

UltraMax O₂

OXYGEN ANALYZER

Instructions for Use

ENGLISH



NOTE: The latest edition of this operating manual can be downloaded from our website at www.maxtec.com

NOTE: The UltraMax O2 is for use only by trained personnel. Before use, all individuals using the UltraMax O2 should become familiar with the information contained in this Operation Manual. Adherence to these instructions is necessary for safe, effective product performance. Thoroughly read all instructions and labeling provided with this device and any other equipment that will be used.

CLASSIFICATION

Protection against electric shock..... Internally powered equipment
Protection against water.....IPX1
Mode of operation.....Continuous
Sterilization..... See section 6.0
Flammable anaesthetic mixture.....Not for use in presence of flammable anaesthetic mixtures
Power specification.....1.8-3.2V  32mW10mA

CAUTION: Federal law restricts this device to sale by or on the order of a physician or other licensed healthcare practitioner.



Product Disposal Instructions:

The sensor, batteries, and circuit board are not suitable for regular trash disposal. Return sensor to Maxtec for proper disposal or dispose according to local guidelines. Follow local guidelines for disposal of other components.

INDICATIONS FOR USE

The UltraMax O2 Oxygen Analyzer is a tool used to measure oxygen purity, flow and pressure at the outlet of an oxygen concentrator. It is not intended to be used by patients who are prescribed oxygen, nor is it intended to continuously monitor or confirm oxygen delivery to a patient. The UltraMax O2 Oxygen Analyzer is intended to be used in an environment where oxygen concentrators are being serviced or repaired. This includes Hospitals, Nursing Homes, Extended Care Facilities, Patient Homes, and Respiratory Device Service and Repair Centers.

WARRANTY

Under normal operating conditions, Maxtec warrants the UltraMax O2 to be free from defects of workmanship or materials for a period of Three (3) years from the date of shipment from Maxtec, provided that the unit is properly operated and maintained in accordance with Maxtec's operating instructions. Based on Maxtec product evaluation, Maxtec's sole obligation under the foregoing warranty is limited to making replacements, repairs, or issuing credit for equipment found to be defective. This warranty extends only to the buyer purchasing the equipment directly from Maxtec or through Maxtec's designated distributors and agents as new equipment.

Routine maintenance items, such as batteries, are excluded from warranty. Maxtec and any other subsidiaries shall not be liable to the purchaser or other persons for incidental or consequential damages or equipment that has been subject to abuse, misuse, mis-application, alteration, negligence or accident.

These warranties are exclusive and in lieu of all other warranties, expressed or implied, including warranty of merchantability and fitness for a particular purpose.

PRINCIPLE OF OPERATION

The UltraMax O2 Oxygen Analyzer measures oxygen concentration and flow using ultrasound technology and measures pressure using a piezoresistive silicon pressure sensor.

WARNINGS

Indicates a potentially hazardous situation, if not avoided, could result in death or serious injury.

- ◆ Not for use in an MRI environment.
- ◆ Improper use of the UltraMax O2 can cause inaccurate oxygen readings leading to improper treatment and/or patient harm. Follow the procedures outlined in this user manual.
- ◆ The UltraMax O2 is for checking oxygen concentrators only.

- ⊘ **DO NOT** use the UltraMax O2 for continuous oxygen monitoring.
- ⊘ **DO NOT** use the UltraMax O2 to measure the oxygen concentration of a concentrator when flowing at rates lower than its optimal performance as specified by the concentrator manufacturer; generally 4 LPM or less on concentrators that have a maximum flow of 10 LPM, and 1 LPM or less on concentrators that have a maximum flow of 5 LPM.
- ◆ Not for use in anesthesia applications or for measuring oxygen concentration from any sources other than conventional oxygen concentrators.
- ◆ Not for use with inhalation agents. Operating the UltraMax O2 in flammable or explosive environments may result in fire or explosion.
- ◆ Not suitable for use in the presence of flammable anesthetic mixtures.
- ◆ Oxygen rapidly accelerates combustion.
- ⊘ **DO NOT** smoke while using the UltraMax O2 for checking oxygen concentrators.

Users must become thoroughly familiar with the information contained in this Operation Manual before use. Strict adherence to the operating instructions is necessary for safe, effective product performance. This product will perform only as designed if operated in accordance with the manufacturer's operating instructions.

- ◆ Use only genuine Maxtec accessories. Failure to do so may seriously impair the performance of the UltraMax O2. Repair or alteration of the UltraMax O2 by anyone other than an authorized Maxtec service representative could cause the product to fail to perform as designed.
- ◆ Use of the UltraMax O2 near devices that generate electrical fields may cause erratic readings.
- ◆ If the UltraMax O2 is ever exposed to liquids from spills or immersion, immediately remove the batteries and let the device dry completely. When dry, replace the batteries and check for proper operation.
- ⊘ **DO NOT** autoclave or expose the UltraMax O2 to high temperatures (>60°C).
- ⊘ **DO NOT** use ethylene oxide sterilization.
- ⊘ **DO NOT** expose the UltraMax O2 to irradiation, vacuum, steam, or harsh chemicals.
- ⊘ **DO NOT** expose the UltraMax O2 to pressure greater than 50 psi. Exposure to pressure above 50 psi could cause leaks in the device which may adversely affect performance in flow and pressure readings.

CAUTIONS

Indicates a potentially hazardous situation, if not avoided, could result in minor or moderate injury and property damage.

- ◆ Replace the batteries with high quality AA Alkaline or Lithium batteries.
- ⊘ **DO NOT** use rechargeable batteries.
- ◆ When not in use for periods greater than 30 days remove the batteries to protect the UltraMax O2 from potential battery leakage.
- ◆ Avoid dropping the UltraMax O2 to prevent damage which may adversely affect its performance. If damage to the device is suspected, perform the calibration verification procedure in Section 2.3 of this operating manual.
- ◆ Avoid foreign matter entry into the UltraMax O2.
- ⊘ **DO NOT** use the UltraMax O2 to check a concentrator with a humidifier in place. Humidity from a humidifier could damage the device.
- ⊘ **DO NOT** check a concentrator while holding the mode button or the reading will be inaccurate.
- ◆ Following storage in extremely hot or cold conditions, allow the gas to flow through the analyzer long enough for the internal sensors to reach the gas stream temperature, or wait for the analyzer to equilibrate to room temperature before use.

Symbol Guide

The following symbols and safety labels are found on the UltraMax O2:

	Warning		Authorized Representative in the European Community
	Low Battery		Serial Number
	Do not throw away. Follow local guidelines for disposal		Catalog Number
	Meets ETL standards	<i>LPM</i>	Liter per minute flow
	Manufacturer	<i>PSI</i>	Pounds per square inch
	Date of Manufacture	<i>KPA</i>	Kilopascals
	Medical Device	<i>%</i>	Percent
	Ingress Protection Rating		Gas sample inlet
	Federal law (USA) restricts this device to sale by or on order of a physician.		Gas sample outlet
	Latex free		Direct current
	On/Off Button		DO NOT
	Mode Button		Caution
	Follow instructions for use		

1.0 SYSTEM OVERVIEW

1.1 Description & Principle of Operation

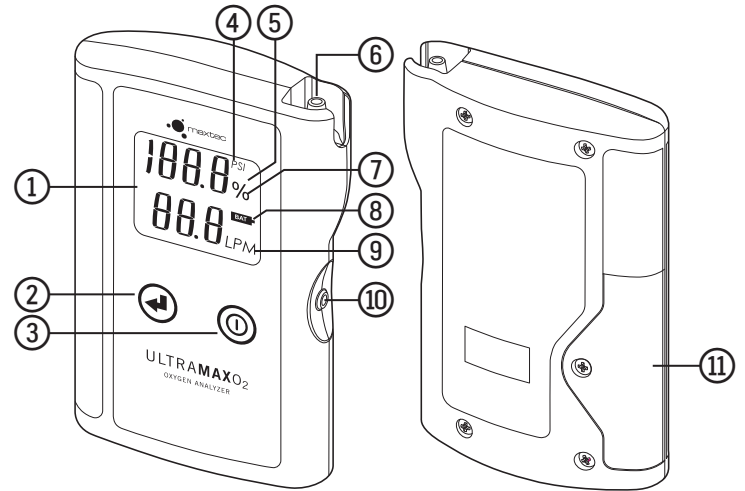
The UltraMax O2 is an oxygen analyzer designed to check the oxygen concentration, flow and outlet pressure of oxygen concentrators. The UltraMax O2 provides unparalleled performance and reliability from its advanced design that includes the following features and operational benefits:

- Accurate oxygen measurements.
- No in-field calibration required.
- Convenient ability to measure pressure in PSI or kPa.
- Durable, compact design.
- Large, easy-to-read, liquid crystal display (LCD).
- Shielded, reinforced sample gas inlet port.
- Long battery life with 2 AA batteries.
- Auto-off after 4 minutes.
- Low battery indication.
- Self-diagnostics.
- Easy to clean.

1.2 Indication for Use

The UltraMax O2 Oxygen Analyzer is a tool used to measure oxygen purity, flow and pressure of an oxygen concentrator. The UltraMax O2 Oxygen Analyzer is intended to be used in an environment where oxygen concentrators are being serviced or repaired. This includes Hospitals, Nursing Homes, Extended Care Facilities, Patient Homes, and Respiratory Device Service and Repair Centers.

1.3 Component Identification



- 3 1/2 DIGIT DISPLAY** — The LCD provides direct readout of oxygen concentration, gas flow and gas pressure. The LCD also displays error codes as necessary.
- MODE BUTTON** — Switches between measuring the concentration of gas produced by an oxygen concentrator and pure oxygen (for calibration verification).
- ON/OFF BUTTON** — Turns the device on or off.
- PSI** — Indicates the pressure measurement is in units of pounds per square inch.
- KPA** — Indicates the pressure measurement is in units of kilopascals.
- GAS SAMPLE INLET** — Used to receive the gas sample.
- % SYMBOL** — Illuminated next to the concentration measurement.
- LOW BATTERY INDICATOR** — Indicates the voltage of the batteries is below normal operating levels.
- LPM** — Illuminated next to the flow measurement. (Not shown when in calibration verification mode).
- GAS SAMPLE OUTLET** — Used as an outlet for the gas sample and as a trigger for pressure measurement when occluded.
- BATTERY DOOR**
GAS SAMPLE TUBING — Used to connect to gas sample sources (not shown).

2.0 OPERATING INSTRUCTIONS

2.1 Oxygen, Flow and Pressure Measurement

To check oxygen concentration, flow and pressure of a gas sample from a concentrator:

Connect the gas sample tubing to the gas sample inlet of the UltraMax O2.

1. Attach the other end of the gas sample tubing to the oxygen concentrator.
2. Initiate the flow of gas to the UltraMax O2 at a rate of 1-10 liters per minute (2 liters per minute is recommended). Ensure the concentrator's output is stable per the concentrator manufacturer's recommendations.
3. Turn on the UltraMax O2.
4. Allow the oxygen reading to stabilize for approximately 10 seconds before reading the oxygen concentration and flow.
5. To check pressure, cover the gas sample outlet with thumb or finger while gas is flowing.
6. Wait 5 seconds for the display to read pressure.

DO NOT hold the mode button while checking a concentrator or the reading will be inaccurate.

2.2 Switching Pressure Units of Measure

The UltraMax O2 can measure pressure in PSI or kPa. The UltraMax O2 is factory set to measure in PSI. To switch to kPa:

1. Using a #1 Phillips screwdriver loosen the battery door screw and remove the battery door.
2. Toggle the switch inside the battery compartment.
3. Replace the battery door and tighten the battery door screw.

2.3 Calibration Verification Procedure

A calibration verification mode is provided to verify that the UltraMax O2 is functioning properly. To perform the calibration verification:

1. Turn on the UltraMax O2.
2. Connect a source of pure oxygen ($\geq 99.95\%$) to the gas sample inlet.
3. Flow 2-5 LPM of gas into the UltraMax O2. Ensure that the gas flowing to the UltraMax O2 is at a stable temperature.
4. Press and hold the mode button. While holding the mode button, the gas measurement should read between 98.5 and 101.5% oxygen. If the gas measurement is not within this range, call Maxtec Customer Service. Calibration verification mode is indicated by "CAL" and "VER" flashing on screen beneath the gas measurement.

3.0 FACTORS INFLUENCING ACCURATE READINGS

3.1 Effects of Temperature

The UltraMax O2 compensates for temperature and will perform within specifications throughout the operating temperature range. However, taking measurements during rapid changes in gas temperature should be avoided.

3.2 Effects of Humidity

The UltraMax O2 has a humidity sensor to detect and compensate for the humidity of gas entering the device. However, high levels (condensing) of humidity can affect the accuracy and reliability of the UltraMax O2. To prevent possible damage:

Avoid usage in environments of greater than 95% relative humidity.

DO NOT use this device in a breathing circuit.

DO NOT breathe or blow into the UltraMax O2.

3.3 Effects of Other Gases

The UltraMax O2 is designed to measure two different types of gas mixtures:

- Oxygen, nitrogen and argon from oxygen concentrators.
- Pure oxygen during calibration verification mode.

Any other concentrations or combinations of gases will cause the UltraMax O2 to measure oxygen concentration incorrectly.

3.4 Effects of Low Flow

Oxygen concentrators function on the principle of removing nitrogen gas from air, leaving concentrated oxygen and argon at a specific oxygen to argon ratio. This operating principle may be altered when concentrators are set to flow at the low end of their operational range. At low flows they may output a low oxygen concentration, e.g. 85% to 91%, for reasons other than high nitrogen, possibly due to an increase in argon content. The UltraMax O2 requires that the ratio of oxygen to argon remain constant in order to guarantee an accuracy of $\pm 1.5\%$ oxygen.

DO NOT use the UltraMax O2 to measure the oxygen concentration of a concentrator when flowing at rates lower than its optimal performance as specified by the concentrator manufacturer; generally 4 LPM or less on concentrators that have a maximum flow of 10 LPM, and 1 LPM or less on concentrators that have a maximum flow of 5 LPM.

4.0 ERROR CODES

The UltraMax O2 has self diagnostic features built into the software to detect faulty readings outside of normal operating ranges. The codes, descriptions and recommended actions are:

E01: Oxygen measurement out of range Hi ($\geq 102.0\%$ calculated by algorithm). Recommended Action: Verify that the UltraMax O2 is being used in the correct mode (Concentrator or Calibration Verification mode). If error code repeats; perform a calibration verification per section 2.3 of this manual. If error code repeats again; contact Maxtec Customer Service.

E02: Oxygen measurement out of range Low ($\leq 2.0\%$ calculated by algorithm). Recommended Action: Verify that the UltraMax O2 is being used in the correct mode (Concentrator or Calibration Verification mode). If error code repeats; perform a calibration verification per section 2.3 of this manual. If error code repeats again; contact Maxtec Customer Service.

E03: Device memory corrupt or missing. Recommended Action: Return the UltraMax O2 to the manufacturer for factory repair.

E04: Signal reading not stable. Recommended Action: Return the UltraMax O2 to the manufacturer for factory repair.

E05: Pressure measurement out of Range Hi (≥ 50 PSI). Recommended Action: Check the pressure on a known gas source pressure. If error code repeats; contact Maxtec Customer Service.

E06: Outside of operating temperature Hi ($\geq 40^\circ$ C). Recommended action: The UltraMax O2 is too hot, cool the device closer to room temperature before use.

E07: Outside of operating temperature Low ($\leq 15^\circ$ C). Recommended action: The UltraMax O2 is too cold, warm the device closer to room temperature before use.

E08: Device self check found error. Recommended Action: Remove and replace the batteries. If error code repeats; return the UltraMax O2 to the manufacturer for factory repair.

5.0 CHANGING THE BATTERIES

Batteries should be changed by service personnel. Use only brand name batteries. Replace with two AA batteries and insert per orientation marked on the device. Batteries should be changed when the **BAT** icon illuminates. The icon will remain lit until the batteries are changed. If the battery power level is too low the UltraMax O2 will not power on until the batteries are changed.

5.1 Battery Replacement Procedure

1. Using a #1 Phillips screwdriver loosen the battery door screw and remove the battery door.
2. Remove the batteries.
3. Insert new batteries ensuring correct polarity. **DO NOT** use rechargeable batteries.
4. Replace the battery door and tighten the battery door screw.
5. If the UltraMax O2 does not power on when done verify the batteries are installed correctly and that the batteries are fresh.

6.0 CLEANING AND MAINTENANCE

Use caution to prevent any fluid from entering the UltraMax O2.

- ⊘ **DO NOT** soak or immerse the UltraMax O2 in fluid.
- ⊘ **DO NOT** autoclave or expose the UltraMax O2 to ethylene oxide sterilization.

6.1 Cleaning

Wipe down the exterior surfaces of the UltraMax O2 with a moist cloth and mild hand or dish soap (pH 6-8).

6.2 Maintenance

Replace the batteries with high quality AA Alkaline or Lithium batteries.

- ⊘ **DO NOT** use rechargeable batteries.
 - When not in use for periods greater than 30 days, remove the batteries to protect the UltraMax O2 from potential battery leakage.
 - Store the UltraMax O2 between -15°C and 60°C (5°F - 140°F)

7.0 SPECIFICATIONS

Oxygen

Oxygen Measurement Range (from a concentrator)	20.9 - 96%
Oxygen Measurement Accuracy	±1.5 % of full scale at constant temperature and optimal flow*
Oxygen Measurement Resolution	0.1% Oxygen

Flow

Flow Measurement Range	0 - 10 LPM
Flow Measurement Accuracy	±0.2 LPM
Flow Measurement Resolution	0.1 LPM

Pressure

Pressure Measurement Range	0.5 - 50 (PSI), 3.4 - 344 (kPa)
Pressure Measurement Accuracy	±0.5% (PSI), ±0.5% (kPa)
Pressure Measurement Resolution	0.1 (PSI), 0.1 up to 199, 1 from 200 to 344 (kPa)
Response Time	≤17 seconds
Warm-up Time	< 1 second
Operating Temperature	15°C - 40°C (59°F-104°F)
Storage Temperature	-15°C - 60°C (5°F-140°F)
Pressure	800 - 1000 mBars
Humidity	0 - 95% (non-condensing)
Power Requirements	2 AA Alkaline batteries (2 x 1.5 Volts)
Battery Life	≥ 1,100 hours (16,500 read cycles)
Low Battery Indication	"Low Battery" icon displayed on LCD
Dimensions	3.16" x 5.10" x 1.04" (80.3mm x 129.5mm x 26.4mm)
Weight	0.4 lbs (181 g)

8.0 SPARE PARTS AND ACCESSORIES

8.1 Included with Your Unit

PART NUMBER	ITEM
R211M11	Operating Manual and Instructions for Use*
RP46P05	Gas Sample Tubing

8.2 Optional Accessories

PART NUMBER	ITEM
R221P15	Soft Cover

Repair of this equipment must be performed by a qualified service technician experienced in repair of portable hand held medical equipment.

Equipment in need of repair shall be sent to:

Maxtec
Customer Service Department
2305 South 1070 West
Salt Lake City, UT 84119

(Include RMA number issued by Customer Service)

9.0 ELECTROMAGNETIC COMPATIBILITY

The information contained in this section (such as separation distances) is in general specifically written with regard to the UltraMax O2. The numbers provided will not guarantee faultless operation but should provide reasonable assurance of such. This information may not be applicable to other medical electrical equipment; older equipment may be particularly susceptible to interference.

Note: Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this document and the remainder of the instructions for use this device.

Portable and mobile RF communications equipment can affect medical electrical equipment.

Cables and accessories not specified within the instructions for use are not authorized. Using other cables and/or accessories may adversely impact safety, performance and electromagnetic compatibility (increased emission and decreased immunity).

Care should be taken if the equipment is used adjacent to or stacked with other equipment; if adjacent or stacked use is inevitable, the equipment should be observed to verify normal operation in the configuration in which it will be used.


ELECTROMAGNETIC EMISSIONS		
This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should assure that it is used in such an environment.		
EMISSIONS	COMPLIANCE ACCORDING TO	ELECTROMAGNETIC ENVIRONMENT
RF Emissions (CISPR 11)	Group 1	The UltraMax O2 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.
CISPR Emissions Classification	Class A	The UltraMax O2 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic Emissions (IEC 61000-3-2)	Class A	
Voltage Fluctuations	Complies	

ELECTROMAGNETIC IMMUNITY			
This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should assure that it is used in such an environment.			
IMMUNITY AGAINST	IEC 60601-1-2: (4TH EDITION) TEST LEVEL		ELECTROMAGNETIC ENVIRONMENT
	Professional Healthcare Facility Environment	Home Healthcare Environment	
Electrostatic discharge, ESD (IEC 61000-4-2)	Contact discharge: ±8 kV Air discharge: ±2 kV, ±4 kV, ±8 kV, ±15 kV		Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be kept at levels to reduce electrostatic charge to suitable levels.
Electrical fast transients / bursts (IEC 61000-4-5)	Power supply lines: ±2 kV Longer input / output lines: ±1 kV		
Surges on AC mains lines (IEC 61000-4-5)	Common mode: ±2 kV Diferential mode: ±1 kV		
3 A/m power frequency magnetic field 50/60 Hz (IEC 61000-4-8)	30 A/m 50 Hz or 60 Hz		Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips and short interruptions on AC mains input lines (IEC 61000-4-11)	Dip >95%, 0.5 periods Dip 60%, 5 periods Dip 30%, 25 periods Dip >95%, 5 seconds		Equipment which emits high levels of power line magnetic fields (in excess of 30A/m) should be kept at a distance to reduce the likelihood of interference. If user requires continued operation during power mains interruptions, ensure that batteries are installed and charged. Ensure that battery life exceeds longest anticipated power outages or provide an additional uninterruptible power source.

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.

This equipment is intended for use in the electromagnetic environment specified below. The customer or the user of this equipment should assure that it is used in such an environment.			
IMMUNITY TEST	IEC 60601-1-2: 2014 (4TH EDITION) TEST LEVEL		ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
	Professional Healthcare Facility Environment	Home Healthcare Environment	
Conducted RF coupled into lines (IEC 61000-4-6)	3V (0.15 - 80 MHz) 6V (ISM bands)	3V (0.15 - 80 MHz) 6V (ISM & Amateur bands)	Portable and mobile RF communications equipment (including cables) should be used no closer to any part of the recommended separation distance calculated from the equation applicable to the frequency of the transmitter as below. Recommended sparation distance: $d=1.2 \sqrt{P}$ $d=1.2 \sqrt{P}$ 80 MHz to 800 MHz $d=2.3 \sqrt{P}$ 800 MHz to 2.7 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 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: 
Radiated RF immunity (IEC 61000-4-3)	3 V/m 80 MHz - 2.7 GHz 80% @ 1 KHz AM Modulation	10 V/m 80 MHz - 2.7 GHz 80% @ 1 KHz AM Modulation	

Recommended separation distances between portable and mobile RF communications equipment and the equipment			
RATED MAXIMUM OUTPUT POWER OF TRANSMITTER W	Separation distance according to frequency of transmitters in meters		
	150 kHz to 80 MHz $d=1.2/\sqrt{P}$ \sqrt{P}	80 MHz to 800 MHz $d=1.2/\sqrt{P}$ \sqrt{P}	800MHz to 2.5 GHz $d=2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

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 equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

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