

• Ultra MaxO2™

OPERATING MANUAL & INSTRUCTIONS FOR USE

R221P11





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NOTE: The Ultra $MaxO_2$ 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:

Classification:	Class II electrical device
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 pre-	esence of flammable anaesthetic mixtures
Power specification:	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 UltraMaxO₂ is an oxygen analyzer for checking the oxygen concentration, flow and outlet pressure of oxygen concentrators.

WARRANTY:

Under normal operating conditions, Maxtec warrants the UltraMaxO₂ 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 UltraMaxO₂ 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 UltraMaxO₂ can cause inaccurate oxygen readings leading to improper treatment and/or patient harm. Follow the procedures outlined in this user manual.
- The UltraMaxO₂ is for checking oxygen concentrators only.
- DO NOT use the UltraMaxO₂ for continuous oxygen monitoring.
- DO NOT use the UltraMaxO₂ 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 UltraMaxO₂ in flammable or explosive environments may result in fire or explosion.
- Not suitable for use in the presence of flammable anesthetic mixtures.
- 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 UltraMaxO₂. Repair or alteration of the UltraMaxO₂ by anyone
 other than an authorized Maxtec service representative could cause the product to
 fail to perform as designed.
- Use of the UltraMaxO₂ near devices that generate electrical fields may cause erratic readings.
- If the UltraMaxO₂ 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 UltraMaxO₂ to high temperatures (>60°C).
- DO NOT use ethylene oxide sterilization. performance in flow and pressure readings.

- DO NOT expose the UltraMaxO₂ to irradiation, vacuum, steam, or harsh chemicals.
- DO NOT expose the UltraMaxO₂ to pressure greater than 50 psi. Exposure to
 pressure above 50 psi could cause leaks in the device which may adversely affect

: 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 UltraMaxO₂ from potential battery leakage.
- Avoid dropping the UltraMaxO₂ 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 UltraMaxO₂.

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∴ 1.0 SYSTEM OVERVIEW

1.1 Description & Priciple of Operation

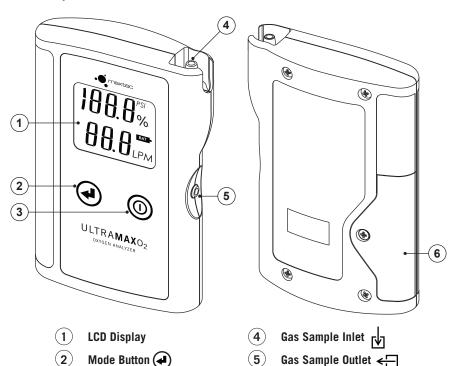
The $UltraMaxO_2$ is an oxygen analyzer designed to check the oxygen concentration, flow and outlet pressure of oxygen concentrators. The $UltraMaxO_2$ provides unparalleled performance and reliability from its advanced design that includes the following features and operational benefits:

- 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.

ON/OFF Button (1)

- Long battery life with 2 AA batteries.
- Auto-off after 4 minutes.
- Low battery indication.
- Self-diagnostics.
- Easy to clean.

1.2 Component Identification



Battery Door

1.3 Symbol Guide

The following symbols and safety labels are found on the UltraMaxO₂:

/i/

Attention, consult accompanying documents



On/off button



Authorized representative in the European Community



Mode button



Do not throw away. Follow local guidelines for disposal



Low battery



Evaluated by ETL (Intertek Testing Laboratories)

LPM

Liter per minute flow



Manufacturer

PSI

Pounds per square inch

IPX1

Ingress protection

kPa

Kilopascals

 $\mathbf{k}_{\!\!\mathbf{X}}$ only Restricted to sale by or on order of a medical professional

%

Percent



Latex free



Gas sample inlet



Serial number



Gas sample outlet



Catalog number



Direct current



Consult accompanying documents

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 UltraMaxO₂.
- 2. Attach the other end of the gas sample tubing to the oxygen concentrator.
- 3. Initiate the flow of gas to the UltraMaxO₂ 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 UltraMaxO₂
- 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.

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:

- 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 UltraMaxO₂.
- 2. Connect a source of pure oxygen (≥99.95%) to the gas sample inlet.
- 3. Flow 2-5 LPM of gas into the UltraMaxO₂. Ensure that the gas flowing to the UltraMaxO₃ 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 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 UltraMaxO₂ 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 UltraMaxO₂.

3.3 Effects of Other Gases

The UltraMaxO₂ 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 UltraMaxO2 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 UltraMaxO₂ 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 UltraMaxO2 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 UltraMaxO₂ 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 Customer Service.

- E02: Oxygen measurement out of range Low (≤-2.0% calculated by algorithm).
 Recommended Action: Verify that the UltraMaxO₂ 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 Customer Service.
- E03: Device memory corrupt or missing.
 Recommended Action: Return the UltraMaxO₂ to the manufacturer for factory repair.
- E04: Signal reading not stable.
 Recommended Action: Return the UltraMaxO₂ 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 Customer Service.
- E06: Outside of operating temperature Hi (≥40° C).
 Recommended action: The UltraMaxO₂ is too hot, cool the device closer to room temperature before use.
- E07: Outside of operating temperature Low (≤15° C).
 Recommended action: The UltraMaxO₂ 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 UltraMaxO₂ to the manufacturer for factory repair.

∴ 5.0 CHANGING THE BATTERIES

Batteries should be changed when the battery icon illuminates. The battery icon will remain lit until the batteries are changed. If the battery power level is too low the UltraMaxO₂ will not power on until the batteries are changed.

5.1 Battery Replacement Procedure

- Using a #1 Phillips screwdriver loosen the battery door screw and remove the battery door.
- 2. Remove the batteries.
- Insert new batteries ensuring correct placement. DO NOT use rechargeable batteries.
- 4. Replace the battery door and tighten the battery door screw.
- 5. If the UltraMaxO₂ 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 UltraMaxO₂.
- DO NOT soak or immerse the UltraMaxO₂ in fluid.
- DO NOT autoclave or expose the UltraMaxO₂ to ethylene oxide sterilization.

6.1 Cleaning

 Wipe down the exterior surfaces of the UltraMaxO₂ 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 UltraMaxO₂ from potential battery leakage.
- Store the UltraMaxO₂ between -15°C and 60°C (5°F 140°F)

∴ 7.0 SPECIFICATIONS

OXYGEN				
Oxygen Measurement Range: (from a concentrator)	20.9 - 96%	20.9 - 96%		
Oxygen Measurement Accuracy:		±1.5 % of full scale at constant temperature and optimal flow*		
Oxygen Measurement Resolution:	0.1% Oxygen	0.1% Oxygen		
FLOW				
Flow Measurement Range:	0 - 10 LPM	0 - 10 LPM		
Flow Measurement Accuracy:	±0.2 LPM	±0.2 LPM		
Flow Measurement Resolution:	0.1 LPM	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	≤17 seconds		
Warm-up Time:	< 1 second	< 1 second		
Operating Temperature:	15°C - 40°C (59	15°C - 40°C (59°F-104°F)		
Storage Temperature:	-15°C - 60°C (5	-15°C - 60°C (5°F-140°F)		
Pressure:	800 - 1000 mE	800 - 1000 mBars		
Humidity:	0 - 95% (non-	0 - 95% (non-condensing)		
Power Requirements:	2 AA Alkaline	2 AA Alkaline batteries (2 x 1.5 Volts)		
Battery Life:	≥ 1,100 hours	≥ 1,100 hours (16,500 read cycles)		
Low Battery Indication:	"Low Battery" i	"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*

RP46P11-003 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.maxtecinc.com.