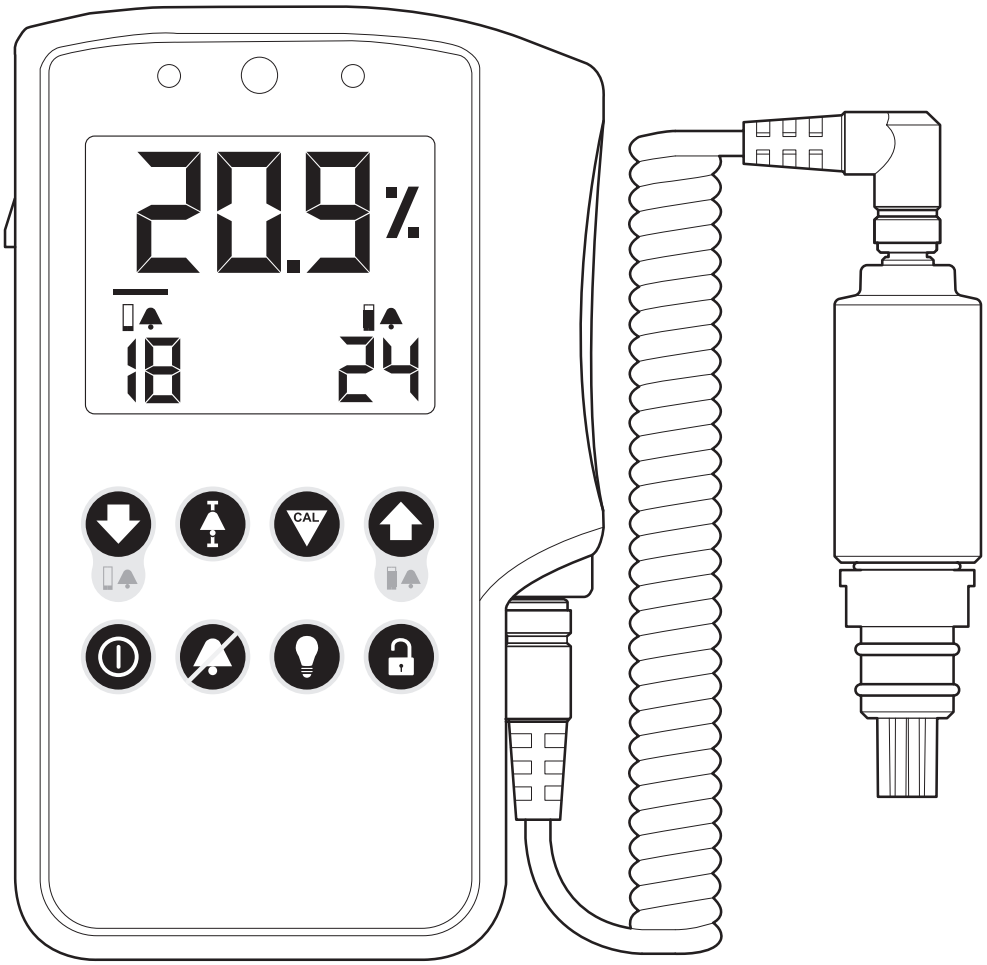

MaxO2 ME

Instructions for Use

ENGLISH

maxtec

R230M01-001 REV. H

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CE-0123

ETL CLASSIFIED
Intertek
9700630

Conforms to:
AAMI STD ES60601-1, ISO STD 80601-2-55, IEC STDS 60601-1-6, 60601-1-8 & 62366
Certified to:
CSA STD C22.2 No. 60601-1

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

This manual describes the function, operation and maintenance of the Maxtec Model MaxO2 ME oxygen monitor. The MaxO2 ME utilizes the Maxtec Max-550E oxygen sensor and is engineered for fast response, maximum reliability and stable performance. The MaxO2 ME is designed primarily for continuous monitoring of oxygen levels delivered by medical oxygen delivery equipment and respiratory care systems. Adjustable high and low level alarm set points make the MaxO2 ME ideal for use in neonatal, anesthesia and respiratory care.

CLASSIFICATION

Protection against electric shock ..... II, Type B
Protection against water IPX1
Mode of operation ..... Continuous
Sterilization ..... See section 6.1
Flammable anesthetic mixture ..... See section 8.1
Power specification ..... 7.5V(MAX) ⎓ 1.9W.250mA(MAX)

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. There are no special considerations for the disposal of the product packaging.

WARRANTY

The MaxO2 ME Monitor is designed for medical oxygen delivery equipment and systems. Under normal operating conditions, Maxtec warrants the MaxO2 ME Monitor to be free from defects of workmanship or materials for a period of two (2) years from the date of receipt from Maxtec, provided that the unit is properly operated and maintained in accordance with Maxtec's operating instructions. Based on Maxtec's 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 the Max-550E oxygen sensor in the MaxO2 ME Monitor to be free from defects in material and workmanship for a period of two (2) years from Maxtec's date of shipment in a MaxO2 ME 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, 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.**

NOTE: In order to obtain optimum performance from your MaxO2 ME monitor, all operation and maintenance must be performed in accordance with this manual. Please read the manual thoroughly before using the monitor and do not attempt any repair or procedure that is not described herein. Maxtec cannot warrant any damage resulting from misuse, unauthorized repair or improper maintenance of the instrument.

EMC Notice

This equipment uses, generates, and can radiate radio frequency energy. If not installed and used in accordance with the instructions in this manual, electromagnetic interference may result. The equipment has been tested and found to comply with the limits set forth in IEC 60601-1-2 for medical products. These limits provide reasonable protection against electromagnetic interference when operated in the intended use environments described in this manual.

MRI Notice

This equipment contains electronic and ferrous components, whose operation can be affected by intense electromagnetic fields. Do not operate the MaxO2 ME in an MRI environment or in the vicinity of high-frequency surgical diathermy equipment, defibrillators, or shortwave therapy equipment. Electromagnetic interference could disrupt the operation of the MaxO2 ME.

WARNINGS ⚠

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

- Before use, all individuals who will be using the MaxO2 ME 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.
- This product is not intended as a life-sustaining or life-supporting device.
- Medical Oxygen should meet the requirements of USP.
- The Alarm limits can be set to levels that would render them useless for a particular patient's clinical condition. Ensure that the delivered oxygen level and flow rate are set to values prescribed by the patient's physician. Also ensure that the high and low alarm limits are set to levels such that they will sound if the oxygen level is outside of safe limits. Be sure to review and, if necessary, re-set the alarm limits when the patient's clinical condition changes or when the patient's physician prescribes a change in oxygen therapy.
- To avoid explosion, **DO NOT** operate the oxygen monitor in the presence of flammable anesthetics or in an atmosphere of explosive gases. Operating the oxygen monitor in flammable or explosive atmospheres may result in fire or explosion.
- Never allow an excess length of cable near the patient's head or neck, as such could result in strangulation. Secure excess cable to the bed rail or suitable object.
- Never use a MaxO2 ME monitor with a cable that appears worn, cracked or has damaged insulation.
- The oxygen sensors contain a weak acidic solution encapsulated in a plastic housing. Under normal operating conditions the solution (electrolyte) is never exposed. In case of a leak or if damaged, **DO NOT** use the oxygen sensor.
- Use only genuine Maxtec accessories and replacement parts. Failure to do so may seriously impair the monitor's performance. Repair or alteration of the MaxO2 ME beyond the scope of the maintenance instructions or by anyone other than an authorized Maxtec service person could cause the product to fail to perform as designed. No modification of this equipment allowed.
- Calibrate the MaxO2 ME weekly when in operation and if environmental conditions change significantly. (I.e., Temperature, Humidity, Barometric Pressure. Refer to section 2.2 Calibration of this manual).
- Use of the MaxO2 ME near devices that generate electrical fields may cause erratic readings.
- If the MaxO2 ME is ever exposed to liquids (from spills or immersion) or to any other physical abuse, turn the instrument OFF, remove batteries and allow to dry completely, then power ON. This will allow the unit to go through its self test and make sure everything is operating correctly.

- Never autoclave, immerse in liquid or expose the MaxO2 ME (including sensor) to high temperatures (>50°C). Never expose the device to liquid, pressure, irradiation vacuum, steam, or chemicals.
- To protect the unit from potential leaky battery damage always remove batteries when the unit is going to be stored (not in use for 30 days or more) and replace dead batteries with recognized name brand AA Alkaline batteries.
- **DO NOT** use rechargeable batteries.
- **DO NOT** attempt to replace oxygen sensor or batteries while the device is in use.
- This device does not contain automatic barometric pressure compensation.
- Not for use in an MRI environment.
- Battery replacement by inadequately trained personnel could result in a safety hazard.
- Electrical shock or damage to the equipment may occur if an inappropriate external power supply is used. Maxtec recommends using only the Maxtec approved external power supply, as listed in 9.0 Spare Parts and Accessories.

NOTE: The MaxO2 ME oxygen monitor has been manufactured with a low alarm setting adjustable down to 15% that requires deliberate action to set it below 18%. See section 3.1 Alarm Setting Procedure.

- **DO NOT** clean or dry the MaxO2 ME with a high pressure air gun. Applying high pressure air to the MaxO2 ME may damage components and render the system inoperable.
- **DO NOT** over clean the MaxO2 ME. Repeated use of a cleaning agent can cause residue buildup on critical components. Excessive residue buildup can affect the MaxO2 ME's performance.
- When cleaning the MaxO2 ME: **DO NOT** use harsh abrasives. **DO NOT** immerse the MaxO2 ME in liquid sterilizing agents or liquids of any kind. **DO NOT** spray cleaning solution directly onto the device. **DO NOT** allow cleaning solution to pool on the device.
- **DO NOT** sterilize the MaxO2 ME. Standard sterilization techniques may damage the monitor.
- If the MaxO2 ME does not function as outlined in section 2.0, contact a Maxtec trained service technician or Maxtec for service.
- **DO NOT** allow the sensor to come in contact with exhaled patient gases or other potential sources of contamination. The sensor face cannot be decontaminated if it comes in contact with infectious agents.
- 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.
- **DO NOT** expose the sensor face to liquids or allow humidity to condense on the face of the sensor as this may impair the function of the MaxO2 ME.
- The MaxO2 ME and sensor are non-sterile devices.
- Regularly inspect the MaxO2 ME and associated components for damage or electrolyte leakage prior to use.
- **DO NOT** use if damaged.
- **DO NOT** obstruct alarm.
- **DO NOT** smoke in an area where oxygen is being administered.
- The MaxO2 ME may only be calibrated using 20.9% oxygen (room air) or 100% oxygen. Calibration at other concentrations will result in inaccurate readings.
- The oxygen sensor should be operated in an upright position (sensor face downwards). Operating the oxygen sensor upside down may cause the sensor to function improperly.
- When using the approved external power supply, functional batteries must also be installed in the device. The device will not operate solely on the external power supply.
- In the event of exposure to an ELECTROMAGNETIC DISTURBANCE the analyzer may display an E06 or E02 error message. If this occurs, refer to Section 5.0 for instructions to resolve the problem.

SYMBOL GUIDE

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

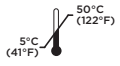
	Attention, consult accompanying documents		On/Off Key
	Consult Instructions For Use		Calibration Key
	Do Not		Calibration Reminder
	Unlock Key		Silent Key
	Backlight Key		Smart Alarm Key
	High Alarm Indicator		Low Alarm Indicator
	Smart Alarm Mode Indicator		Alarm Silence Indicator
	Down (Low Alarm) Key		Up (High Alarm) Key
	Low Battery Indicator		Sleep Mode Indicator
	Federal law (USA) restricts this device to sale by or on order of a physician		Meets ETL Standards
	Manufacturer		Direct Current
	Date of Manufacture		Medical Device
	Warning		Two means of patient protection (double insulated)
	Caution		Power Supply Meets CEC Tier 3 and EU Phase 2 Standards
	Conforms to EU Requirements		Authorized Representative in the European Community
	For use in dry indoor locations		Storage Temperature Range
	Serial Number		Catalog Number
	Complies with Directive 2011/65/EU		Ingress Protection Rating
	Combined UL / CSA Mark		Corrosive
	Do not throw away. Follow local guidlines for disposal.		Type B Applied Parts
	MR Unsafe		

TABLE OF CONTENTS

1.0 SYSTEM OVERVIEW

1.1 Base Unit Description

The MaxO2 ME is a handheld oxygen analyzer/monitor capable of measuring the oxygen concentration from 0% to 100% in a sample gas. A Max-550E oxygen sensor outputs a voltage which is used by the MaxO2 ME to determine the concentration of oxygen based on a calibration at room air or 100% oxygen. The MaxO2 ME contains alarms that can be controlled by the user to set a maximum or minimum allowable oxygen concentration.

- Oxygen sensor of approximately 1,500,000 O2 percent hours.
- External probe with 10 ft., extendable cable and diverter fitting for standard 15 mm "T" adapter.
- Operation using 4 AA alkaline batteries (4 x 1.5 volts) for approximately 5000 hours of performance with typical use.
- Oxygen-specific, galvanic sensor that achieves 90% of final value in approximately 15 seconds at room temperature.
- 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.
- Adjustable high-level and low-level alarming capability with flashing LED and audible indication of alarm conditions.
- Smart high-low alarm setting to help adjust alarm settings quickly
- Back-light display with auto ambient light level detection.
- Sleep Mode operation to extend battery life.

Indication for Use:

The MaxO2 ME oxygen monitor is intended for continuous monitoring of the concentration of oxygen being delivered to patients ranging from newborns to adults.

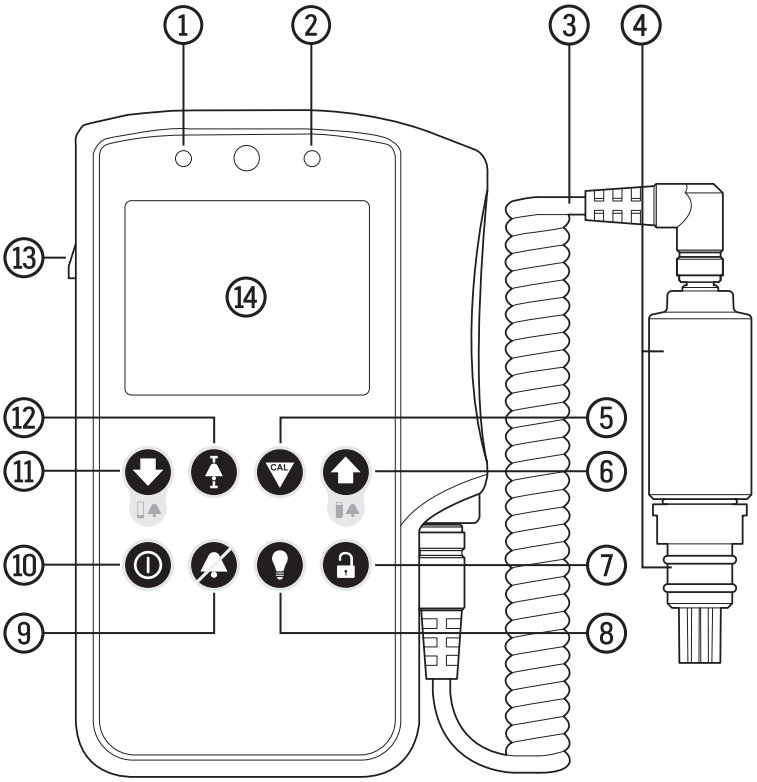
It can be used in the hospital and sub-acute settings. The MaxO2 ME is not a life supporting device.

1.2 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
- Operation of visible and audible alarms

1.3 Component Identification



① **LOW ALARM LED —** In a low alarm condition, the yellow "LOW ALARM" LED will flash once every two seconds, accompanied by the audio buzzer. If the Oxygen level is below 18%, the red "LOW ALARM" LED will flash twice per second accompanied by the audio buzzer.

② **HIGH ALARM LED —** In a high alarm condition, the yellow "HIGH ALARM" LED will flash once every two seconds accompanied by the audio buzzer.

③ **COILED CABLE —** The coiled cable allows the sensor to be positioned up to 8 feet from the side of the unit.

④ **OXYGEN SENSOR WITH DIVERTER —** The sensor (with diverter) is designed to fit industry standard, 15mm I.D. "T" adapters.

⑤ **CALIBRATION KEY —** This key is used to calibrate the device. The device must be in the unlocked state for the key to operate. See section 2.2 for instructions on calibrating.

⑥ **UP (ALARM HIGH) —** The up key is used in setting the high alarm limit. The device must be in the unlocked state for the key to operate. See section 3.1.2 for instructions on setting the high alarm limit.

⑦ **UNLOCK KEY —** The unlock key is used to unlock and lock the instrument.

⑧ **BACKLIGHT —** The backlight key will manually activate the backlight for 30 seconds. See section 3.4 for more information on backlighting operation.

⑨ **ALARM SILENCE KEY —** In an alarm condition, pressing the SILENT key will deactivate the audible alarm for 2 minutes.

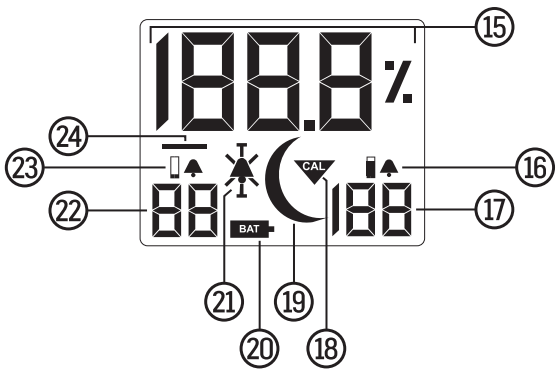
⑩ **ON/OFF KEY —** This key is used to turn the device on or off. To turn the device OFF, the button must be held while a rapid 3-2-1 countdown takes place to prevent accidental power-off.

⑪ **DOWN (ALARM LOW) —** The down key is used in setting the low alarm limit. The device must be in the unlocked state for the key to operate. See section 3.1.1 for instructions on setting the low alarm limit.

⑫ **SMART ALARM KEY —** The smart alarm key is used to help set the High-Low Alarm window quickly. This automatically sets oxygen alarms at ±3%.

⑬ **EXTERNAL POWER SUPPLY PORT —** The port provides connection for the external power supply. See section 3.6 for more information on the power adapter.

⑭ **LCD DISPLAY —** The liquid crystal display (LCD) provides direct readout of oxygen concentrations. The digits also display error codes, alarm set modes and calibration codes as necessary.



⑮ **OXYGEN CONCENTRATION —** Current oxygen concentration percentage from the oxygen sensor.

⑯ **HIGH ALARM INDICATOR —** High alarm symbol used for identifying the high alarm setpoints and when a high alarm is triggered.

⑰ **OXYGEN HIGH ALARM LIMIT —** High oxygen alarm setpoint. Audible and visual alarms will trigger when this limit is exceeded. Double dashes (--) indicates the alarm is inactive.

⑱ **CALIBRATION REMINDER —** CAL The calibration reminder symbol is located at the bottom of the display. This symbol will be lighted after one week has elapsed from the previous calibration.

⑲ **SLEEP MODE INDICATOR —** The sleep mode Indicator is used to reduce battery consumption. See section 3.5 Sleep Mode Operation.

⑳ **LOW BATTERY INDICATOR —** BAT The low battery indicator is located at the bottom of the display and is only activated when the voltage on the batteries are below a normal operating level and need to be replaced.

㉑ **ALARM SILENCE/SMART ALARM INDICATOR —** When the silent key is pressed the indicator will display with cross bars to alert condition. When Smart Alarm Mode Button is pressed the indicator will display with T-bars to alert condition.

㉒ **OXYGEN LOW ALARM LIMIT —** Low oxygen alarm setpoint. Audible and visual alarms will trigger when this limit is exceeded.

㉓ **LOW ALARM INDICATOR —** Low alarm symbol used for identifying the low alarm setpoints and when a low alarm is triggered.

㉔ **<18% ALARM INDICATOR —** The <18% alarm indicator is located above the Low Alarm Indicator digits. When the low alarm setting is set below <18%, the indicator will flash each second to alert the operator of this special condition. See section 3.1.1 for setting this low alarm condition.

1.4 Max-550E Oxygen Sensor

The Max-550E is a galvanic, partial pressure sensor that is specific to oxygen. It consists of two electrodes (a cathode and an anode), a FEP membrane and an electrolyte. Oxygen diffuses through the FEP membrane and immediately reacts electrochemically at a gold cathode. Concurrently, oxidation occurs electrochemically at a 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.

⚠ **CAUTION:** The Max-550E 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.

⚠ **CAUTION:** Dropping or severely jarring the sensor after calibration may shift the calibration point enough to require recalibration.

⚠ **CAUTION:** The flow diverter for the sensor is for use with flowing gases only.

⃠ **DO NOT** use the diverter when performing static sampling, such as in incubators, oxygen tents, oxygen hoods, etc.

2.0 SETUP PROCEDURE

2.1 Battery Installation/Replacement

All MaxO2 ME units are powered by four, AA, alkaline batteries (4 x 1.5 Volts) and are shipped without the batteries installed. The battery compartment is accessible from the back side of the unit. Batteries should be changed by qualified service personnel. Use only brand name batteries. Replace with four AA batteries and insert per orientation marked on the device.

When batteries are installed in the MaxO2 ME, the unit initiates a self diagnostic test. All segments of the LCD readout are turned on for approximately 2 seconds. The audio buzzer sounds and the high and low alarm LEDs are illuminated. When the diagnostic test is completed successfully, the word "CAL" will display and then automatically initiate a calibration.

⚠ **WARNING:** Battery replacement by inadequately trained personnel could result in a safety hazard. The MaxO2 ME will automatically perform a new calibration any time the batteries are removed or replaced. Ensure that the sensor is exposed to either 20.9% oxygen (room air) or 100% oxygen when changing the batteries to avoid mis-calibration.

To install the batteries:

1. Release the thumb screw by turning it counter-clockwise until it pops out.
2. Install the four, AA, alkaline batteries (4 x 1.5 Volts) in the unit, observing the orientation shown on the plastic inside the compartment.
3. Slide the battery compartment cover back onto the case. Press in on the thumb screw while turning it clockwise until it engages the thread in the enclosure. Turn until it is lightly tightened. ⃠ **DO NOT** over-tighten.

⚠ **WARNING:** Electrical shock or damage to the equipment may occur if an inappropriate external power supply is used. Maxtec recommends using only the Maxtec approved external power supply as listed in Section 9.0 Spare Parts and Accessories.

To protect the unit from potential leaky battery damage always remove batteries when the unit is going to be stored (not in use for 30 days or more) and replace dead batteries with recognized name brand AA Alkaline batteries.

2.2 Calibrating the MaxO2 ME Monitor

2.2.1 Before You Begin

A protective film covering the threaded sensor face must be removed; wait approximately 20 minutes for the sensor to reach equilibrium.

Next, the MaxO2 ME monitor should be calibrated. Thereafter, Maxtec recommends calibration on a weekly basis. However, more frequent calibration will not adversely affect product performance.

Calibration of the instrument should be performed when the temperature of the gas stream changes by more than 3 degrees Celsius.

Changes in barometric pressure can affect the oxygen reading. A 1% change in the barometric pressure results in an error of 1% of actual reading (Example: If you are reading a 50% oxygen

mix and the barometric pressure drops from 1000mbar to 990mbar the reading will drop to: 50% x (990/1000) = 49.5%). Maxtec recommends that you re-calibrate after changing point-of-use elevation by more than 500 feet (150m).

In addition, calibration is recommended if the user is unsure when the last calibration procedure was performed or if the measurement value displayed is in question.

It is best to calibrate the MaxO2 ME monitor at a pressure and flow similar to your clinical application.

NOTE: Before beginning calibration the Max-550E sensor 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 "Factors Influencing Calibration and Performance" in this manual. The main display is capable of reading oxygen in the range of 0-105%. This additional range beyond physically possible concentration is to allow the user to be able to see if the device is reading accurately by testing in room air or 100% oxygen.

2.2.2 To Calibrate the MaxO2 ME Monitor to 20.9% Oxygen

1. Ensure the sensor is in room air and has had sufficient time to equilibrate with room temperature.
2. Using the ON/OFF key, make sure the unit is powered on.
3. Allow the oxygen reading to stabilize. This will normally take about 30 seconds or more.
4. Press the Unlock key to unlock the keypad. Note the LOW, Smart Alarm, CAL, and HIGH icons will begin to flash indicating the SET OPERATING MODE.
5. Press the CALIBRATION key on the keypad. The word "CAL" will appear on the display for approximately 5 seconds and then finish with 20.9%.
6. The unit is now calibrated and in the normal operating mode.

2.2.3 To Calibrate the MaxO2 ME Monitor to 100% Oxygen (recommended)

1. Place the external probe in a stream of medical grade USP or greater than 99% purity oxygen. Expose the sensor to the calibration gas at a regulated pressure and flow at a rate of 1-10 liters per minute (2 liters per minute is recommended).
2. Using the ON/OFF key, make sure the unit is in the normal operating mode.
3. Allow the oxygen reading to stabilize. This will normally take about 30 seconds or more.
4. Press the Unlock key to unlock the keypad. Note the LOW, Smart Alarm, CAL and HIGH icons will begin to flash indicating the SET OPERATING MODE.
5. Press the CALIBRATION key on the keypad. The word "CAL" will appear on the display for approximately 5 second and then finish with 100.0%.
6. The unit is now calibrated and in the normal operating mode.

2.2.4 Factors Influencing Oxygen Calibration

The primary factors influencing oxygen measurement on the MaxO2 ME monitor are temperature, pressure, and humidity.

Effects of Temperature

The MaxO2 ME monitor will hold calibration and read correctly within +/-3% when in thermal equilibrium within the operating temperature range. The device accuracy will be better than +/-3% if operated at the same temperature at which it was calibrated. The device must be thermally stable when calibrated and allowed to thermally stabilize after experiencing temperature changes before reading is accurate. For these reasons, the following is recommended:

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

Pressure Effect

Readings from the MaxO2 ME monitor are proportional to the partial pressure of oxygen. The partial pressure of Oxygen (PO2) is equal to the percentage of oxygen (%O2) times the absolute pressure (AP) at which the sample environment is measured (PO2=%O2 x AP).

Thus the readings are proportional 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:

1. Calibrate the MaxO2 ME monitor at the same pressure as the sample gas.
2. If sample gases flow through tubing, use the same apparatus and flow rates when calibrating as when measuring.

Humidity Effect

The MaxO2 ME monitor can be used in applications where the relative humidity of the sample gas ranges from 0 to 95%, non-condensing. However, it should be noted that water vapor exerts its own pressure in the same manner as oxygen does in a sample gas stream.

For example, if the monitor is calibrated in dry gas and then the gas is humidified, the monitor will correctly display a reading which is slightly lower than previously displayed. This is due to the dilution of oxygen in the sample gas by water vapor.

This fact is important to note in systems where there exist both "wet" and "dry" gas streams such as in a ventilator circuit. If the monitor is measuring oxygen on the "dry side" of the ventilator, it will correctly indicate an oxygen concentration slightly greater than actually found in the "wet side" (delivered to the patient). The water vapor has diluted the gas stream.

Additionally, gas streams of high humidity may tend to condense on the sensor. Condensation on the sensor may eventually affect performance. For this reason, it is recommended that the sensor be mounted in a vertical position, facing downward to prevent condensate from flowing onto the sensing surface.

3.0 OPERATING INSTRUCTIONS

3.1 Alarm Setting Procedure

3.1.1 Low Alarm Setting

To adjust the low alarm setting:

1. Press the Unlock key to unlock the keypad. Note the LOW, Smart Alarm, CAL and HIGH icons will begin to flash indicating the SET OPERATING MODE.
2. Press the DOWN (LOW ALARM) key on the keypad.

NOTE: The Low Alarm digits begin to flash indicating the Low Alarm manual setting.

3. Use the UP and DOWN keys to set the low alarm to the desired value. Pressing the arrow keys changes the value in 1% increments. If the keys are held down for more than 1 second the display will scroll at a rate of 1% per second.

NOTE: If 30 seconds elapse between key actuations, the system will store the latest low alarm value and will revert to normal operation. If this occurs inadvertently, simply repeat the alarm setting procedure.

There is a special condition that allows the low oxygen alarm to be set below 18%. To access this condition press the DOWN arrow key for three seconds while the low alarm reading displays 18%. The alarm setting can now be adjusted to 17, 16, or 15%. A bar will blink above the setting to provide further indication that the alarm has been set to this special <18% condition.

The low alarm value cannot be set lower than 15%, nor can it be set closer than 1% from the high alarm value. For example, if the high alarm is set at 25%, the system will not accept a low alarm setting greater than 24%.

4. When the low alarm value is set, press the Unlock key to accept the low alarm setting and return to normal operation.

NOTE: The default low alarm setting is 18% 02. Removing the batteries or shutting the unit OFF will reset the low alarm limit to 18% if it is set to <18%.

3.1.2 High Alarm Setting

To adjust the high alarm setting:

1. Press the Unlock key to unlock the keypad. Note the LOW, SMART ALARM, CAL and HIGH icons will begin to flash indicating the SET OPERATING MODE.
2. Press the UP (HIGH ALARM) key on the key pad.

NOTE: The High Alarm digits begin to flash indicating the High Alarm manual setting.

3. Use the UP and DOWN keys to set the high alarm to the desired value. Pressing the arrow keys changes the value in 1% increments. If the keys are held down for more than 1 second the display will scroll at a rate of 1% second.

NOTE: If 30 seconds elapse between key actuations, the system will store the latest high alarm setting and will revert to normal operation. If this occurs inadvertently, simply repeat the alarm setting procedure.

When the high alarm setting is set above 100% the high alarm will indicate two dashes --. This special condition turns off or deactivates the high alarm.

4. When the high alarm value is set, press the Unlock key again to accept the high alarm setting and return to normal operation.

NOTE: The default high alarm setting is 50% oxgyen. Removing the batteries will reset the high alarm limit to 50%.

3.1.3 Smart Alarm Mode

NOTE: Smart alarms function as alarm guardrails which simultaneously set the low and high alarms to ± 3% oxgyen of the current reading. This range can be broadened by pressing the up button or narrowed by pressing the down button.

1. Press the unlock key to unlock the keypad. Note the LOW, Smart Alarm, CAL and HIGH icons will begin to flash indicating the SET OPERATING MODE.
2. Press the Smart Alarm key on the keypad. Note the LOW digits, Alarm Mode and HIGH digits begin a slow flash indicating SMART ALARM MODE. The high alarm will now be set to be equal to the current reading +3% (rounded to the nearest interger). The low alarm will now be set to be equal to the current reading -3% (rounded to the nearest integer but never lower than 18%).
3. Pressing the Up key will add one to the high alarm setting and subtract one from the low alarm setting. Pressing the Down key will subtract one from the high alarm setting and add one to the low alarm setting. In other words, the Up Arrow widens the alarm band and the down arrow tightens the alarm band. This feature will not set the alarm levels above 100% or below 18% for oxygen.
4. Once the desired alarm settings are attained, press the Unlock key to save the settings and return to normal operation mode. If 30 seconds elapse without a key press by the user, the device will automatically save the new alarm settings and return to normal operation mode.

3.2 Basic Operation

To check the oxygen concentration of a sample gas:

1. Using the ON/OFF key, make sure the unit is in the power on mode and properly calibrated.
2. Place the external flow diverter in the sample gas stream. When using a standard "T" adapter, make sure the sensor is mounted in the adapter with the flow diverter pointing downward. This will prevent moisture from potentially draining into the sensor membrane.

NOTE: It is important that a tight fit exists between the diverter and the "T" adapter.

3. Initiate flow of the sample gas to the sensor.

3.3 Alarm Conditions and Priorities

In the event of either a low alarm or high alarm condition, the corresponding LED will begin to flash, accompanied by the audio buzzer. Pressing the SILENT key will deactivate the buzzer but the LED and the alarm value digits on the display will continue to flash until the alarm condition has been rectified. If the alarm condition still exists 120 seconds after silencing the audio buzzer, the beeper will start to sound again.

A low alarm condition will remain until the actual concentration is 0.1% higher than the low alarm setting. A high alarm condition will remain until the the actual concentration is 0.1% lower than the high alarm setting.

To help differentiate the level of priority, the monitor provides three unique audible sequences.

ALARM	ALARM PRIORITY	LOW ALARM LED	HIGH ALARM LED	AUDIBLE ALARM	AUDIBLE ALARM REPEAT
Line Power Plugged In	Informational	Off	Off	2 Pulses	No Repeat
Line Power Unplugged	Informational	Single Yel-low Pulse	Single Yellow Pulse	2 Pulses	No Repeat
External DC Power Supply Voltage Out of Range	Informational	Solid Yellow	Solid Yellow	2 Pulses	Every 15 Sec.
Battery Voltage too low for device to operate (E04)	Medium	Pulsing Yellow	Pulsing Yellow	3 Pulses	Every 25 Sec.
Oxygen level above the high alarm setting	Medium	Off	Pulsing Yellow	3 Pulses	Every 25 Sec.
Oxygen level below the low alarm setting	Medium	Pulsing Yellow	Off	3 Pulses	Every 25 Sec.
Oxygen level below the low oxygen alarm setting and lower than 18%	High	Pulsing Red	Off	5+5 Pulses	Every 15 Sec.

3.4 Backlight Operation

To turn on the backlighting:

1. When the unit is on, pressing the Backlight key will turn the backlighting on for 30 seconds. Additional presses will turn off the backlighting.
2. If the device is being used in a dark location, press any key to activate the back light.

⚠ **CAUTION:** Excessive use of the backlight can reduce the life of the batteries.

3.5 Sleep Mode Operation

To use the sleep mode function:

1. Remove the batteries from the unit.
2. Locate the sleep mode switch in the battery compartment and set to the ON position.
3. Replace the batteries in the unit.

The unit will now perform a normal boot-up operation with sleep mode enabled. With sleep mode enabled the unit will function with all the same parameters as outlined above with one new feature. While in the ON mode, the unit will time-out after 90 seconds to a battery saving condition. This condition will be indicated by a crescent moon on the display. While in this condition any key that is pressed will return the unit to the ON mode and reset the 90 second time-out counter. In sleep mode, the device will continue to monitor the oxygen level and will activate the alarm if an alarm condition occurs.

3.6 External Power Supply Operation

To extend the life of the batteries a Maxtec approved external power supply can be purchased. Once connected to the unit, total power is supplied by the external power supply. The batteries are still required to be in the unit and will provide emergency power in the event main AC power is lost.

NOTE: Use only the Maxtec approved external power supply in Section 9.0 Spare Parts and Accessories.

NOTE: The power supply is not a battery charger. **DO NOT** use rechargeable batteries.

WARNING: Do not position the equipment in a way that it would be difficult to unplug the power supply. Unplugging the power supply is the only means of disconnecting or isolating the equipment from AC mains power.

4.0 SENSOR REMOVAL AND REPLACEMENT

The MaxO2 ME is shipped with a new Max 550E oxygen sensor.

Although the sensor has a very long expected life, eventually the sensor will require replacement. Removing or installing a sensor, when necessary, is a very simple procedure.

To remove and install a new sensor:

1. Grasp the sensor in one hand and, with the other hand, unscrew the cable connector counter-clockwise at the sensor.
2. Pull out the cable connector plug from the expired sensor.
3. Unscrew the flow diverter from the sensor and discard the expired sensor or return it to Maxtec for proper disposal.

NOTE: The sensor contains lead and lead acetate, be sure to dispose of expired sensors in accordance with hospital, local, state and federal regulations.

4. Remove the new sensor from the packaging and remove the protective film from the sensor face.
5. Insert the cable connector plug into the receptacle of the new sensor and tighten the cable connector.
6. Screw the flow diverter onto the new sensor.
7. Wait approximately 20 minutes for the sensor to reach equilibrium.
8. Calibrate the new sensor.

NOTE: If the monitor is on when the sensor is detached and replaced, the monitor will automatically force a re-calibration. The display will read "CAL".

NOTE: If the cable locking nut is not fully fastened onto the sensor, then the sensor may not function properly.

5.0 PROBLEM SOLVING

The MaxO2 ME monitors 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.

NOTE: The operator must be facing the device and positioned within 4 meters to distinguish the visual alarm indicators. Audible alarms can be distinguished as long as the operator is in the same room and the ambient noise level is typical for a clinical setting.

LOW BATTERY ICON BAT: If the low battery icon is displayed on the LCD readout at any time, the batteries should be replaced as quickly as possible.

E01: Calibration error, sensor output lower than expected. See note below.

E02: No sensor attached. Reconnect sensor, see note below.

E03: No Valid Calibration Data Available, make sure unit has reached thermal equilibrium and perform a calibration routine.

E04: Battery Below Minimum Operating Voltage, replace batteries. A medium priority alarm will sound every 25 seconds until the batteries are replaced or become too dead to sound the alarm.

E05: Calibration error, sensor output higher than expected. See note below.

E06: Non-compatible oxygen sensor. Reconnect sensor, see note below.

E07: Calibration error, sensor output is not stable. See note below.

E08: Calibration error, battery too low to preform calibration. Replace batteries and re-calibrate.

NOTE: If you receive a E01, E05, or an E07 error code, correct by ensuring the calibration gas is either room air or 100% oxygen. Also ensure the calibration gas flow, pressure and concentration is constant. Allow sufficient time for the sensor to stabilize in the calibration gas and with room temperature, then attempt to calibrate again.

If these steps do not correct the error, contact Maxtec for technical support.

NOTE: Use only a Maxtec approved Max-550E sensor called out in Section 9.0 Spare Parts and Accessories. The Max 550E sensor is equipped with an authentication chip to ensure the monitor is used with an approved sensor.

NOTE: Correcting E02 or E06 errors:

1. Disconnect the sensor and reconnect, making sure the male plug is fully inserted into the receptacle before tightening the threaded locking shroud. The analyzer should now perform a new calibration with the error cleared.
2. If the error still persists, remove the batteries and external power, wait 30 seconds, then reinstall to perform a factory reset and diagnostic on the analyzer. The analyzer should again perform a new calibration with the error cleared.
3. Contact Maxtec Customer Service Department if the error code cannot be cleared.

6.0 CLEANING AND MAINTENANCE

6.1 Cleaning

The external surfaces of the device and its accessories can be cleaned and disinfected using the process detailed below. Under normal use conditions, the surfaces of the sensor and T-adapter / flow diverter that come in contact with gas delivered to the patient should not become contaminated. If you suspect that the sensing face of the sensor or internal surfaces of the T-adapter / flow diverter have become contaminated, these items should be discarded and replaced. Store the MaxO2 ME in a clean, dry location when not in use.

1. The MaxO2 ME needs to be cleaned between each patient's use.
2. Using Super Sani-Cloth germicidal disposable wipes (medical grade 2-in-1 cleaning / disinfecting wipes) remove all visible contamination from the external surfaces of the device and its accessories. Be sure to closely inspect and remove contamination from seams and recesses on the device that may trap contaminants.
3. After all visible contamination is removed, use a second germicidal wipe to thoroughly wet the surfaces of the device and accessories. Allow to remain wet for 4 minutes. Use additional wipes if needed to assure surfaces are wetted continuously for 4 minutes.
4. Allow device to air dry.
5. Visually inspect each component for visible contamination.

⚠ **CAUTION:** Excessive rubbing of labels may cause them to become illegible.

DO NOT spray cleaning solutions directly onto the monitor, sensor or buzzer opening.

DO NOT immerse the MaxO2 ME or sensor into liquid decontamination agents.

DO NOT use strong solvent cleaners.

DO NOT allow cleaning liquids to contact the face of the sensor as this may impair the readings of the sensor.

DO NOT attempt to sterilize the MaxO2 ME with steam, ethylene oxide or irradiation.

6.2 Alarm Testing

Periodic testing of alarms should be performed on a yearly basis.

To check the low alarm, adjust the low alarm setting to 23% or higher and expose the sensor to room air (20.9%). The low alarm LED should flash with the alarm sound.

To check the high alarm, adjust the low alarm setting to 17% or lower and the high alarm setting to 18% and expose the sensor to room air (20.9%). The high alarm LED should flash with the alarm sound. If one or both alarms malfunction, contact Maxtec Certified Service Technician.

6.3 Replacing Sensor Cable

After extended use or abuse to the sensor cable, the cable may begin to wear and lose its ability to properly retract.

The cable can be removed and replaced by disconnecting the threaded locking shroud at the sensor and monitor ends of the cable. Use only the Maxtec approved cable called out in Section 9.0 Spare Parts and Accessories.

NOTE: Ensure the cable locking shroud is fully threaded on the sensor and the monitor.

7.0 SPECIFICATIONS

7.1 Base Unit Specifications

Measurement Range 0.0-100%
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 temperature 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 ..... 4, AA Alkaline batteries (4 X 1.5 Volts)
Battery Life ..... approximately 5000 hours in typical use
Low Battery Indication ..... "LOW BAT" icon displayed on LCD
Sensor Type ..... Maxtec Max-550E galvanic fuel cell
Expected Sensor Life ..... >1,500,000% O2 Hours over 2 years in typical applications
Alarm System ..... high/low alarms, flashing red/yellow LEDs, nominal 975Hz audio buzzer (according to IEC 60601-1-8 Audible Alarms in Medical Equipment)
Alarm Volume (all priorities) ..... 70 dB(A) ± 7 dB(A) at 1 meter
Low Oxygen Alarm Range ..... 15%-99% (>1% lower than high alarm)
High Oxygen Alarm Range ..... 16%-100% (>1% higher than low alarm)
Alarm Accuracy ..... exact to displayed alarm value
Dimensions ..... 3.6"(W) x 5.8"(H) x 1.2"(D) [91mm x 147mm x 30mm]
Weight ..... approximately 0.89 lbs. (.40 kg)
Cable Length ..... 9 ft. (3m) fully extended
Diverter Fitting ..... fits industry standard, 15 mm "T" adapter

8.0 APPLICATIONS

8.1 Exposure to Anesthetic Gases

Because of the unique chemistry of the oxygen sensors provided with the MaxO2 ME monitor, there are no significant effects when exposed to commonly used anesthetic gases, however, the monitor is not designed for exposure to flammable gas mixtures (See WARNING page 2).

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

NOTE: Balance mixture 30% O2/70%N2O, unless otherwise specified.

8.2 Calibration Techniques in Pressurized Systems

Similar to other oxygen sensors, the Maxtec MAX series sensors measure the partial pressure of oxygen in a gas stream. This is correlated to read "percent oxygen" on the MaxO2 ME monitor. It is important to note that the sensor output is directly proportional to the partial pressure of oxygen. Thus, one must take into consideration the effect of exposing the sensor to various gas sample pressures.

For example, if a monitor is calibrated to read 20.9% in ambient air (atmospheric pressure) and then exposed to a pressurized gas sample containing a known concentration of oxygen, the monitor will display a reading greater than the actual oxygen percentage.

This is because the monitor was originally calibrated at atmospheric pressure (0 PSIG) then exposed to a higher pressure sample (i.e., 5 PSIG).

The greater the difference in pressure, the greater the difference in sensor signal (oxygen reading on the monitor).

If a monitor is calibrated on a pressurized gas sample containing a known concentration of oxygen and then exposed to ambient air (atmospheric pressure), the monitor will display a reading less than the actual oxygen percentage.To avoid confusion, the monitor can be calibrated at a single point on a gas stream similar to the application. If, for example, the purpose of the monitor is to measure oxygen in a concentrator or anesthesia application, the optimal results may be attained by calibrating the instrument on a gas of similar concentration and pressure. This would typically be done by connecting to a cylinder of a known high concentration of oxygen calibration gas and adjusting the flow and pressure to match the application before calibrating the instrument.

8.3 Calibration Errors

The MaxO2 ME monitor has a self test feature built into the software to detect faulty calibrations. During calibration, if the signal from the oxygen sensor is outside the limits stored within the instrument's memory, a flashing E01 or E05 error code is displayed. The error code is displayed to indicate that either the sensor should be replaced or that there is a fault in the calibration process. A few simple hints can prevent calibration errors. If you try to calibrate the monitor before the reading has stabilized, the E01 or E05 error code may appear. For example, if the monitor had just been calibrated on a known high concentration of oxygen source gas and then exposed to ambient air, you should wait until the reading has stabilized.

If you try to calibrate in room air before the sample line has cleared, the sensor may actually be exposed to residual oxygen. The signal from the sensor would still be high and considered out of range for air, thus resulting in an E05 or E07 error code. The proper procedure is to wait for the reading to stabilize before calibration.

Also note that the monitor may sense that the concentration is changing and an E07 error code will display.

Sensors come supplied with a flow diverter. The flow diverter helps direct the gas in a T-adapter up to the sensor for analysis. The flow diverter should be only used with a flowing gas. When using the sensor in a non-flowing environment, remove the diverter tip.

9.0 SPARE PARTS AND ACCESSORIES

PART NUMBER	ITEM
R140P02	Max-550E Sensor
R228P87	Battery Cover
R228P16	Sensor Cable
R228P10	Kickstand
R230M01	MaxO2 ME Operation Manual
R207P17	Barbed Concentrator Adapter for Sensor
R205P86	Monitor/Analyzer Wall Mount Bracket
R206P75	Monitor/Analyzer Pole Mount Clamp
RP16P02	Maxtec Approved Tee Adapter (15mm I.D.)
R110P10-001	Sensor Flow Diverter
R230P10	Maxtec Approved External Power Supply

Repair of this equipment must be performed by a Maxtec Certified Service Technician experienced in repair of portable hand held medical equipment.
Equipment in need of repair should be sent to:
Maxtec
Service Department
2305 South 1070 West
Salt Lake City, Ut 84119
1.800.748.5355
(Include RMA number issued by Customer Service)

10.0 ELECTROMAGNETIC COMPATIBILITY

The information contained in this section (such as separation distances) is in general specifically written with regard to the MaxO2 ME monitor. The numbers provided will not guarantee faultless operation but should provide reasonable assurance of such. This information may not be applicable to other medical electrical equipment; older equipment may be particularly susceptible to interference.

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

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

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

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

ELECTROMAGNETIC EMISSIONS		
This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should assure that it is used in such an environment.		
EMISSIONS	**COMPLIANCE ACCORDING TO**	**ELECTROMAGNETIC ENVIRONMENT**
RF Emissions (CISPR 11)	Group 1	The MaxO2 ME uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

CISPR Emissions Classification	Class A	The Max02 ME is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. **NOTE:** The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic Emissions (IEC 61000-3-2)	Class A	
Voltage Fluctuations	Complies	

ELECTROMAGNETIC IMMUNITY

This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should assure that it is used in such an environment.

IMMUNITY AGAINST	IEC 60601-1-2: (4TH EDITION) TEST LEVEL		ELECTROMAGNETIC ENVIRONMENT
	Professional Healthcare Facility Environment	Home Healthcare Environment	
Electrostatic discharge, ESD (IEC 61000-4-2)	Contact discharge: ±8 kV Air discharge: ±2 kV, ±4 kV, ±8 kV, ±15 kV		Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be kept at levels to reduce electrostatic charge to suitable levels. 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.
Electrical fast transients / bursts (IEC 61000-4-5)	Power supply lines: ±2 kV Longer input / output lines: ±1 kV		
Surges on AC mains lines (IEC 61000-4-5)	Common mode: ±2 kV Diferential mode: ±1 kV		
3 A/m power frequency magnetic field 50/60 Hz (IEC 61000-4-8)	30 A/m 50 Hz or 60 Hz		
Voltage dips and short interruptions on AC mains input lines (IEC 61000-4-11)	Dip>95%, 0.5 periods Dip 60%, 5 periods Dip 30%, 25 periods Dip >95%, 5 seconds		

Recommended separation distances between portable and mobile RF communications equipment and the equipment

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER W	Separation distance according to frequency of transmitters in meters		
	150 kHz to 80 MHz d=1.2/V1] √P	80 MHz to 800 MHz d=1.2/V1] √P	800MHz to 2.5 GHz d=2.3 √P
0.01	*0.12*	*0.12*	*0.23*
0.1	*0.38*	*0.38*	*0.73*
1	*1.2*	*1.2*	*2.3*
10	*3.8*	*3.8*	*7.3*
100	*12*	*12*	*23*

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 recommended separation distance calculated from the equation applicable to the frequency of the transmitter as below. **Recommended sparation distance:** d=1.2 √P d=1.2 √P 80 MHz to 800 MHz d=2.3 √P 800 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF immunity (IEC 61000-4-3)	3 V/m 80 MHz - 2.7 GHz 80% @ 1 KHz AM Modulation	10 V/m 80 MHz - 2.7 GHz 80% @ 1 KHz AM Modulation	

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

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

2305 South 1070 West
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