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maxtec MaxO2 Plus AE Oxygen Analyzer

This manual describes the function, operation and maintenance of the Maxtec Model MaxO2+ A and AE oxygen analyzer. The MaxO2+ family of Oxygen Analyzers utilizes the Maxtec Max-250 oxygen sensor and is engineered for fast response, maximum reliability and stable performance. The MaxO2+ is designed as a tool for use by qualified personnel to spot-check or measure oxygen concentration of delivered air/oxygen mixtures. The MaxO2+ A and AE Analyzers are not intended for use in continuous monitoring of oxygen delivery to a patient.

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.

CLASSIFICATION

- Protection against electric shock …….Internally Powered Equipment

- Protection against water ……. IP33
- Mode of operation …….. Continuous
- Sterilization ……. See section 7
- Needs Applied Parts ……. Type BF (entire device)
- Flammable anesthetic mixture ……. Not suitable for use in presence of a flammable anesthetic mixture

There are no specific diseases or conditions this device directly helps to screen, monitor, treat, diagnose, or prevent. For purposes of emergency medical services (EMS) this device is transportable in a road ambulance and is considered hand-held. It may also be pole-mounted using the optional dovetail adapter.

WARRANTY

The MaxO2+ Analyzer is designed for medical oxygen delivery equipment and systems. Under normal operating conditions, Maxtec warrants the MaxO2+ Analyzer to be free from defects of workmanship or materials for a period of 2-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.

Maxtec warrants Max-250 oxygen sensor in the MaxO2+ Analyzer to be free from defects in material and workmanship for a period of 2-years from Maxtec's date of shipment in a MaxO2+ unit. Should a sensor fail prematurely, the replacement sensor is

warranted for the remainder of the original sensor warranty period. 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, 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.

WARNINGS

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

- Never install the sensor in a location that will expose the sensor to patient's exhaled breath or secretions, unless you intend to dispose of the sensor, flow diverter and tee adapter.
- 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.
- NOT FOR USE in an MRI environment.
- Device specified for dry gas only.
- Never allow an excess length of tubing, lanyard or sensor cable near the patient's head or neck, which may result in strangulation.
- Before use, all individuals who will be using the MaxO2+ must become thoroughly familiar with the information contained in this Operation Manual. Strict adherence to the operating instructions is necessary for safe, effective product performance.
- This product will perform only as designed if installed and operated in accordance with the manufacturer's operating instructions.
- Use only genuine Maxtec accessories and replacement parts. Failure to do so may seriously impair the analyzer's performance. Repair or alteration of the MaxO2+ beyond the scope of the maintenance instructions or by anyone other than an authorized Matec service person could cause the product to fail to perform as designed. No modification of this equipment allowed.
- Calibrate the MaxO2+ weekly when in operation, or if environmental conditions change significantly. (i.e., Elevation, Temperature, Pressure, Humidity — refer to

Section 3 of this manual).

- Use of the MaxO2+ near devices that generate electrical fields may cause erratic readings.
- If the MaxO2+ is ever exposed to liquids (from spills or immersion) or to any other physical abuse, turn the instrument OFF and then ON. This will allow the unit to go through its self-test to assure everything is operating correctly.
- Never autoclave, immerse or expose the MaxO2+ (including sensor) to high temperatures (>70°C). Never expose the device to pressure, irradiation vacuum, steam, or chemicals.
- This device does not contain automatic barometric pressure compensation.
- 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 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.
- NOT FOR USE with inhalation agents. Operating the device in flammable or explosive atmospheres may result in fire or explosion.
- This product is not intended as a life-sustaining or life-supporting device.
- Medical oxygen should meet the requirements of USP.
- The MaxO2+ and sensor are non-sterile devices.
- In the event of exposure to an ELECTROMAGNETIC DISTURBANCE the analyzer may display an E06 or E02 error message. If this occurs, turn the instrument OFF, remove the batteries and wait 30 seconds. Then, re-load the batteries and allow the unit to go through its self-test diagnostics to make sure everything is functioning correctly.
- Gas leaks that cause room air to mix with the gas sample may cause inaccurate oxygen readings. Ensure the O-rings on the sensor and flow diverter are in place and intact prior to use.
- Use of the oxygen sensor beyond the expected service life may result in degraded performance or reduced accuracy of the oxygen sensor. Refer to section 6 for replacement of the oxygen sensor.

CAUTIONS

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

- Federal Law (USA) restricts this device to sale by or on the order of a physician.
- Replace the batteries with recognized high-quality AA Alkaline or Lithium batteries. DO NOT use RECHARGEABLE BATTERIES.
- If the unit is going to be stored (not in use for 1 month), we recommend that you remove the batteries to protect the unit from potential battery leakage.
- The Maxtec Max-250 oxygen sensor is a sealed device containing a mild 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.
- DO NOT use ethylene oxide sterilization
- DO NOT immerse the sensor in any cleaning solution, autoclave or expose the sensor to high temperatures.
- Dropping sensor can adversely affect its performance.
- The device will assume a percent oxygen concentration when calibrating. Be sure to apply 100%oxygen, or ambient air concentration to the device during calibration or the device will not calibrate correctly.

NOTE: Product is not made with natural rubber latex

NOTE: SERIOUS incident(s) that occur in relation to the device should be reported to Maxtec and the competent authority of the Member State in which the user and/or patient is established. Serious Incident(s) is defined as directly or indirectly led, might have led, or might lead to the death of a patient, user, or other person; the temporary or permanent serious deterioration of the patient’s user’s or other person’s state of health; of serious public health threat.

SYMBOL GUIDE

The following symbols and safety labels are found on the MaxO2+:

	Follow instructions for use		On/Off Button
	Warning		Calibration Button
	Meets ETL standards		Do not throw away. Follow local guidelines for disposal
	DO NOT	%	Percent
	Low Battery		Serial Number
	Calibration Required		Lot code/Batch code
	Caution	IP33	Ingress Protection Rating
	Federal law (USA) restricts this device to sale by or on order of physician		Authorized Representative in the European Community
	Manufacturer		Catalog Number
	Date of Manufacture		Medical Device
	Atmospheric Pressure Range		Responsible Person in the UK
	Unique Device Identifier		Applied Parts - Type BF
	MR Unsafe		Temperature Range
	Single Use		Humidity Range

OVERVIEW

Indications for Use

MaxO2+ Oxygen analyzers are intended as tools for the use by trained personnel, under the direction of a physician, to spot-check or measure oxygen concentration in air/oxygen mixtures being delivered to patients ranging from newborns to adults. It can be used in pre-hospital, hospital, and sub-acute settings. The MaxO2+ oxygen analyzers are not a life supporting device.

Essential Device Performance

Essential performance are the operating characteristics of the device without which would result in an unacceptable risk. The following items are considered essential performance:

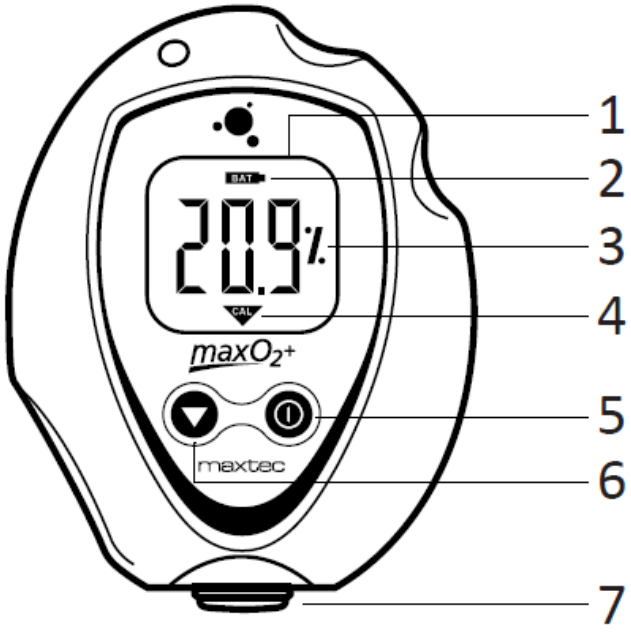
- Oxygen measurement accuracy

Base Unit Description

The MaxO2+ analyzer provides unparalleled performance and reliability due to an advanced design that includes the following features and operational benefits.

- Extra-life oxygen sensor of approximately 1,500,000 O2 percent hours (2-year warranty)
- Durable, compact design that permits comfortable, hand-held operation and easy to clean Operation using only two AA Alkaline batteries (2 x 1.5 Volts) for approximately 5000 hours of performance with continuous use. For extra extended long life, two AA Lithium batteries may be used.
- Oxygen-specific, galvanic sensor that achieves 90% of final value in approximately 15 seconds at room temperature.
- Large, easy-to-read, 3 1/2-digit LCD display for readings in the 0-100% range.
- Simple operation and easy one-key calibration.
- Self-diagnostic check of analog and microprocessor circuitry.
- Low battery indication.
- Calibration reminder timer that alerts the operator, using a calibration icon on the LCD display, to perform a unit calibration.

Component Identification



1. 3-DIGIT LCD DISPLAY — The 3-digit liquid crystal display (LCD) provides direct readout of oxygen concentrations in the range of 0 – 105.0% (100.1% to 105.0% used for calibration determination purposes). The digits also display error codes and calibration codes as necessary.
2. LOW BATTERY INDICATOR — The low battery indicator is located at the top of the display and is only activated when the voltage on the batteries is below a normal operating level.
3. "%" SYMBOL — The "%" sign is located to the right of the concentration number and is present during normal operation.
4. CALIBRATION SYMBOL — CAL The calibration symbol is located at the bottom of the display and is timed to activate when a calibration is necessary.
5. ON/OFF KEY — This key is used to turn the device on or off.
6. CALIBRATION KEY — This key is used to calibrate the device. Holding the key for more than three seconds will force the device to enter a calibration mode.
7. SAMPLE INLET CONNECTION — This is the port at which the device is connected to determine oxygen concentration.

Max-250 Oxygen Sensor

The Max-250+ oxygen sensor offers stability and extra life. The Max-250+ is a galvanic, partial pressure sensor that is specific to oxygen. It consists of two electrodes (a

cathode and an anode), a teflon membrane and an electrolyte. Oxygen diffuses through the teflon membrane and immediately reacts at a gold cathode. Concurrently, oxidation occurs electrochemically at the lead anode, generating an electrical current and providing a voltage output. Electrodes are immersed in a unique gelled weak acid electrolyte which is responsible for the sensors long life and motion insensitive characteristic. Since the sensor is specific to oxygen, the current generated is proportional to the amount of oxygen present in the sample gas. When no oxygen is present, there is no electrochemical reaction and therefore, negligible current is produced. In this sense, the sensor is self-zeroing.

NOTE: The Max-250 oxygen sensor indirectly contacts the patient through the breathing gas pathway.

OPERATING INSTRUCTIONS

Getting Started

Protect Tape

Prior to turning on the unit, a protective film covering the threaded sensor face must be removed. After removing the film, wait approximately 20 minutes for the sensor to reach equilibrium.

Automatic Calibration

After the unit is turned on it will automatically calibrate to room air. The display should be stable and reading 20.9%.

CAUTION: The device will assume a percent oxygen concentration when calibrating. Be sure to apply 100% oxygen, or ambient air concentration to the device during calibration or the device will not calibrate correctly.

To check the oxygen concentration of a sample gas: (after the unit has been calibrated):

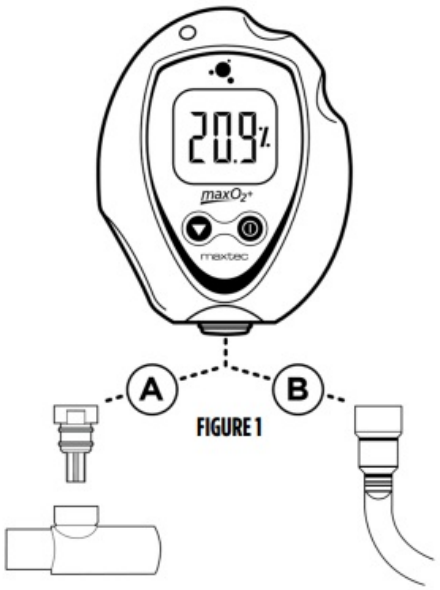


FIGURE 1

1. Connect the Tygon tubing to the bottom of the analyzer by threading the barbed adapter onto the oxygen sensor. (FIGURE 1, B)
2. Attach the other end of the sample hose to the sample gas source and initiate flow of the sample to the unit at a rate of 1-10 liters per minute (2 liters per minute is recommended).
3. Using the “ON/OFF” key, make sure the unit is in the power “ON” mode.
4. Allow the oxygen reading to stabilize. This will normally take about 30 seconds or more.

Calibrating the MaxO2+ Oxygen Analyzer

NOTE: We recommend use of medical grade USP or >99% purity oxygen when calibrating the MaxO2+.

The MaxO2+ Analyzer should be calibrated upon initial power-up. Thereafter, Maxtec recommends calibration on a weekly basis. To serve as a reminder, a one-week timer is started with each new calibration. At the end of one week a CAL reminder icon will appear on the bottom of the LCD. Calibration is recommended if the user is unsure when the last calibration procedure was performed, or if the measurement value is in question.

Start calibration by pressing the Calibration key for more than 3 seconds. The MaxO2+ will automatically detect if you are calibrating with 100% oxygen or 20.9% oxygen (normal air). DO NOT attempt TO CALIBRATE TO ANY OTHER

CONCENTRATION.

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.
- The CAL reminder Icon is blinking at the bottom of the LCD.
- If you are unsure about the displayed O2 percentage. (see Factors influencing accurate readings.)

For ID testing, (or optimum accuracy) a new calibration is required when:

- The measured O2 percentage in 100% O2 is below 99.0% O2.
- The measured O2 percentage in 100% O2 is above 101.0% O2.
- The CAL reminder Icon is blinking at the bottom of the LCD.
- If you are unsure about the displayed O2 percentage (see Factors influencing accurate readings).
- A simple calibration may be made with the sensor open to static ambient air. For optimum accuracy Maxtec recommends that the Sensor be placed in a closed loop circuit where gas flow is moving across the sensor in a controlled manner. Calibrate with the same type of circuit and flow that you will use in taking your readings.

In Line Calibration

(Flow Diverter – Tee Adapter)

1. Attach the diverter to the MaxO2+ by threading it on to the bottom of the sensor.
2. Insert the MaxO2+ in the center position of the tee adapter. (FIGURE 1, A)
3. Attach an open-ended reservoir to the end of the tee adapter. Then start the calibration flow of oxygen at two liters per minute.
4. Six to 10 inches of corrugated tubing works well as a reservoir. A calibration oxygen flow to the MaxO2+ of two liters per minute is recommended to minimize 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 two minutes to ensure that the sensor is completely saturated with the calibration gas.

6. If the MaxO2+ is not already turned on, do so now by pressing the analyzer “ON” button.
7. Press the Cal button on the MaxO2+ until you read the word CAL on the analyzer display. This can take approximately 3 seconds. The analyzer will now look for a stable sensor signal and a good reading. When obtained, the analyzer will display the calibration gas on the LCD.

NOTE: Analyzer will read “Cal Err St” if the sample gas has not stabilized.

Direct Flow Calibration (Barb)

1. Attach the Barbed Adapter to the MaxO2+ by threading it on to the bottom of the sensor.
2. Connect the Tygon tube to the barbed adapter. (FIGURE 1, B)
3. Attach the other end of the clear sampling tube to a source of oxygen with a known oxygen concentration value. Initiate flow of the calibration gas to the unit. Two 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 two minutes to ensure that the sensor is completely saturated with the calibration gas.
5. If the MaxO2+ is not already turned on, do so now by pressing the analyzer “ON” button.
6. Press the Cal button on the MaxO2+ until you read the word CAL on the analyzer display. This can take approximately 3 seconds. The analyzer will now look for a stable sensor signal and a good reading. When obtained, the analyzer will display the calibration gas on the LCD.

FACTORS INFLUENCING ACCURATE READINGS

Elevation/Pressure Changes

- Changes in elevation result in a reading error of approximately 1% of reading per 250

feet.

- In general, calibration of the instrument should be performed when elevation at which the product is being used changes by more than 500 feet.
- 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.

Temperature Effects

The MaxO2+ will hold calibration and read correctly within ±3% when at 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:

- 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.
- **CAUTION:** “CAL Err St” may result from a sensor that has not reached thermal equilibrium
- When used in a breathing circuit, place the sensor upstream of the heater.

Pressure Effects

Readings from the MaxO2+ are proportional to the partial pressure of oxygen. The partial pressure is equal to the concentration times the absolute pressure.
Thus, the readings are proportional to the concentration if the pressure is held constant. Therefore, the following are recommended:

- Calibrate the MaxO2+ 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.

Humidity Effects

Humidity (non-condensing) has no effect on the performance of the MaxO2+ 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 moisture 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.

HELPFUL HINT: Dry sensor by lightly shaking moisture out or flow a dry gas at two liters per minute across the sensor membrane.

CALIBRATION ERRORS AND ERROR CODES

The MaxO2+ 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.

E02: No sensor attached

- MaxO2+A: Open unit and disconnect and reconnect sensor. Unit should perform an auto calibration and should read 20.9%. If not, contact Maxtec Customer Service for possible sensor replacement.
- MaxO2+AE: Disconnect and reconnect external sensor. Unit should perform an auto calibration, and should read 20.9%. If not, contact Maxtec Customer Service for possible sensor replacement or cable replacement.

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

- Replace batteries.

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 calibration. If unit repeats this error more than three times, contact Maxtec 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

- Replace batteries.

CHANGING THE BATTERIES

Warning: Battery replacement by inadequately trained personnel could result in a safety hazard.
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.

Should the batteries require changing, the device will indicate this in one of two ways:

- The battery icon on the bottom of the display will begin to flash. This icon will continue to flash until the batteries are changed. The unit will continue to function normally for approx. 200 hours.
- If the device detects a very low battery level, an error code of “E04” will be present on the display, and the unit will not function until the batteries are changed.
- To change the batteries, begin by removing the three screws from the back of the device. A #1 Phillips screwdriver is required to remove these screws.
- Once the screws are removed, gently separate the two halves of the device.
- The batteries can now be replaced from the back half of the case. Be sure to orient the new batteries as indicated in the embossed polarity on the back case.

NOTE: If the batteries are installed incorrectly the batteries will not make contact and the device will not operate.

- Carefully, bring the two halves of the case together while positioning the wires so they are not pinched between the two case halves.
- The gasket separating the halves will be captured on the back case half.
- Reinsert the three screws and tighten until the screws are snug. (FIGURE 2).

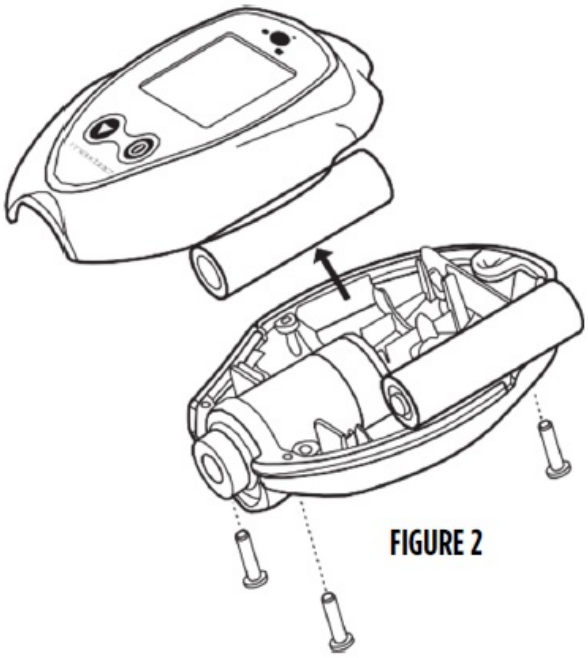


FIGURE 2

The device will automatically perform a calibration and begin displaying % of oxygen.

- HELPFUL HINT: If unit does not function, verify that the screws are tight to allow

proper electrical connection.

- HELPFUL HINT: (MAXO2+AE): Before closing the two case halves together, verify that the keyed slot on top of the coiled cable assembly is engaged on the small tab located on the back case. This is designed to position the assembly in the correct orientation and prevent it from rotating. Improper positioning could hinder the case halves from closing and prevent operation when tightening the screws.

Warning: Do not attempt to replace the battery while the device is in use.

CHANGING THE OXYGEN SENSOR

MaxO2+A Model

- The oxygen sensor should be replaced whenever the performance is degraded or a calibration error cannot be resolved.
- Should the oxygen sensor require changing, the device will indicate this by presenting “Cal Err lo” on the display after initiating a calibration.
- To change the oxygen sensor, begin by removing the three screws from the back of the device.

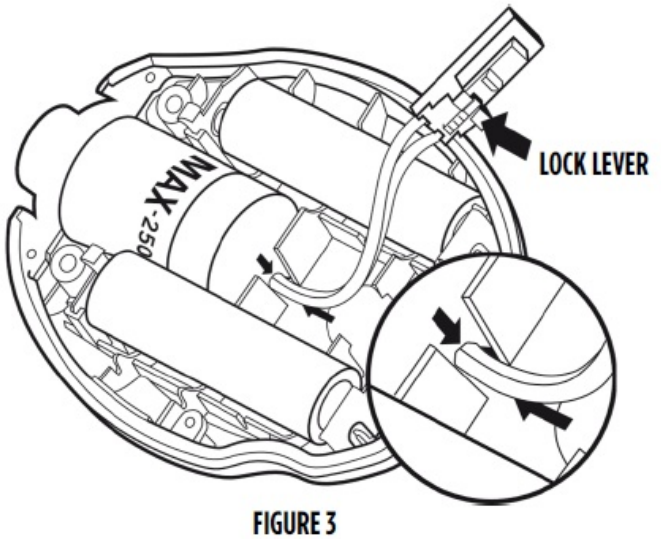


FIGURE 3

- A #1 Phillips screwdriver is required to remove these screws.
- Once the screws are removed, gently separate the two halves of the device.
- Disconnect the oxygen sensor from the printed circuit board by pressing the unlock lever first and then pulling the connector out of the receptacle. The oxygen sensor can now be replaced from the back half of the case.
- HELPFUL HINT: Be sure to orient the new sensor by aligning the red arrow on the

sensor with the arrow in the back case. A small tab is located on the back case that is designed to engage the sensor and prevent it from rotating within the case. (FIGURE 3)

- NOTE: If the oxygen sensor is installed incorrectly, the case will not come back together and the unit may be damaged when the screws are reinstalled.
- NOTE: If the new sensor has red tape over the outside, remove it, then wait 30 minutes before calibrating.
- Reconnect the oxygen sensor to the connector on the printed circuit board. Carefully bring the two halves of the case together while positioning the wires to ensure they are not pinched between the two case halves. Make sure the sensor is fully inserted and in the proper orientation.
- Reinsert the three screws and tighten until the screws are snug. Verify the unit operates prop- erly. The device will automatically perform a calibration and begin displaying % of oxygen.

Warning: Do not attempt to replace oxygen sensor while the device is in use.

MaxO2+AE Model

- Should the oxygen sensor require changing, the device will indicate this by presenting “Cal Err lo” on the display.
- Unthread the sensor from the cable by rotating the thumbscrew connector counterclockwise and pull the sensor from the connection. Replace the new sensor by inserting the electrical plug from the coiled cord into the receptacle on the oxygen sensor. Rotate the thumbscrew clockwise until snug. The device will automatically perform a calibration and begin displaying % of oxygen.

CLEANING AND MAINTENANCE

- Store the MaxO2+ analyzer in a temperature similar to its ambient environment of daily use.
- The instruction given below describes the methods to clean and disinfect the instrument, sensor and its accessories (e.g. flow diverter, tee adapter):

Instrument Cleaning

- When cleaning or disinfecting the exterior of the MaxO2+ analyzer, take appropriate care to prevent any solution from entering the instrument.
- DO NOT attempt to clean or service MaxO2+ while device is in use.
- DO NOT immerse unit in fluids.
- The MaxO2+ analyzer surface may be cleaned using a mild detergent and a moist cloth.
- The MaxO2+ analyzer is not intended for steam, ethylene oxide or radiation sterilization.
- Cleaning should be performed between patients.
- NOTE: The device should be discontinued from service if material degradation or cracking or observed.
- NOTE: Care should be taken to ensure the sensor is not exposed to excessive amounts of lint or dust which could accumulate in the senor membrane and impair performance. Direct sunlight should also be avoided since it may cause degradation of the device materials or the device to overheat affecting performance.

Oxygen Sensor

- Warning: Do Not install the sensor and flow diverter in a location that could expose the sensor to patient contaminants, unless you intend to dispose of the sensor and flow diverter after use. The internal surfaces of the sensor or flow diverter which contact the patient gas stream cannot be cleaned.
- Clean the sensor with a cloth moistened with isopropyl alcohol (65% alcohol/water solution).
- Maxtec does not recommend use of spray disinfectants because they can contain salts, which can accumulate in the sensor membrane and impair readings.
- The oxygen sensor is not intended for steam, ethylene oxide or radiation sterilization.

NOTE: Under typical use conditions, the surfaces of the sensor and flow diverter in contact with gas delivered to the patient should not become contaminated. If you suspect that the sensor or flow diverter have become contaminated these items should be discarded and replaced. The tee adapter is specified as a single use. Reuse of single use items may result in patient cross contamination or loss of component integrity.

SPECIFICATIONS

Base Unit Specifications

- Expected Service Life
  ……
  7 Years
- Measurement Range
  ……
  ..0-100%
- Resolution
  ……
  0.1%
- 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 ……. 90% of final value in approximately 15 seconds at 23°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)
- Power Requirements…… 2, AA Alkaline batteries (2 x 1.5 Volts)

- Battery Life …… approximately 5000 hours with continuous use
- Low Battery Indication…….. “BAT” icon displayed on LCD
- Sensor Type ……. Maxtec Max-250 series galvanic fuel cell
- Expected Sensor Life …….. > 1,500,000 O2 percent hours minimum (2-year in typical medical applications)
- A Model dimensions…….. 3.0”(W) x 4.0”(H) x 1.5”(D) [76mm x 102mm x 38mm]
- A Weight …… 0.4 lbs (170g)
- AE Model Dimensions ……. 3.0”(W) x 36.0”(H) x 1.5”(D) [76mm x 914mm x38mm] Height includes length of external cable (retracted)
- AE Weight …… 0.6 lbs (285g)
- Drift of Measurement …… < +/-1% of full scale at constant temperature, pressure and humidity
- Wattage Rating ……. 3V ⎓ 0.2mW
- Storage temperature limits to operational use:
- Cool-Down time …… 5 Minutes
- Warm-up time …….. 30 Minutes

Sensor Specifications

- Type ……. Galvanic fuel sensor (0-100%)

- Life …….. 2-years in typical applications

INTERFERENT	VOLUME % DRY	INTERFERENCE IN O2%
Nitrous Oxide	60% Balance O_2	< 1.5%
Halothane	4%	< 1.5%
Isoflurane	5%	< 1.5%
Enflurane	5%	< 1.5%
Sevoflurane	5%	< 1.5%
Desflurane	15%	< 1.5%
Helium	50% Balance O2	< 1.5%

MAXO2+ SPARE PARTS AND ACCESSORIES

Included With Your Unit

PART NUMBER	ITEM (EXPECTED SERVICE LIFE)	A MODEL	AE MODEL
R217M40	User Guide & Operating Instructions (N/A)	X	X
RP76P06	Lanyard (Lifetime of MaxO2+)	X	X
R110P10-001	Flow Diverter (2 Years)	X	X
RP16P02	“T” Adapter (Single Use)	X	X

R217P23	Dovetail Bracket (N/A)		x
R125P02-011	Max-250+ Oxygen Sensor (2 Years)	x	

R125P03-002	Max-250E Oxygen Sensor (2 Years)		x

Standard Replacement Parts and Accessories

PART NUMBER	ITEM	A MODEL	AE MODEL
R125P02-011	Max-250+ Oxygen Sensor	x	
R125P03-002	Max-250E Oxygen Sensor		x
R115P85	Max-250ESF Oxygen Sensor		x
R217P08	Gasket	x	x
RP06P25	#4-40 Pan Head Stainless Steel Screw	x	x
R217P16-001	Front Assembly (Includes Board & LCD)	x	x
R217P11-002	Back Assembly	x	x
R217P19	Coiled Cable Assembly		x
R217P09-001	Overlay	x	x
RP16P02	“T” Adapter	x	x

Optional Accessories

Optional Adapters

PART NUMBER	ITEM
RP16P02	Tee Adapter
R103P90	Perfusion Tee Adapter
RP16P05	Pediatric Tee Adapter

R207P17	Threaded Adapter with Tygon Tubing

Mounting Options (requires dovetail R217P23)

PART NUMBER	ITEM
R206P75	Pole Mount
R205P86	Wall Mount
R100P10	Rail Mount
R206P76	Horizontal Pole Mount

NOTE: Repair of this equipment must be performed by a qualified service technician experi- enced in repair of portable hand held medical equipment.

Equipment in need of repair shall be sent to:

Maxtec
Service Department 2305 South 1070 West Salt Lake City, Ut 84119 (Include RMA number issued by customer service)

ELECTROMAGNETIC COMPATIBILITY

The MaxO2+ is suitable for the electromagnetic environment of typical hospital and home healthcare settings. The user should assure that it is used in such an environment. During the immunity resting described below the MaxO2+ will analyze oxygen concentration within specification.

- WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 CM (12 inches) to any part of the MaxO2+, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- WARNING: The MaxO2+ should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the MaxO2+ should be observed

to verify normal operation. If operation is not normal, the MaxO2+ or the equipment should be moved.

- WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- WARNING: Avoid exposure to known sources EMI (electromagnetic interference) such as diathermy, lithotripsy, electrocautery, RFI (Radio Frequency Identification), and electromagnetic security systems such as anti-theft/electronic article surveillance systems, metal detectors. Note that the presence of RFID devices may not be obvious. If such interference is suspected, re-position the equipment, if possible, to maximize distances.

<table>
<tr><th colspan="3">ELECTROMAGNETIC EMISSIONS</th></tr>
<tr><td colspan="3">This equipment is intended for use in the electromagnetic environment specified belo w. The user of this equipment should assure that it is used in such an environment.</td></tr>
<tr><th>EMISSIONS</th><th>COMPLIANC E ACCORDI NG TO</th><th>ELECTROMAGNETIC ENVIRONMENT</th></tr>
<tr><td>RF Emissions (CIS PR 11)</td><td>Group 1</td><td>The MaxO2+ uses RF energy only for its intern al function. Therefore, its RF emissions are ver y low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>CISPR Emissions Classification</td><td>Class B</td><td rowspan="3">The MaxO2+ is suitable for use in all establish ments other than domestic and those directly c onnected to the public low-voltage power suppl y network that supplies buildings used for dome stic purposes.</td></tr>
<tr><td>Harmonic Emission s (IEC 61000-3-2)</td><td>N/A</td></tr>
<tr><td>Voltage Fluctuation s (IEC 61000-3-3)</td><td>N/A</td></tr>
</table>

The MaxO2+ was also tested for radiated immunity to RF wireless communication equipment at the test levels below

Frequency (HZ)	**Modulation**	**Level V/m**
385	PULSE, 18 Hz, 50% DC	27
450	FM, 1 kHz Sine, ±5 Hz Deviation	28
710, 745, 780	PULSE, 217 Hz, 50% DC	9
810, 870, 930	PULSE, 18 Hz, 50% DC	28
1720, 1845, 1970	PULSE, 217 Hz, 50% DC	28
2450		28
5240, 5500, 5785		9

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: 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		
Electrical fast transients / bursts (IEC 61000-4-4)	N/A		

Surges on AC mains lines (IEC 61000-4-5)	N/A		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. 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.
Power Frequency (50/60Hz) Magnetic Field (IEC 61000-4-8)	30 A/m50 Hz or 60 Hz		
Voltage dips and short interruptions on AC mainsInput lines(IEC 61000-4-11)	N/A		
Conducted RF coupled into lines (IEC 61000-4-6)	N/A	N/A	
Radiated RF immunity(IEC 61000-4-3)	3 V/m	10 V/m	
	80 MHz – 2,7 GHz80% @ 1 KHzAM Modulation	80 MHz – 2,7 GHz80% @ 1 KHzAM Modulation	

Radiated fields to close proximity (IEC 61000-4-39)	8 A/m at 30 kHz (CW Modulation)65 A/m at 134.2 kHz(2.1 kHz PM, 50% duty cycle)7.5 A/m at 13.56 MHz(50 kHz PM, 50% duty cycle)	Avoid exposure to known sources of EMI (electromagnetic interference) such as diathermy, lithotripsy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems, metal detectors.Note that the presence of RFID devices may not be obvious. If such interference is suspected, reposition the equipment, if possible, to maximize distances.

Maxtec

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ETL CLASSIFIED
Intertek
9700630

Conforms to:
ANSI/AAMI STD ES60601-1
IEC STDS 60601-1-6, 60601-1-11, 60601-1-12
Certified to:
CSA STD C22.2 No. 60601-1

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

WWW.MAXTEC.COM • 800-748-5355

FAQ

- **Q: Can the MaxO2+ be used in an MRI environment?**
  A: No, the MaxO2+ is not suitable for use in an MRI environment.
- **Q: What should I do if the device is exposed to liquids?**
  A: If the MaxO2+ is ever exposed to liquids, contact authorized service personnel for inspection and potential repair.
- **Q: How often should I calibrate the MaxO2+?**
  A: It is recommended to calibrate the MaxO2+ weekly when in operation or if significant environmental conditions change.

Documents / Resources

	maxtec MaxO2 Plus AE Oxygen Analyzer [pdf] Instruction Manual MaxO2 Plus, MaxO2 Plus AE Oxygen Analyzer, AE Oxygen Analyzer, Oxygen Analyzer, Analyzer

References

- User Manual

AE Oxygen Analyzer, Analyzer, MaxO2 Plus, MaxO2 Plus AE Oxygen Analyzer, maxtec, OXYGEN ANALYZER

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