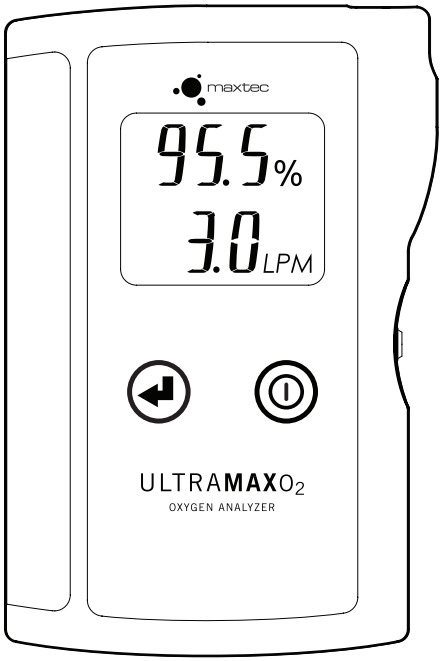

UltraMaxO2™

OXYGEN ANALYZER

OPERATING MANUAL &
INSTRUCTIONS FOR USE

R221P11

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NOTE: The UltraMaxO_2 is for use only by trained personnel. Before use, all individuals using the UltraMaxO_2 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.

CLASSIFICATIONS

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 batteries and circuit board are not suitable for regular trash disposal. Follow local guidelines for proper disposal

INDICATIONS FOR USE

The UltraMaxO_2 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 UltraMaxO_2 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 UltraMaxO_2 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 UltraMaxO_2 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 UltraMaxO_2 can cause inaccurate oxygen readings leading to improper treatment and/or patient harm. Follow the procedures outlined in this user manual.
- The UltraMaxO_2 is for checking oxygen concentrators only.

⊘ DO NOT use the UltraMaxO_2 for continuous oxygen monitoring.

⊘ DO NOT use the UltraMaxO_2 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 UltraMaxO_2 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 UltraMaxO_2 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 UltraMaxO_2. Repair or alteration of the UltraMaxO_2 by anyone other than an authorized Maxtec service representative could cause the product to fail to perform as designed.
- Use of the UltraMaxO_2 near devices that generate electrical fields may cause erratic readings.
- If the UltraMaxO_2 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 UltraMaxO_2 to high temperatures (>60°C).

⊘ DO NOT use ethylene oxide sterilization.

⊘ DO NOT expose the UltraMaxO_2 to irradiation, vacuum, steam, or harsh chemicals.

⊘ DO NOT expose the UltraMaxO_2 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 UltraMaxO_2 from potential battery leakage.

» Avoid dropping the UltraMaxO_2 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 UltraMaxO_2.

⃠ DO NOT use the UltraMaxO_2 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.

TABLE OF CONTENTS

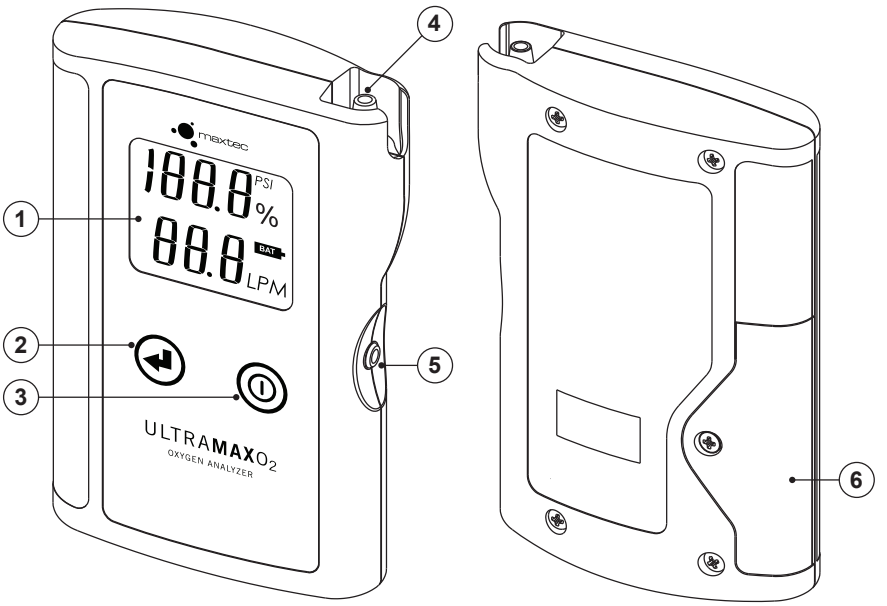
1.0 SYSTEM OVERVIEW

1.1 Description & Principle of Operation

The UltraMaxO_2 is an oxygen analyzer designed to check the oxygen concentration, flow and outlet pressure of oxygen concentrators. The UltraMaxO_2 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 Component Identification



1. **LCD Display**
2. **Mode Button**
3. **ON/OFF Button**
4. **Gas Sample Inlet**
5. **Gas Sample Outlet**
6. **Battery Door**

1.3 Symbol Guide

The following symbols and safety labels are found on the UltraMaxO_2:


Warning

BAT Low battery


Do not throw away. Follow local guidelines for disposal


Evaluated by ETL (Intertek Testing Laboratories)


Manufacturer

IPX1 Ingress protection

℞ only Federal law (USA) restricts this device to sale by or on order of a physician

Latex free


On/off button


Mode button


Follow instructions for use

EC REP Authorized representative in the European Community

SN Serial number

REF Catalog number

LPM Liter per minute flow

PSI Pounds per square inch

kPa Kilopascals

% Percent


Gas sample inlet


Gas sample outlet


Direct current


Do Not

1.4 Component Description

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.

ON/OFF Button - Turns the device on or off.

Mode Button - Switches between measuring the concentration of gas produced by an oxygen concentrator and pure oxygen (for calibration verification).

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).

KPA - Indicates the pressure measurement is in units of kilopascals.

PSI - Indicates the pressure measurement is in units of pounds per square inch.

"%" symbol - Illuminated next to the concentration measurement.

Gas Sample Inlet - Used to receive the gas sample.

Gas Sample Outlet - Used as an outlet for the gas sample and as a trigger for pressure measurement when occluded.

Gas Sample Tubing - Used to connect to gas sample sources.

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:

1. Connect the gas sample tubing to the gas sample inlet of the UltraMaxO_2.
2. Attach the other end of the gas sample tubing to the oxygen concentrator.
3. Initiate the flow of gas to the UltraMaxO_2 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.
4. Turn on the UltraMaxO_2.
5. Allow the oxygen reading to stabilize for approximately 10 seconds before reading the oxygen concentration and flow.
6. To check pressure, cover the gas sample outlet with thumb or finger while gas is flowing.
7. 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 UltraMaxO_2 can measure pressure in PSI or kPa. The UltraMaxO_2 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 UltraMaxO_2 is functioning properly. To perform the calibration verification:

1. Turn on the UltraMaxO_2.
2. Connect a source of pure oxygen (≥99.95%) to the gas sample inlet.
3. Flow 2-5 LPM of gas into the UltraMaxO_2. Ensure that the gas flowing to the UltraMaxO_2 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 UltraMaxO_2 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 UltraMaxO_2 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 UltraMaxO_2. 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 UltraMaxO_2.

3.3 Effects of Other Gases

The UltraMaxO_2 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 UltraMaxO_2 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 UltraMaxO_2 requires that the ratio of oxygen to argon remain constant in order to guarantee an accuracy of +/-1.5% oxygen.

⃠ DO NOT use the UltraMaxO_2 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 UltraMaxO_2 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 (≥102.0% calculated by algorithm). Recommended Action: Verify that the UltraMaxO_2 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 (≤-2.0% calculated by algorithm). Recommended Action: Verify that the UltraMaxO_2 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 UltraMaxO_2 to the manufacturer for factory repair.

E04: Signal reading not stable. Recommended Action: Return the UltraMaxO_2 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 (≥40° C). Recommended action: The UltraMaxO_2 is too hot, cool the device closer to room temperature before use.

E07: Outside of operating temperature Low (≤15° C). Recommended action: The UltraMaxO_2 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 UltraMaxO_2 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 UltraMaxO_2 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 UltraMaxO_2 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 UltraMaxO_2.

DO NOT soak or immerse the UltraMaxO_2 in fluid.

DO NOT autoclave or expose the UltraMaxO_2 to ethylene oxide sterilization.

6.1 Cleaning

Wipe down the exterior surfaces of the UltraMaxO_2 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 UltraMaxO_2 from potential battery leakage.

» Store the UltraMaxO_2 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	**PSI**	**kPa**
Pressure Measurement Range:	0.5 - 50	3.4 - 344
Pressure Measurement Accuracy:	±0.5%	±0.5%
Pressure Measurement Resolution:	0.1	0.1 up to 199, 1 from 200 to 344
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)	

*See section 3.4 (pg. 4) of this operating manual for information on the effects of low flow.

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

* An electronic version of this Operating Manual and Instructions for Use are available on-line at www.maxtec.com.

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)