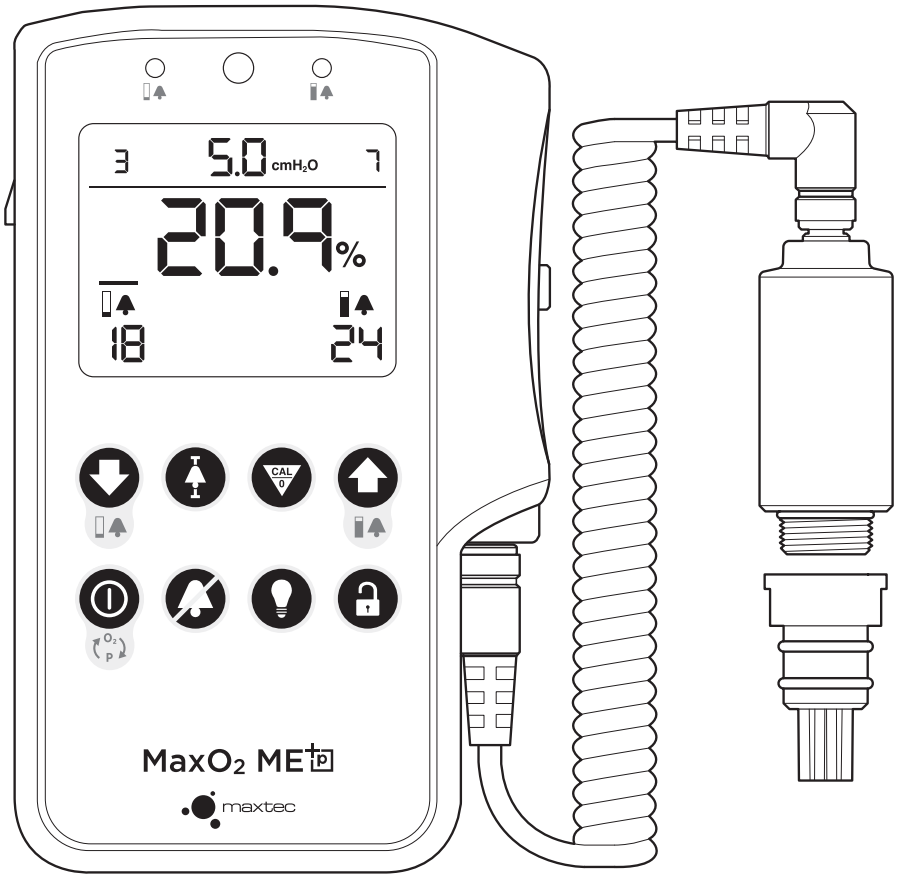

MaxO2® ME+p

Instructions for Use

ENGLISH

maxtec

R230M06 REV. C

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Intertek
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MEE

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 is intended for healthcare professionals. This device should only be used by clinically trained operators with sufficient knowledge, training and understanding of this manual.

This manual describes the function, operation and maintenance of the Maxtec Model MaxO2 ME+p oxygen and pressure monitor. The MaxO2 ME+p utilizes the Maxtec MAX-550E oxygen sensor and is engineered for fast response, maximum reliability and stable performance. The MaxO2 ME+p 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+p ideal for use in neonatal, anesthesia and respiratory care.

CLASSIFICATION

Protection against electric shock	Class II
Ingress Protection	IPX2
Mode of operation	Continuous
Sterilization	See section 7.1
Applied Parts	Type B (Entire Device)
Flammable anesthetic mixture	See section 9.1

Product Disposal Instructions:

The sensor, batteries, and circuit board are not suitable for regular trash disposal. Be sure to dispose of expired sensors in accordance with hospital, local, state, and federal regulations, or return to Maxtec for proper disposal or recovery. Follow local guidelines for disposal of other components. There are no special considerations for the disposal of the product packaging.

WARRANTY

The MaxO2 ME+p monitor is designed for medical oxygen delivery equipment and systems. Under normal operating conditions, Maxtec warrants the MaxO2 ME+p monitor to be free from defects of workmanship or materials for a period of two (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'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+p 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+p 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+p 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+p 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+p.

WARNINGS

FAILURE TO COMPLY WITH THESE WARNINGS AND CAUTIONS COULD RESULT IN INSTRUMENT DAMAGE AND POSSIBLY JEOPARDIZE THE WELL BEING OF THE PATIENT AND/OR HEALTH CARE PROFESSIONAL.

- Before use, all individuals who will be using the MaxO2 ME+p 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+p 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+p 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+p weekly when in operation and if environmental conditions change significantly. (I.e., Temperature, Humidity, Barometric Pressure. Refer to section 2.3 Calibrating the MaxO2 ME+p Monitor).
- Use of the MaxO2 ME+p near devices that generate electrical fields may cause erratic readings.
- If the MaxO2 ME+p 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+p (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 10.0 Spare Parts and Accessories.
- NOTE: The MaxO2 ME+p 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+p with a high pressure air gun. Applying high pressure air to the MaxO2 ME+p may damage components and render the system inoperable.

⃠ **DO NOT** over clean the MaxO2 ME+p. Repeated use of a cleaning agent can cause residue buildup on critical components. Excessive residue buildup can affect the MaxO2 ME+p's performance.

- When cleaning the MaxO2 ME+p: ⃠ **DO NOT** use harsh abrasives. ⃠ **DO NOT** immerse the MaxO2 ME+p 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+p. Standard sterilization techniques may damage the monitor.

- If the MaxO2 ME+p does not function as outlined in section 2.0, contact a Maxtec trained service technician or Maxtec for service.

⃠ **DO NOT** disassemble the MaxO2 MaxO2 ME+p. All service should be performed by a Maxtec Certified Service Technician.

⃠ **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+p.

- The MaxO2 ME+p and sensor are non-sterile devices.
- Regularly inspect the MaxO2 ME+p 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+p 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.
- To reduce the risk of cross contamination, only single use pressure monitoring line with an inline filter should be used with this device.

⃠ **DO NOT** allow liquids or debris to enter the pressure monitor port.

- Replace the pressure monitoring line if condensation build-up occurs.
- In order to reduce the potential issues associated with condensation, the pressure monitoring line connector should be positioned at least 10 inches (25cm) below the monitor.

⃠ **DO NOT** use for pressure in excess of 60 cmH_2O.

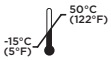
⃠ **DO NOT** connect pressure monitoring line to patient IV line.

- Secure the pressure monitoring line to avoid kinks and unintended disconnects.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the European Member State in which the user and/or patient is established as applicable.

TABLE OF CONTENTS

SYMBOL GUIDE

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

	On/Off and Mode Key		Silent Key		Federal law (USA) restricts this device to sale by or on order of a physician
	Calibration/Zero Key		Smart Alarm Key		Attention, consult accompanying documents *(blue background with white pictogram)*
	Calibration Reminder		Low Alarm Indicator		Single Use
	Unlock Key		Alarm Silence Indicator		Serial Number
	Backlight Key		Up (High Alarm) Key		Catalog Number
	High Alarm Indicator		Direct Current		Complies with Directive 2011/65/EU
	Smart Alarm Mode Indicator		Two means of patient protection (double insulated)		Ingress Protection Rating
	Down (Low Alarm) Key		Regulatory Compliance Mark		Combined UL / CSA Mark
	Power Supply Indicator		Meets ETL Standards		Corrosive
	Battery Indicator		Storage Temperature Range		Do not throw away. Follow local guidlines for disposal.
	Manufacturer		Date of Manufacture		Type B Applied Parts
	Warning		Do Not		Pressure Mode
	Caution		For use in dry indoor locations		Oxygen Mode
	MR Unsafe		Humidity Limitation		Power Plug Polarity
	Non-DEHP		Batch Code		Not Manufactured with Natural Rubber Latex
	Unique Device Identifier				

1.0 SYSTEM OVERVIEW

1.1 Base Unit Description

The MaxO2 ME+p is a handheld monitor capable of measuring the oxygen concentration from 0% to 100% and pressure from -15 – 60 cmH20 in a sample gas. This device should only be used by clinically trained operators with sufficient knowledge, training and understanding of this manual. A MAX-550E oxygen sensor outputs a voltage which is used by the MaxO2 ME+p to determine the concentration of oxygen based on a calibration at room air (21% 02) or pure (100% 02) oxygen. The pressure reading displayed is a 2 second mean pressure, relative to the ambient conditions, ie. referenced to ambient as 0. The monitor provides user adjustable low and high alarm limits which, when exceeded, trigger an audible and visual alarm. The associated low and high alarm limits are displayed to the left and right of the readings respectively. The monitor indirectly contacts the patient through the breathing gas pathway via the MAX-550 Oxygen sensor membrane

- Oxygen sensor of approximately 1,500,000 02 percent hours.
- External oxygen sensor 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.
- Battery level indicator.

- 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.

Indication for Use:

The MaxO2 ME+p is an oxygen monitor with integrated pressure monitoring intended for continuous monitoring of the concentration of oxygen and pressure being delivered to patients ranging from newborns to adults. It can be used in the hospital and subacute settings. The MaxO2 ME+p is not intended as a life-supporting device or life sustaining 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
- Pressure 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 **PRESSURE MONITOR PORT —** This port is used for connecting pressure monitoring line for pressure monitoring.

④ **COILED CABLE —** The coiled cable allows the sensor to be positioned up to 8 feet from the side of the unit.

⑤ **OXYGEN SENSOR WITH DIVERTER —** The sensor (with diverter) is designed to fit industry standard, 15mm I.D. "T" adapters.

⑥ **CALIBRATION KEY —** This key is used to calibrate or zero the device. The device must be in the unlocked state for the key to operate. See section 2.3 for instructions on calibrating.

⑦ **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.

⑧ **UNLOCK KEY —** The unlock key is used to unlock and lock the instrument.

⑨ **BACKLIGHT —** The backlight key will manually activate the backlight for 30 seconds. See section 3.4 for more information on backlighting operation.

⑩ **ALARM SILENCE KEY —** In an alarm condition, pressing the SILENT key will deactivate the audible alarm for 2 minutes.

⑪ **ON/OFF AND MODE 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. This button is also used to toggle between oxygen (02) and pressure (P) modes when the device is unlocked.

⑫ **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.

⑬ **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% or pressure alarms at ±2 cmH_20.

⑭ **EXTERNAL POWER SUPPLY PORT —** The port provides connection for the external power supply. See section 3.6 for more information on the power adapter.

⑮ **LCD DISPLAY—**The liquid crystal display (LCD) provides direct readout of oxygen concentrations and pressures. The digits also display error codes, alarm set modes and calibration codes as necessary.

⑯ **PRESSURE READING —** Current pressure reading of the sample in centimeters of water (cmH_20).

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

⑱ **OXYGEN CONCENTRATION —** Current oxygen concentration percentage from the oxygen sensor.

⑲ **HIGH ALARM INDICATOR —** High alarm symbol used for identifying the high alarm setpoints and when a high alarm is triggered.

⑳ **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.

㉑ **POWER SUPPLY INDICATOR —** Indicates when the device is connected and receiving power from an external power supply. **NOTE:** Batteries are still required for proper operation.

㉒ **CALIBRATION REMINDER —** 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 oxygen calibration.

㉓ **BATTERY INDICATOR —** The battery indicator is located at the bottom of the display and bars indicate approximate battery level remaining.

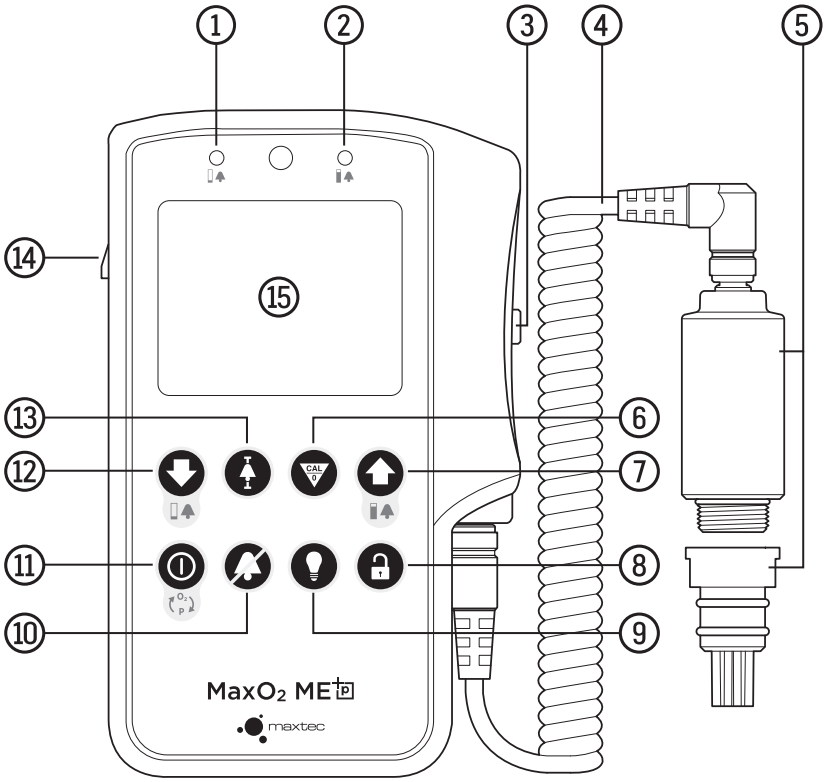
㉔ **ALARM SILENCE/SMART ALARM INDICATOR —** When the silent key is pressed the indicator will display with cross bars to alert condition. When Smart Alarm Mode Button is pressed the indicator will display with T-bars to alert condition.

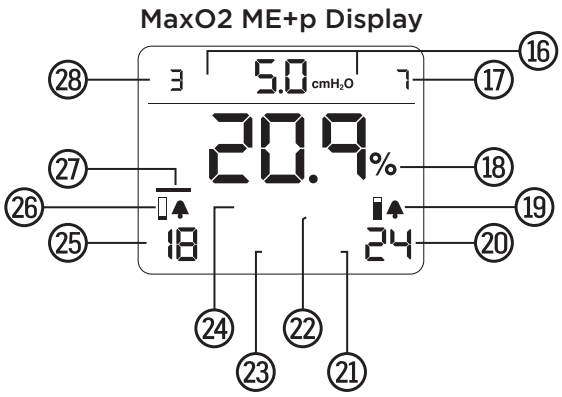
㉕ **OXYGEN LOW ALARM LIMIT —** Low oxygen alarm setpoint. Audible and visual alarms will trigger when this limit is exceeded.

㉖ **LOW ALARM INDICATOR —** Low alarm symbol used for identifying the low alarm setpoints and when a low alarm is triggered.

㉗ **<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.

㉘ **LOW PRESSURE ALARM LIMIT —** Low pressure alarm setpoint. Audible and visual alarms will trigger when this limit is exceeded. Double dashes (--) indicates the alarm is inactive.





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. Be sure to dispose of expired sensors in accordance with hospital, local, state, and federal regulations, or return 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+p 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+p, 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+p 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 10.0 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.

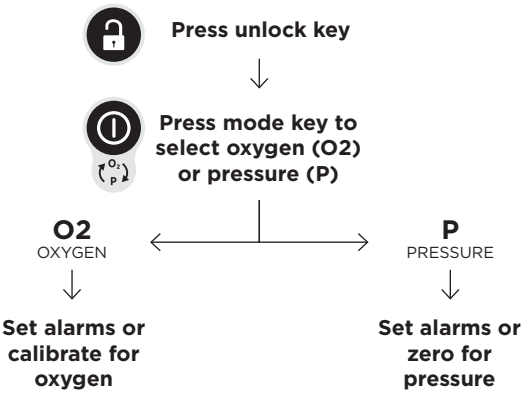
BATTERY ICON : The battery bars indicate the approximate remaining power in the batteries.

Indicator	Battery Level
	100%
	80%
	60%
(1 bar flashing)	40%
(Outline flashing)	20%
+ E04 (Outline flashing + E04)	0%

2.2 Adjusting Alarm and Calibration Modes

You must select oxygen O2 or pressure P mode prior to adjusting alarms or performing a calibration/zero. To set the device mode:

1. Unlock the device by pressing the unlock key.
2. Once unlocked the display will flash and you can toggle either oxygen O2 or pressure P mode by pressing the power/mode key.
3. The respective alarms and calibration may now be performed.



2.3 Calibrating the MaxO2 ME+p Monitor

2.3.1 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+p 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+p 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.

Perform a zero calibration if the monitor displays a non-zero pressure reading prior to use.

2.3.2 To Calibrate the MaxO2 ME+p 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. Verify device is in O2 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.

2.3.3 To Calibrate the MaxO2 ME+p 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. Verify device is in O2 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.

2.3.4 Factors Influencing Oxygen Calibration

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

Effects of Temperature

The MaxO2 ME+p 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+p 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+p 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+p 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.

2.3.5 Zero Calibration

A zero calibration resets the zero point of the pressure sensor, the measurement when no pressure is connected. Perform a zero calibration if the monitor displays a non-zero pressure reading when no pressure is connected.

To zero the device:

1. Ensure no pressure is connected to the device and open to room air.
2. Unlock the device by pressing the unlock key.
3. Select pressure mode by pressing the power/mode button until P is shown on the display.
4. Press the CAL/0 button. The display will flash '0.0' until the zeroing has been completed.
5. Verify the pressure display reads 0.0 cmH_2O once zeroing is complete.

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.

   Select oxygen or pressure by pressing the power/mode key.

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% or 1 cmH_2O increments. If the keys are held down for more than 1 second the display will scroll at a rate of 1% or 1 cmH_2O 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 and off (––) for pressure. 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.

   Select oxygen or pressure by pressing the power/mode key.

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% or 1 cmH_2O increments. If the keys are held down for more than 1 second the display will scroll at a rate of 1% or 1 cmH_2O per 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% or 60 cmH_2O 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 and 15 cmH_2O pressure. Removing the batteries will reset the high alarm limits to 50% and 15 cmH_2O.

3.1.3 Smart Alarm Mode

NOTE: Smart alarms function as alarm guardrails which simultaneously set the low and high alarms to ± 3% oxgyen or ± 2 cmH_20 of the current oxygen or pressure 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. Select oxygen or pressure by pressing the power/mode key .
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% or + 2 cmH_20 (rounded to the nearest integer). The low alarm will now be set to be equal to the current reading -3% or - 2 cmH_20 (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 or above 60 cmH_20 or below 1 cmH_20 for pressure.
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.

3.1.4 Pressure Monitoring and Alarms

The monitor displays the mean pressure using a 2 second average. Pressure monitoring begins immediately once the device is powered on. The device will activate an audible and visual (LED) alarm whenever the alarm limits are exceeded, however the pressure alarms are delayed by 3 seconds to allow for momentary fluctuations in pressure and reduce unnecessary alarm disturbances.

By default, the pressure alarms are set to off (--) for the LOW alarm and and 15 cmH_20 for the HIGH alarm. Pressure alarms are automatically saved in the device memory and recalled to the last settings whenever the device is powered on/off. Alarm default setpoints are only reset by removing and re-installing the batteries.

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.

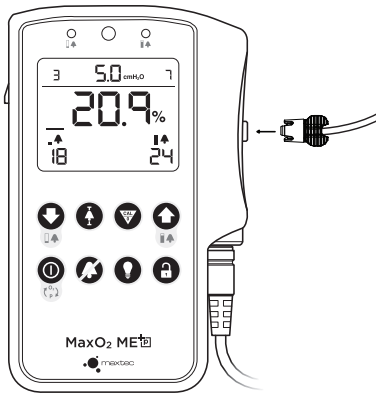
3. Initiate flow of the sample gas to the sensor.

3.2.1 Pressure Monitoring Operation

The monitor measures pressure using pressure monitoring line with moisture control tubing that includes and inline filter. The filter protects the monitor from moisture and reduces the risk of cross contamination. The pressure monitoring line and filter is single use and should always be discarded between patients. When in use on a single patient in an ongoing procedure, it must be discarded and replaced every 30 days or sooner

To begin pressure monitoring:

1. Perform a zero calibration if the monitor displays a non-zero pressure reading. (See section 2.3.5)
2. Locate the pressure monitor port on the device and push in the connector of pressure monitoring line until it clicks into place.



3. Locate and attach the other end of the pressure monitoring line into the circuit to be monitored using the Luer connector.
4. Adjust the low and high pressure alarms to the desired range. Alternatively, the pressure alarms may be set automatically using the smart alarm button.
5. The device will now monitor pressure between the set range.

WARNING: In order to reduce the potential issues associated with condensation in the pressure monitoring line, the pressure monitoring line connector should be positioned at least 10 inches (25 cm) below the monitor.

WARNING: To reduce the risk of cross contamination, only single use pressure monitoring line with an inline filter should be used with this device.

WARNING: This product may expose you to chemicals known to the state of California to cause cancer and/or reproductive harm. For more information, go to www.p65warnings.ca.gov

DO NOT allow liquids or debris to enter the pressure monitor port.

- Replace the pressure monitoring line if condensation build-up occurs.

DO NOT use for pressure in excess of 60 cmH_20.

DO NOT connect pressure monitoring line to patient IV line.

- The pressure monitoring line is intended to be used on an individual patient during a single procedure then disposed of. The pressure monitoring line must be discarded and replaced between each patient and procedure. When in use on a single patient in an ongoing procedure, it must be discarded and replaced every 30 days or sooner. The pressure monitoring line is NOT intended to be reprocessed.

3.2.2 Disabling Oxygen Monitoring

The MaxO2 ME+p may be used to monitor pressure only by disabling the oxygen monitor. The oxygen monitoring function may be disabled by disconnecting the oxygen sensor and cable. The MaxO2 ME+p will display an E02 error indicating a sensor disconnect. Acknowledge the error by pressing the alarm silence key. This will clear the error and the display will read - - -, indicating the oxygen sensor has been removed and no oxygen reading is available. In this configuration, the MaxO2 ME+p will only monitor pressure in the upper portion of the display with the associated low and high alarms. The oxygen monitoring function may be restored by reattaching the oxygen sensor and cable, which will trigger an automatic calibration of the oxygen sensor.

NOTE: The oxygen sensor disconnect error (E02) will repeat anytime the device is turned off with the oxygen sensor disconnected.

WARNING: Disconnecting the oxygen sensor will disable all oxygen monitoring functions and alarms.

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.

An alarm condition will remain until the actual oxygen concentration or pressure is within the alarm range.

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 Yellow Pulse	Single Yellow Pulse	2 Pulses	No Repeat
External DC Power Supply Voltage Out of Range	Informational	Solid Yellow	Solid Yellow	2 Pulses	Every 35 Sec.
No oxygen sensor attached (E02)	Medium	Pulsing Yellow	Pulsing Yellow	3 Pulses	Every 25 Sec.
Battery Voltage too low for device to operate (E04)	Medium	Pulsing Yellow	Pulsing Yellow	3 Pulses	Every 25 Sec.
Oxygen/ pressure level above the high alarm setting	Medium	Off	Pulsing Yellow	3 Pulses	Every 25 Sec.
Oxygen/pressure 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.

3.3.1 Multiple Alarms

When multiple alarms occur the LOW or HIGH alarm LED will flash respectively along with the numeric alarm values that have been triggered. If both a LOW and HIGH alarm are triggered at the same time the highest priority LED and tone will be produced. The alarm LEDs and tones will automatically default to the highest priority alarm. Alarms will automatically clear once the reading has returned within the specified alarm window.

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 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 10.0 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+p 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, or return to Maxtec for proper disposal or recovery.

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".

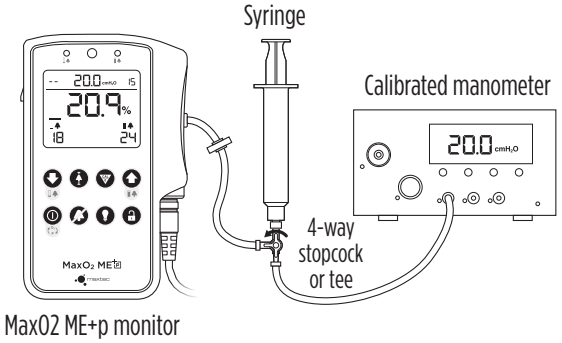
NOTE: If the cable locking nut is not fully fastened onto the sensor, then the sensor may not function properly.

5.0 PRESSURE MONITOR TESTS

5.1 Pressure Monitor Accuracy Test

A Pressure Monitor Accuracy Test is recommended annually to verify performance of the pressure monitor. The process involves applying a known pressure to the device and confirming the readings using a calibrated manometer (pressure gauge). Use a calibrated manometer with accuracy ≤ ±0.5 cmH2O.

1. Turn the device on and zero the pressure reading. (See section 2.3.5)
2. Use a clean syringe with a 4-way stopcock or tee and create the test setup shown.
3. Slowly apply pressure with the syringe to several test points across the range of pressure measurement ⚠ **WARNING:** Do not exceed 60 cmH2O. Over pressurizing the device may result in permanent damage to the pressure sensor.
4. The readings between the device and the calibrated manometer should be within ±1.0 cmH2O. Contact Maxtec technical service if the device fails to function as expected.



6.0 TROUBLESHOOTING

The MaxO2 ME+p 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.

E01: Calibration error, sensor output lower than expected. See applicable note at end of Trouble shooting section.

E02: No sensor attached. Reconnect sensor, see applicable note at end of Trouble shooting section.

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 applicable note at end of Trouble shooting section.

E06: Non-compatible oxygen sensor. Reconnect sensor, see applicable note at end of Trouble shooting section.

E07: Calibration error, sensor output is not stable. See applicable note at end of Trouble shooting section.

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

E09: Pressure out of range, too high. The pressure applied to the monitor port has exceeded the device maximum pressure. Remove the pressure or adjust within the allowable range.

E10: Pressure out of range, too low. The pressure applied to the monitor port has exceeded the device minimum pressure. Remove the pressure or adjust within the allowable range.

E11: Pressure zero calibration unstable. Ensure pressure is stable and attempt a new zero calibration. If error persists, contact Maxtec technical service.

E12: Pressure CAL/0 out of range.

E13: Pressure sensor error. No valid pressure sensor data. Remove batteries from device to reset and perform a new CAL/0. If error persists, contact Maxtec technical service.

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 10.0 Spare Parts and Accessories. The Max550E 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.

7.0 CLEANING AND MAINTENANCE

7.1 Cleaning

NOTE: Device should be cleaned and disinfected prior to patient use.

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+p in a clean, dry location when not in use.

1. 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.
2. 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.
3. Allow device to air dry.
4. Visually inspect each component for visible contamination.

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

NOTE: Be sure to thoroughly clean and disinfect the areas depicted. These regions are contacted during normal use and may contribute to cross contamination if not disinfected properly. To prevent overcleaning, if sanitation is required, sanitization should be limited to once between each patient use. Other necessary cleanings should be done with a germicidal wipe or mild detergent and water.

NOTE: the device should be discontinued from service if material degradation or cracking are observed.

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

⃠ **DO NOT** immerse the MaxO2 ME+p 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+p with steam, ethylene oxide or irradiation.

⃠ **DO NOT** allow liquids to enter the pressure monitor port.

7.2 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.

7.3 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 listed in Section 10.0 Spare Parts and Accessories.

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

8.0 SPECIFICATIONS

8.1 Base Unit Specifications

Expected Service Life	7 years
Measurement Range	0.0-100% O2
Resolution	0.1% O2
Accuracy and Linearity	±1% O2 of full scale at constant temperature, R.H. and pressure when calibrated at full scale
Total Accuracy	±3% O2 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)
Power Specification ..... 7.5V(MAX) ⎓ 1.9W.250mA(MAX)
Battery Life ..... approximately 5000 hours in typical use
Low Battery Indication ..... 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 1.01 lbs. (0.46 kg)
Cable Length ..... 9 ft. (3m) fully extended
Diverter Fitting ..... fits industry standard, 15 mm "T" adapter

8.2 Pressure Monitor Specifications

Pressure measurement range ..... -15.0 - 60.0 cmH_2O
Display resolution ..... 0.5 cmH_2O
Pressure Accuracy ..... ±1.0 cmH_2O
High Pressure Alarm Range ..... 1-60 cmH_2O, Off (--)
Low Pressure Alarm Range ..... (--) Off, 1-30 cmH_2O
Pressure Alarm Resolution ..... 1 cmH_2O

9.0 APPLICATIONS

9.1 Exposure to Anesthetic Gases

Because of the unique chemistry of the oxygen sensors provided with the MaxO2 ME+p 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 II).

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%N20, unless otherwise specified.

9.2 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+p 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.

9.3 Calibration Errors

The MaxO2 ME+p 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.

10.0 SPARE PARTS AND ACCESSORIES

PART NUMBER	ITEM
R140P02	Max-550E Sensor
R228P09	Battery Cover
R228P16	Sensor Cable
R228P10	Kickstand
R230M06	Max02 ME+p 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
R228P45	Pressure Monitor Port Cover
R229P18-015	Pressure Monitoring Line with Moisture Control Tubing (Qty 15)

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)

11.0 ELECTROMAGNETIC COMPATIBILITY

The Max02 ME+p is suitable for the electromagnetic environment of typical hospital settings. The user should assure that it is used in such an environment.

During the immunity testing described below the Max02 ME+p will monitor oxygen and pressure 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 Max02 ME+p, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ WARNING: The Max02 ME+p should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Max02 ME+p should be observed to verify normal operation. If operation is not normal, the Max02 ME+p or the other 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 of EMI (electromagnetic interference) such as diathermy, lithotripsy, electrocautery, RFID (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, reposition the equipment if possible, to maximize distances.

ELECTROMAGNETIC EMISSIONS		
EMISSION TESTS	**COMPLIANCE**	**ELECTROMAGNETIC ENVIRONMENT – GUIDANCE**
RF Emissions CISPR 11	Group 1	The Max02 ME+p 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.
RF Emissions CISPR 11	Class A	The Max02 ME+p is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: WARNING: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Max02 ME+p or shielding the location.
Harmonic Emissions IEC 61000-3-2	NA	
Voltage fluctuations / flicker emissions IEC 61000-3-3	NA	

ELECTROMAGNETIC IMMUNITY		
IMMUNITY TEST	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT – GUIDANCE**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact ± 2, 4, 8 and 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% .5 Periods 0% 1 Period 70% 25 Periods 0% 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Max02 ME+p requires continued operation during power mains interruptions beyond that provided by the battery, it is recommended that the Max02 ME+p is powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m 50 and 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the A/C. mains voltage prior to application of the test level.		

ELECTROMAGNETIC IMMUNITY		
IMMUNITY TEST	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT – GUIDANCE**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 V rms in ISM bands	The Max02 ME+p is suitable for the electromagnetic environment of typical hospital settings.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	

The Max02 ME+p has been tested to comply with the immunity requirements of AIM 7351731, Medical Electrical Equipment & System Electromagnetic Immunity Test for RFID Readers.

The Max02 ME+p 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

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