maxtec Handi Plus Medical Handheld Oxygen Analyzer Instruction Manual

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maxtec Handi Plus Medical Handheld Oxygen Analyze

Handi+ Medical Device

The Handi+ Medical Device is a Class II medical device that provides continuous oxygen monitoring. It is designed to deliver safe and effective oxygen therapy to patients in various healthcare settings. The device has been tested with various anesthesia gases, including nitrous oxide, Halothane, Isoflurane, Enflurane, Sevoflurane, and Desflurane, and found to have acceptably low
interference.

Classification

The Handi+ Medical Device is a Class II medical device that provides protection against electric shock and water intrusion up
to IPX4. The device operates continuously and does not contain automatic barometric pressure compensation. The device is not
suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. Only the threaded sensor face, flow diverter, and T adapter may be allowed to contact such a gas mixture.

Sterilization

The Handi+ Medical Device can be sterilized using standard sterilization methods, including autoclaving, ethylene oxide (EtO)
gas sterilization, and hydrogen peroxide gas plasma sterilization.
Refer to section 6.0 of the user manual for detailed sterilization instructions.

Product Disposal Instructions

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

Product Usage Instructions

1. Before using the Handi+ Medical Device, all individuals who will be using the product must become thoroughly familiar with the information contained in the user manual.
2. Strict adherence to the operating instructions is necessary for safe and effective product performance.
3. The device should not be used near any type of flame or flammable/explosive substances, vapors, or

atmosphere. It is also not for use in an MRI environment.

4. The Handi+ Medical Device should be used only for its intended purpose of delivering oxygen therapy to patients.
5. Improper use of the device can cause inaccurate oxygen readings, which can lead to improper treatment, hypoxia, or hyperoxia. Follow the procedures outlined in the user manual.
6. If the device is used in the presence of a flammable anesthetic mixture, only the threaded sensor face, flow diverter, and T adapter may be allowed to contact such a gas mixture.
7. If sterilization is necessary, refer to section 6.0 of the user manual for detailed sterilization instructions.
8. Dispose of the Handi+ Medical Device according to local guidelines and/or return it to Maxtec for proper disposal.

For further questions or concerns about the Handi+ Medical Device, contact Maxtec at (800) 748.5355 or email **sales@maxtec.com**.

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

PRODUCT CLASSIFICATION

- Classification ……..Class II medical device
- Protection against electric shock …… Internally powered equipment
- Protection against water …… IPX4
- Mode of Operation ……..Continuous
- Sterilization …… See section 6.0
- Flammable anesthetic mixture ……..Not suitable for use in presence of a flammable mixture

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.

WARRANTY

Maxtec, warrants the Handi+ to be free from defects of workmanship or materials for a period of two-(2) years from the date of shipment from Maxtec, under normal operating conditions and provided that the Handi+ is properly operated and maintained in accordance with Maxtec's operating instructions. Should Handi+ fail prematurely, the replacement Handi+ is warranted for the remainder of the original analyzer warranty period.

Based on Maxtec's product evalua-tion, 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/or agents as new equipment. Routine maintenance items are excluded from this warranty. Maxtec shall not be liable to the purchaser or other persons for incidental or consequential damages or equipment that has been subject to abuse, misuse, misapplication, 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.

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

- Before use, all individuals who will be using this product must become thoroughly familiar with the information contained in this Operation Manual. Strict adherence to the operating instructions is necessary for safe and effective product performance. This product will perform only as designed and only if installed and operated in accordance with the manufacturer's operating instructions.
- Although the sensor of this device has been tested with various anesthesia gases including nitrous oxide, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane and found to have acceptably low interference, the device in entirety (including electronics) is not suit-able for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. Only the threaded sensor face, flow diverter, and "T" adapter may be allowed to contact such a gas mixture.
- This device does not contain automatic barometric pressure compensation.
- DO NOT use near any type of flame or flammable/explosive substances, vapors or atmosphere.
- Not for use in an MRI environment.
- Improper use of this device can cause inaccurate oxygen readings which can lead to improper treatment, hypoxia or hyperoxia. Follow the procedures outlined in this user manual.

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

- The Maxtec MAX-250 oxygen sensor is a sealed device containing a weak acid electrolyte, lead (Pb), and lead acetate. Lead and lead acetate are hazardous waste constituents and should be disposed of properly, or returned to Maxtec for proper disposal or recovery.
- The Handi+ is not intended for steam, ethylene oxide or radiation sterilization.
- DO NOT autoclave or expose the sensor to high temperatures.
- DO NOT immerse the Handi+ oxygen analyzer in any cleaning solution.
- The flow diverter provided with the Handi+ is for use with flowing gases only.
- DO NOT use the diverter when performing static sampling (e.g., in incubators, oxygen tents, oxygen hoods).
- DO NOT attempt any repairs or procedures, which are not described in this Operation Manual. Maxtec cannot warrant this product from damage resulting from misuse, unau-thorized repair or improper maintenance of this product.
- The Federal (USA) law restricts this device to sale by or on the order of a physician.
- There are no internal user-serviceable parts.
- Never install the sensor in a location that will expose the sensor to patient's exhaled breath or secretions.

SYMBOL GUIDE

The following symbols and safety labels are found on the Handi+:

	Follow instructions for use		On/Off Button
	Warning		Calibration Button
ETL CLASSIFIED Intertek 9700630	Meets ETL standards		Do not throw away. Follow local guidelines for disposal
	Do Not		Manufacturer
	Contains acid		Caution

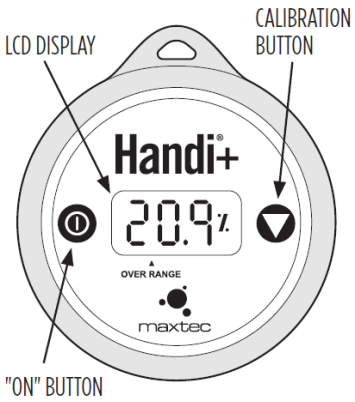
REF	Catalog Number	SN	Serial Number
LOT	Lot code/Batch code	IPX4	Ingress Protection Rating
Rx only	Federal law (USA) restricts this device to sale by or on order of a physician	EC REP	Authorized Representative in the European Community
	Date of Manufacture	MD	Medical Device
-15°C (5°F) 50°C (122°F)	Storage Temperature Range		

INTRODUCTION

Component Identification

LCD DISPLAY: A 3-digit display provides a direct readout of oxygen concentration in the range of 0 – 100%. The display is blank when the Handi+ enters its Sleep (power off) mode. The Handi+ will automatically enter the Sleep mode after approximately 1.3 minutes from the last time the ON button was pressed.

ON/OFF BUTTON: Use this button to turn the Handi+ on and off. When the Handi+ is in the Sleep (power off) mode, the LCD display is blank. The analyzer turns off after 1.3 minutes if no buttons are pressed.



CALIBRATION BUTTON: Press the calibration (CAL) button to adjust the calibration value to reflect the known oxygen concentration. To simplify operation, the Handi+ Analyzer automatically determines the calibration gas being used as room air (20.9%) or high grade (100%).

FLOW DIVERTER: The flow diverter is designed to fit industry standard 15 mm I.D. “T” adapters.

OVER RANGE INDICATOR: The appearance of a decimal point after the first digit means that the Handi+ is reading in excess of 99.9%.

Example: 0.0.0 = 100% 0.0.1 = 101% 0.0.2 = 102%
(If the display reads > 0.0.3 the Handi+ should be re-calibrated.)

Description
The Maxtec Handi+ oxygen analyzer is designed to monitor oxygen concentration in the patient-breathing environment. It is one of a full line of oxygen analyzers by Maxtec. The Handi+ oxygen analyzer utilizes the Maxtec MAX-250 oxygen sensor and is engineered for fast response, maxi-mum reliability and stable performance. The Handi+ is designed primarily for spot-checking of oxygen levels delivered by medical oxygen delivery equipment and respiratory care systems. Its lightweight, compact size, extended battery life, and “auto off” feature makes this oxygen analyzer ideal for portable oxygen analysis by qualified heath care professionals.

CALIBRATING THE HANDI+

Before You Begin
A protective film covering the threaded sensor face must be removed and the sensor allowed to “breath” for at least 30 minutes. Next, the Handi+ Oxygen Analyzer should be calibrated. Thereafter, Maxtec recommends calibration on a weekly basis. However, more frequent cali-bration will not adversely affect product performance.

Calibrating the Handi+ Oxygen Analyzer
Calibration of the instrument is necessary if the temperature of the gas stream changes by more than 3 degrees Celsius.
Changes in elevation result in calibration error of approximately 1% of reading per 250 feet. In general, calibration of the instrument should be performed when the geographic elevation at which the product is being used changes by more than 500 feet.

In addition, calibration is recommended if the user is unclear when the last calibration procedure was performed or if the measurement value displayed is in question. Calibrate the Handi+ to an oxygen source, which has a traceable certificate and/or USP certifi-cation, of either 20.9% oxygen, as found in room air, or 100% oxygen. It is recommended that the oxygen source be documented at a pressure and flow similar to your clinical application.

NOTE: Before beginning calibration the Handi+ must be in thermal equilibrium. You may also need to be aware of other factors, which affect device calibration values. For more information, refer to section 4.0 “Factors Influencing Calibration and Performance” of this manual.

NOTE: We recommend use of medical grade USP or >99% purity oxygen when calibrating the Handi+.

In Line Calibration (Configuration A)

1. Put the Handi+ in an upright position such that you can read the product label.
2. Connect a sample supply hose to a standard “T” adapter The Maxtec “T” is precision-tapered to insure a tight connection with O-rings of the MAX-250 oxygen sensor diverter.
3. Insert the Handi+ in the center position of the “T” adapter.
4. Attach an open-ended reservoir to the end of the “T” adapter. Then start the calibration flow of oxygen at 1-10 liters per minute.

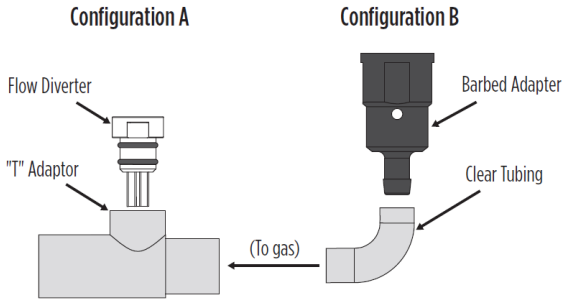
   NOTE: Six to 10 inches of corrugated tubing works well as a reservoir.

   NOTE: A calibration oxygen flow to the Handi+ of 2 liters per minute is recommended to mini-mize the possibility of obtaining a “false” calibration value.
5. Allow the oxygen to saturate the sensor. Although a stable value is usually observed within 30 seconds, allow at least 2 minutes to ensure that the sensor is completely saturated with the calibration gas.
6. If the Handi+ is not already turned on, do so now by pressing the analyzer ON button  .

7. Press the “CAL” button on the Handi+. The calibration gas value on the analyzer display should read 20.9 or 100 depending on the gas stream used.

Direct Flow Calibration (Configuration B)

1. Attach the Barbed Adapter to the Handi+.
2. Connect the clear sampling tube to the Barbed Adapter.
3. Attach the other end of the clear sampling tube to a source of oxygen with a known oxygen concentration value and initiate flow of the calibration gas to the unit at a rate of 1-10 liters per minute (2 liters per minute is recommended).
4. Allow the oxygen to saturate the sensor. Although a stable value is usually observed within 30 seconds, allow at least 2 minutes to ensure complete saturation of the sensor with the calibration gas.
5. If the Handi+ is not already turned on, do so now by pressing the analyzer “ON” button .
6. Press the “CAL” button on the Handi+. The calibration gas value on the analyzer display should read 20.9 or 100 depending on the gas stream used.



OPERATING THE HANDI+

To Check the Oxygen Concentration of a Sample Gas:

1. Maintain the Handi+ in an upright position such that you can read the product label.
2. Place the Handi+ in the sample gas stream.
   IMPORTANT: When using a standard “T” adapter, make sure that the sensor is mounted in the adapter with the flow diverter pointing down. Make sure that there is a tight fit between the flow diverter and the “T” adapter.
3. Start the flow of the sample gas to the sensor.
4. Allow the oxygen sensor to remain in the flow of the sample gas until stable.
5. If the Handi+ is not already turned on, do so now by pressing the analyzer ON button .
6. Read the value displayed on the LCD.
   NOTE: If the Handi+ is used to measure the oxygen concentration with equipment using a heated or humidified gas stream, it is recommended that the Handi+ be placed upstream of the heater and/or humidifier. For more information, refer to “Factors Influencing Calibration and Performance” below.
   For hospital and home care a new calibration is required when:
   - The measured O2 percentage in 100% O2 is below 97.0% O2
   - The measured O2 percentage in 100% O2 is above 103.0% O2.

     For ID testing (or optimum accuracy), a new calibration is required when:
7. The measured O2 percentage in 100% O2 is below 99.0% O2.

8. The measured O2 percentage in 100% O2 is above 101.0% O2.

FACTORS INFLUENCING ACCURATE READINGS

Elevation Changes

- Changes in elevation result in a reading error of approximately 1% of reading per 250 feet.
- A change in altitude greater than 500 ft will require sensor recalibration.
- This device does not automatically compensate for changes in barometric pressure or altitude. If the device is moved to a location of a different altitude, it must be recalibrated before use (see section 2.2).

Temperature Effects
The Handi+ will hold calibration and read correctly within ±3% when in thermal equilibrium within the operating temperature range. The device must be thermally stable when calibrated and allowed to thermally stabilize after experiencing temperature changes before readings are accurate. For these reasons, the following is recommended:

- When used in a breathing circuit, place the sensor upstream of the heater.
- For best results, perform the calibration procedure at a temperature close to the temperature where analysis will occur.
- Allow adequate time for the sensor to equilibrate to a new ambient temperature.

Pressure Effect
Readings from the Handi+ are proportional to the partial pressure of oxygen. The partial pres-sure is equal to the concentration times the absolute pressure. Thus the readings are pro-portional to the concentration if the pressure is held constant. Flow rate of sample gas can affect pressure at the sensor in that back pressure at the sensing point may change. For these reasons, the following is recommended:

- Calibrate the Handi+ at the same pressure as the sample gas.
- If sample gases flow through tubing, use the same apparatus and flow rates when calibrating as when measuring.
- The Handi+ oxygen sensor has been validated at pressures up to 2 atmospheres absolute. Calibration or operation above this pressure is beyond the intended use.

Humidity Effect
Humidity has no effect on the performance of the Handi+ other than diluting the gas, as long as there is no condensation. Depending on the humidity, the gas may be diluted by as much as 4%, which proportionally reduces the oxygen concentration. The device responds to the actual oxygen concentration rather than the dry concentration. Environments where condensation may occur are to be avoided since condensate may obstruct passage of gas to the sensing surface, resulting in erroneous readings and slower response time.

For this reason, the following is recommended:

- Avoid usage in environments greater than 95% relative humidity.
- When used in a breathing circuit, place the sensor upstream of the humidifier.

CALIBRATION ERRORS AND ERROR CODES

The Handi+ analyzers have a self test feature built into the software to detect faulty calibrations, oxygen sensor failures, and low operating voltage. These are listed below, and include possible actions to take, if an error code occurs.

- E03: No valid calibration data available

  Make sure unit has reached thermal equilibrium. Press and hold the Calibration Button ▼ for three seconds to manually force a new calibration.
- E04: Battery below minimum operating voltage

  Unit is at end of life, see “Product Disposal Instructions” for proper disposal.

CAL Err St: O2 Sensor reading not stable
Wait for displayed oxygen reading to stabilize when calibrating the device at 100% oxygen. Wait for unit to reach thermal equilibrium (Please note that this can take up to one half hour, if the device is stored in temperatures outside the specified operating temperature range).

CAL Err lo: Sensor voltage too low
Press and hold the Calibration Button for three seconds to manually force a new calibra-tion. If unit repeats this error more than three times, contact Maxtex Customer Service for possible sensor replacement.

CAL Err hi: Sensor voltage too high
Press and hold the Calibration Button for three seconds to manually force a new calibration. If unit repeats this error more than three times, contact Maxtec Customer Service for possible sensor replacement.

CAL Err Bat: Battery voltage too low to recalibrate
Unit is at end of life, see “Product Disposal Instructions” for proper disposal.

CLEANING AND MAINTENANCE

When cleaning or disinfecting the Handi+, take appropriate care to prevent any solution from entering the analyzer.

- The Handi+ surface may be cleaned using a cloth moistened with 65% isopropyl alcohol/water solution or germicidal wipe.
- The Handi+ may be disinfected using standard topical disinfectants.
- The Handi+ is not intended for steam, ethylene oxide or radiation sterilization.
- Store the Handi+ in a temperature similar to its ambient environment of daily use.

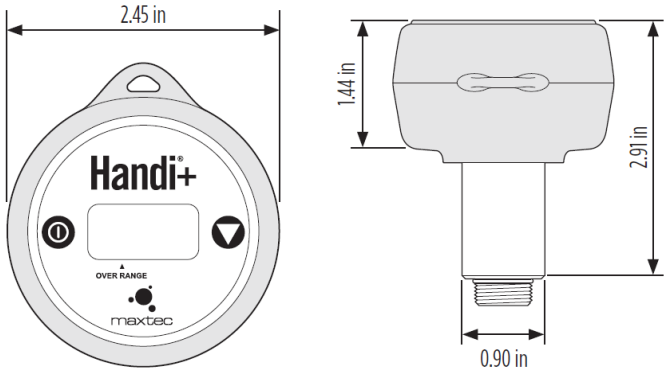
HANDI+ SPECIFICATIONS

Analyzer Specifications

- Measurement Range: ……0.0 – 99.9% oxygen (gas)
- Resolution/Display: …… 0.1%

  The three digit LCD indicates values between 0.0 – 99.9% oxygen Over range indicated by one decimal point on display located after the first digit
- Accuracy and Linearity: ……..1% of full scale at constant temperature, R.H. and pressure when calibrated at full scale

- Total Accuracy: ……±3% actual oxygen level over full operating temp range
- Response Time: ……< 15 seconds for 90% step change. (at 25˚C)
- Warm-up Time: ……None required
- Operating Temperature: ……15˚C – 40˚C (59˚F – 104˚F)
- Storage Temperature: ……..-15˚C – 50˚C (5˚F – 122˚F)
- Atmospheric Pressure: …….. 800-1013 mBars
- Humidity: ……..0-95%(non-condensing)
- Environmental: ……General purpose housing equivalent to NEMA 1 The Handi+ is not waterproof
- Warranty: ……Two (2) years in normal operating conditions
- Power Requirements: ……..Powered by one internal, non-replaceable Lithium battery, CR2450.
  Power on push button automatically shuts off after 80 seconds time-out. Electronics rated general purpose; not for use in
  hazardous areas or for use with flammable gases.
- Sensor Type: ……Maxtec MAX-250 series galvanic fuel cell
- Weight: …….. Approx. 60 grams



Effect of Interferent Gases and Vapors

GAS	VOLUME % DRY	INTERFERENCE IN O2
Nitrous Oxide	75%	< 2%
Halothane	5%	< 2%
Isoflurance	5%	< 2%
Enflurane	5%	< 2%
Sevoflurane	6%	< 2%
Desflurane	15%	< 2%
Carbon Dioxide	10%	< 2%
Helium	70%	< 2%

HANDI+ SPARE PARTS AND ACCESSORIES

Standard Replacement Parts and Accessories

PART NUMBER	ITEM
R218M12	Operation Manual, Handi+
RP16P02	“T” Adapter
R110P10-001	Flow Diverter Fitting
R207P17	Barbed Adapter
R100P92-002	Clear Tubing
RP76P06	Lanyard
R218P09	Handi+ Cover

FREQUENTLY ASKED QUESTIONS

After I calibrate to 20.9%, the display changes as much as ± 1%.

- This is within the normal Handi+ operating tolerance of ± 1% when temperature and pressure are constant.

I have calibrated to 99.9% but when I check my oxy-gen delivery equipment, the Handi+ reads “.0.4” or greater (Over Range Indicator).

- It is recommended that you conduct the calibration procedure again to get another reading. The most likely cause is that the Handi+ has received a “false” calibration value.
- Make sure that the calibration gas is connected to the Handi+ at 2 liters per minute for a minimum of 2 minutes prior to proceeding with calibration.
- This 2-minute equilibration time is necessary to insure that the sensor is completely saturated with the calibration gas.

I have found the reading to drift greater than ± 3% from a know source value. What is the possible cause?

- The sensor may be at or near its useful life.
- Replace your Handi+.
- Sensor life is dependent on the oxygen concentration exposure.
  For example, a sensor which is used to check flow meters once a week for 8 hours will outlast one which is used to analyze oxygen blender performance 24 hours per day, 5 days a week.

ELECTROMAGNETIC COMPATABILITY

The information contained in this section (such as separation distances) is in general specifi-cally written with regard to the Handi+. 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 sus-ceptible 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 electromag-netic 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 equipm ent should assure that it is used in such an environment.		
EMISSIONS	**COMPLIANCE A CCORDING TO**	**ELECTROMAGNETIC ENVIRONMENT**
RF Emissions (CISPR 11)	Group 1	The Handi+ uses RF energy only for its internal function. There fore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

CISPR Emissions Classifi cation	Class A	The Handi+ is suitable for use in all establish- ments other tha n domestic and those directly connected to the public low-volta ge power supply network that supplies buildings used for dome stic purposes. **NOTE:** The EMISSIONS characteristics of this equip- ment m ake 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 n ot offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, su ch 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 equipm ent should assure that it is used in such an environment.		
	IEC 60601-1-2: (4TH EDITION) TEST LEVEL	**ELECTROMAGNETIC**

IMMUNITY AGAINST	Professional Healthcare Facility Environment	Home Healthcare Environment	ENVIRONMENT
Electrostatic discharge, ESD (IEC 61000-4-2)	Contact discharge: ±8 kV Air discharge: ±2 kV, ±4 kV, ±8 kV, ±15 kV		
Electrical fast transients / bursts (IEC 61000-4-4)	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		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. Mains power quality should be that of a typical commercial or hospital environment. 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.
3 A/m power frequency magnetic field 50/60 Hz (IEC 61000-4-8)	30 A/m 50 Hz or 60 Hz		

Voltage dips and short interr uptions on AC mains input li nes (IEC 61000-4-11)	Dip>95%, 0.5 periods Dip 60%, 5 periods Dip 30%, 25 periods Dip >95%, 5 seconds	

Recommended separation distances between portable and mobile RF communications equi pment and the equipment				
RATED MAXIMU M	Separation distance according to f requency			
OUTPUT POWER OF	of transmitters in meters			
TRANSM ITTER W	150 kHz t o 80 MHz d=1.2/V1] ÖP	80 MHz t o 800 M Hz d=1.2 /V1] ÖP	800MHz t o 2.5 GHz d=2.3 ÖP	
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 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 propogation 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 equipment than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter as below.
Radiated RF immunity (IEC 61000-4-3)	3 V/m 80 MHz – 2.7 GHz	10 V/m 80 MHz – 2.7 GHz	
	80% @ 1 KHz AM Modulation	80% @ 1 KHz AM Modulation	Recommended separation distance: d=1.2 ÖP d=1.2 ÖP 80 MHz to 800 MHz d=2.3 ÖP 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:

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) tele-phones 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 mea-sured 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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Documents / Resources

	maxtec Handi Plus Medical Handheld Oxygen Analyzer [pdf] Instruction Manual Handi Plus Medical Handheld Oxygen Analyzer, Handi Plus Medical, Handheld Oxygen Analyzer, Oxygen Analyzer, Analyzer

References

- Maxtec | The leader in oxygen analysis and delivery products