

In order to replace the battery, the alarm unit must be opened and this can only be done during servicing. Servicing the equipment and changing the battery should only be done using Redsense Medical or by personnel authorized by them.

Symbols and terms

The following symbols and terms are used in these instructions and on the product



Symbols and terms

Other symbols displayed on the product and its accessories indicate the following:



Manufactured by Redsense Medical AB – Sweden



Alarm indicator



Last usage date, year-month (YYYY-MM)



On/off indicator



Batchnumber, includes manufacturing year



Warning indicator



Item number



Battery indicator



Serial number, includes manufacturing year



Applied part of type BF –Body Floating (the surface between the equipment and the patient does not conduct electricity)



For single use only



The alarm unit covered by the WEEE directive and must therefore be recycled



Consult the instruction for use



Consult warnings and precautions



Class I laser product



On/Off-button



Class II – double insulation



Do not use if package is damaged



The sensor has been sterilized using Ethylene Oxide (Sensorpatch)

Technical Information

Parameter	Alarm unit	Extension fiber	Sensor patch
Size	128 x100 x 35 mm	Ø10mm x diffent lenghts	140 x 60 x 1 mm
Weight	150 g	ca 10-30 g	150 g
Usage Temperature	+15 to +40 °C	+15 to +40 °C	+15 to +40 °C
Temperature Transportation	-20 to +60 °C	-20 to +60 °C	-20 to +60 °C
Temperature Storage	-10 to +40 °C	-10 to +40 °C	-10 to +40 °C
Usage humidity	<75%	<75%	<75%
Transportation Humidity	<75%	<75%	<75%
Storage Humidity Air pressure	<75%	<75%	<75%
Shelf life	5 years	5 years	See expiry date
EMC precautions	See EMC Information		

The Redsense power adapter is approved according to EN60601-1 01/2006 and EN 60601-1-2 10/2006.10

EMC Information

Redsense has been tested and approved according to the IEC 60601-1-2 standard for electromagnetic compatibility (EMC).

Guidance and manufacturer's declaration – electromagnetic emissions

Redsense is intended for use in the electromagnetic environment specified below. The customer or the user of Redsense should ensure that it is used in such an environment.


Emissions test	Compliance	Electromagnetic environment - guidance
RF-emissions CISPR 11	Group 1	Redsense 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	Redsense 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.
Harmonic emission IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

Redsense is intended for use in the electromagnetic environment specified below. The customer or the user of Redsense should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/-8kVair	+/- 6 kV contact +/-8kVair	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient /Burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input /output lines	+/- 2 kV for power supply lines n/a. for input/ output ines	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 n/a. for 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 (>95% dipinUT) for 0,5 cycle 40%UT (60% dipinUT) for 5 cycles 70%UT(30% dipinUT) for 25 cycles <5%UT(>95% dipinUT) for 5 sec	<5%UT (>95% dipinUT) for 0,5 cycle 40%UT (60% dipinUT) for 5 cycles 70%UT(30% dipinUT) for 25 cycles <5%UT(>95% dipinUT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [Equipment or System] requires continuous operation during power mains interruptions, it is re- commended that the [Equipment or System] be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

Redsense is intended for use in the electromagnetic environment specified below. The customer or the user of Redsense should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of Red- sense, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance 80 MHz to 800 MHz 800 MHz to 2,5 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol.</p> <p>$d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ $d = 2,3\sqrt{P}$</p> 
Radiated RF IEC 61000-4-3	1	3 V/m	
	50 kHz to 80 MHz		
	3 V/m		
	80MHz to 2,5GHz		

Guidance and manufacturer's declaration – electromagnetic immunity

NOTE 1 At 80MHz and 800MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflected 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 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 Redsense is used exceeds the applicable RF compliance level above, Redsense should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating Redsense. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable an mobile RF communications equipment and Redsense

Redsense is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Redsense can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Redsense 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	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1,2\sqrt{P}$	$d = 1,2\sqrt{P}$	$d = 2,3\sqrt{P}$
0.01	0.12	0.12	0.24
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 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.

