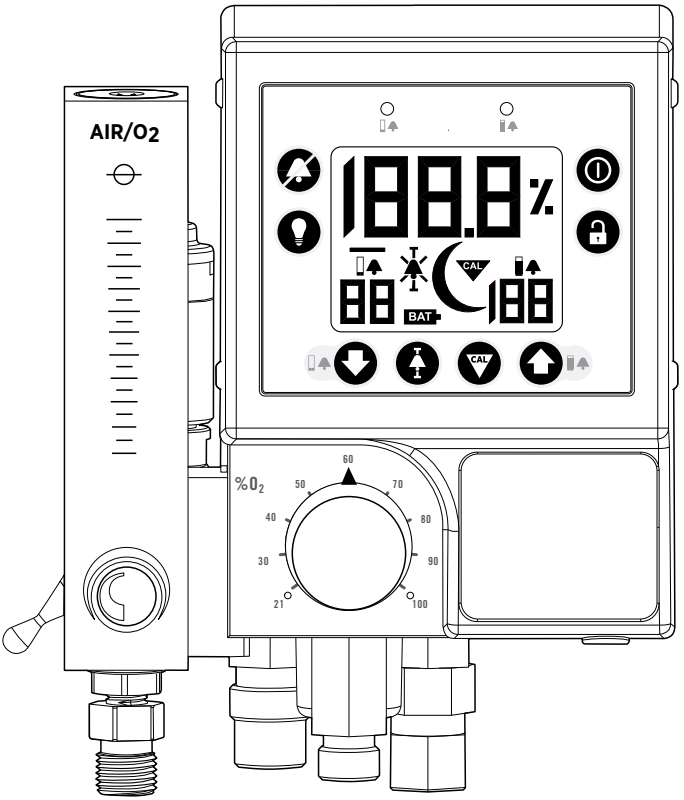


# MAXBlend™ 2

LOW FLOW / HIGH FLOW

## OPERATING MANUAL & INSTRUCTIONS FOR USE

R229P01 / R229P02

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ETL CLASSIFIED

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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

Read this entire manual before attempting to operate or service the MAXBlend2. Attempting to operate the MAXBlend2 without fully understanding its features and functions may result in unsafe operating conditions.

## CLASSIFICATION

Protection class:. . . . . II, Type B
Protection against water: . . . . . IPX1
Mode of operation:. . . . . Continuous
Sterilization:. . . . . See section 6.0
Safety of application in the presence of a flammable anesthetic mixture:. . . . . See section 9.4
Power specification:. . . . . 7.5V(MAX) ⎓ 1.9W/250mA(MAX)

**CAUTION**: Federal law restricts this device to sale by or on the order of a medical professional.

### 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.

## WARRANTY

The MAXBlend2 is designed for air/oxygen delivery. Under normal operating conditions, Maxtec warrants the MAXBlend2 to be free from defects of workmanship or materials for a period of two 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 MAXBlend2 to be free from defects in material and workmanship for a period of two years from Maxtec's date of shipment in a MAXBlend2 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 MAXBlend2, all operation and maintenance must be performed in accordance with this manual. Please read the manual thoroughly before using the MAXBlend2 and do not attempt any repair or procedure that is not described herein. Maxtec cannot warranty any damage resulting from misuse, unauthorized repair or improper maintenance of the instrument.

## EMC Notice

This equipment generates, uses, 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 MAXBlend2 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 MAXBlend2.

## WARNINGS ⚠

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

**The following warnings apply any time you operate or service the MAXBlend2:**

» Always confirm prescribed flow before administering to patient and monitor flow on a frequent basis.
» Always follow ANSI and CGA standards for medical gas products and flowmeters and oxygen handeling.
⦸ **DO NOT** operate the MAXBlend2 unless qualified personnel are in attendance to promptly respond to alarms, inoperative conditions, or sudden malfunctions. Patients on life-support equipment should be visually monitored at all times.
⦸ **DO NOT** ignore audible alarms of the MAXBlend2. Alarms indicate conditions that require your immediate attention.
⦸ **DO NOT** use parts, accessories, or options that have not been authorized for use with the MAXBlend2. Using unauthorized parts, accessories, or options may be harmful to the patient or damage the MAXBlend2.
» Check all audible and visual alarms periodically to ensure they are operating properly. If an alarm fails to activate, contact your Maxtec Certified Service Technician.
⦸ **DO NOT** operate the MAXBlend2 with the monitor powered off or without setting the adjustable alarms. All adjustable alarms must be set to ensure safe operation.
⦸ **DO NOT** steam autoclave or otherwise subject the MAXBlend2 to temperatures above 122°F (50°C).
» If the air or oxygen gas source fails, the pressure differential alarm will sound alerting the clinician that a condition has occurred that may significantly alter the $FiO_2$ and flow output from the MAXBlend2.
» If either the air or oxygen source pressure is reduced or increased sufficiently to create a pressure differential of 20 PSI or more, an audible alarm will sound. This condition may significantly alter the $FiO_2$ and flow output from the MAXBlend2.
⦸ **DO NOT** use humidified oxygen to calibrate this system. If calibrated with humidified oxygen, subsequent oxygen readings will be higher than the true oxygen level.
⦸ **DO NOT** tape, obstruct or remove the alarm during clinical use.
⦸ **DO NOT** occlude the sensor port on the side of the MAXBlend2.
» An air inlet/water filter is recommended for use with the MAXBlend2. See section 6.1.
» If the MAXBlend2 does not function as described in section 2, contact your maxtec distributor or Maxtec Certified Service Technician.
⦸ **DO NOT** use lubricants on the MAXBlend2.

⦸**DO NOT** use the MAXBlend2 until correct performance has been verified. See section 3.0.
» If a condition is detected that could possibly prevent the monitor from continuing to operate safely, it will sound an alarm. If at any time, EOx (i.e. EO2, EO4, etc.) appears on the LCD, refer to section 4.0 or contact a Maxtec Certified Service Technician.
» All service should be referred to a Maxtec Certified Service Technician.
» Elastomer components such as O-rings are designed to function satisfactorily for a minimum of two years. Maxtec recommends that the MAXBlend2 be serviced by Maxtec at a minimum of every two years or if a leak or other performance problem is suspected.
» If the MAXBlend2 is dropped, follow the procedures outlined in section 3.0 for a performance check before reusing the device.
» Always remove the batteries to protect the unit from potential leaky battery damage when the unit is going to be stored (not in use for more than 30 days).
» Always replace batteries with recognized name brand AA alkaline batteries.
» The MAXBlend2 has the ability to set the low oxygen alarm below 18% and can be set as low as 15% (see section 2.3 on setting alarms). This is in accordance with IEC 80601-2-55.

**To prevent risk of burns, fire or injury to person(s):**

» The mixed gas bleed continuously bleeds to atmosphere at the oxygen concentration setting of the control knob. Bleeding oxygen into any closed area could increase the risk of fire or explosion.⦸**DO NOT** operate this device in the presence of any flame or source of ignition; or when using equipment such electrosurgical equipment or defibrillators.
» To avoid explosion,⦸**DO NOT** operate the MAXBlend2 in the presence of flammable anesthetics or in an atmosphere of explosive gases. Operating the MAXBlend2 in flammable or explosive atmospheres may result in fire or explosion.
» Galvanic $O_2$ sensor electrolyte gel is acidic and may cause skin or eye irritation and/or burns. Take care when handling or replacing exhausted or damaged disposable $O_2$ sensors. Be sure to dispose of expired sensors in accordance with hospital and/or governmental regulations ($O_2$ Sensor SDS upon request from Maxtec).
⦸**DO NOT** use or store oils, greases, organic lubricants or any combustible materials on or near this device.

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

⦸**DO NOT** store the MAXBlend2 in hot areas for prolonged periods of time. Temperatures above 80°F (27°C) can shorten battery life.
» To minimize the potential for electrostatic shock, do not use antistatic or electrically conductive hoses with the MAXBlend2.
⦸**DO NOT** clean or dry the MAXBlend2 with a high pressure air gun. Applying high pressure air to the MAXBlend2 may damage components and render the system inoperable.
⦸**DO NOT** over clean the MAXBlend2. Repeated use of a cleaning agent can cause residue buildup on critical components. Excessive residue buildup can affect the MAXBlend2's performance.
» When cleaning the MAXBlend2:⦸**DO NOT** use harsh abrasives.⦸**DO NOT** immerse the MAXBlend2 in liquid sterilizing agents or liquids of any kind.⦸**DO NOT** spray cleaning solution directly onto the sensor port, bleed muffler or buzzer opening.⦸**DO NOT** allow cleaning solution to pool on the front panel,sensor port or bleed muffler.
⦸**DO NOT** sterilize the MAXBlend2. Standard sterilization techniques may damage the blender.
⦸**DO NOT** smoke in an area where oxygen is being used.
» If the MAXBlend2 does not function as outlined in section 2.0, contact a Maxtec trained service technician or Maxtec for service.
⦸**DO NOT** attempt to clean the MAXBlend2 using agents or methods other than those specified in the cleaning section of this document.
» Dropping or severely jarring the sensor after calibration may shift the calibration point enough to require recalibration.

» Always operate the MAXBlend2 with clean, dry medical grade gases. Contaminants or moisture can cause defective operation. Oxygen should have a minimum dewpoint of -80°F (-62°C) or moisture content less than 7.9 PPM (0.0059mg/L). Oxygen "purity" should be at least 99.0% and air used should be medical grade. Water vapor content must not exceed a dew point of 5°F (-15°C) below the lowest ambient temperature to which the delivery system is exposed. Particulate content must not exceed that which would be found immediately downstream of a 15 micron absolute filter. Refer to CGA commodity specifications G-4.3 and G7.1 for more information. Water vapor content of medical air or $O_2$ supply to the blender must not exceed 5.63 x $10^3$ milligrams $H_2O$ per cubic meter of non-condensible gas.

⊘ **DO NOT** disassemble the MAXBlend2. All service should be performed by a Maxtec Certified Service Technician.

⊘ **DO NOT** use humidified oxygen to calibrate this system.

» Be sure the MAXBlend2 is securely mounted. This device is usually mounted to a hospital rail system or an infusion stand. Dropping the device may cause injury or device damage.

» The oxygen sensors contain a weak acidic solution encapsulated in a plastic housing. Under normal operating conditions the solution (electrolyte) is never exposed.

⊘ **DO NOT** use the oxygen sensor if it appears to be damaged or is leaking.

**NOTES:** Indicates supplemental information to assist in use of the device.

» The MAXBlend2 is tested for compliance with ISO 11195, and meets requirements regarding reverse gas flow as delivered.

» Applicable parts used in the MAXBlend2 have been cleaned and degreased for oxygen service. Any lubricants used are designed specifically for the application.

» As long as the absolute pressure of the gas mixture being monitored is constant, the MAXBlend2 will accurately read oxygen concentrations. However, if the absolute pressure varies the reading will fluctuate proportionately as the sensor actually measures the partial pressure of oxygen in the mixture. The sensor readings will also change proportionately with barometric pressure changes. Because of this, daily calibration of the sensor is recommended.

» Users are advised to use pressure regulators which display the outlet pressure.

» All specifications assume the following standard environmental conditions, unless specified otherwise. Ambient and sample gas temperatures of 77°F (25°C); barometric pressure of 30inHg (760mmHg); sea level altitude; ambient relative humidity of 50%; sample gas relative humidity of 0%.

» It is important to note that the oxygen concentration selection scale is provided only as a guideline for selecting $O_2$ concentrations. The clinician should use the MAXBlend2's display panel to adjust the $O_2$ concentration to the desired setting.

» 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.

» This device does not contain automatic barometric pressure compensation.

» 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.

# TABLE OF CONTENTS

# 1.0 INTRODUCTION

The MAXBlend2 is a compact air/oxygen gas mixing device which incorporates the use of a battery powered oxygen monitor. The gas mixing device (blender) provides precise mixing of medical grade air and oxygen, while the monitor measures the selected oxygen concentrations from the blender's gas flow and displays these measured concentrations on a digital display. The monitor provides high and low alarm limits which, when exceeded, cause an audible and visual alarm.

## 1.1 Indication for Use

The MAXBlend2 is designed to provide a continuous air/oxygen gas mixture and to continuously monitor the concentration of oxygen being delivered to infant, pediatric, and adult patients. It is a restricted medical device intended for use by qualified, trained personnel, under the direction of a physician, in professional healthcare settings, i.e., hospital, sub-acute, and nursing-care facilities where the delivery and monitoring of air/oxygen mixtures is required.
This is not intended as a life supporting device.

## 1.2 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 teflon membrane and an electrolyte. Oxygen diffuses through the teflon 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 and lead (Pb). These materials 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 re-calibration.

### 1.3 Symbol Guide

The following symbols and safety labels are found on the MAXBlend2:


ON/OFF Key


Silent Key


Backlight Key


Unlock Key


Smart Alarm Key

CAL (Calibration Key)


Sleep Mode Indicator


High Alarm Indicator


Low Alarm Indicator

Calibration Reminder


Smart Alarm Mode Indicator


Alarm Silence Indicator


Below 18% Alarm Indicator

Low Battery Indicator


DOWN (LOW ALARM) Key


UP (HIGH ALARM) Key

### SYMBOL GUIDE

The following symbols and safety labels are found on the MAXBlend2 and/or labeling:


Do Not


Manufacturer


Direct Current


Warning


Corrosive


Attention, consult accompanying documents


Type B Applied Parts

Ingress Protection Rating

Authorized Representative in the European Community

Catalog Number

Serial Number

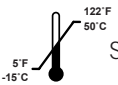
Oxygen Percent

Liters Per Minute


Use No Oil

Oxygen Encriched Air

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



Storage Temperature Range


Do not throw away. Follow local guidelines for disposal.

Meets ETL standards


Outlet


Inlet


Read Flow At Center Of Ball

### POWER SUPPLY SYMBOL GUIDE

The following symbols and safety labels are found on the MAXBlend2 power supply:


Two means of patient protection (double insulated)


Consult Instructions For Use



Complies with Directive 2011/65/EU


Do not throw away. Follow local guidelines for disposal.



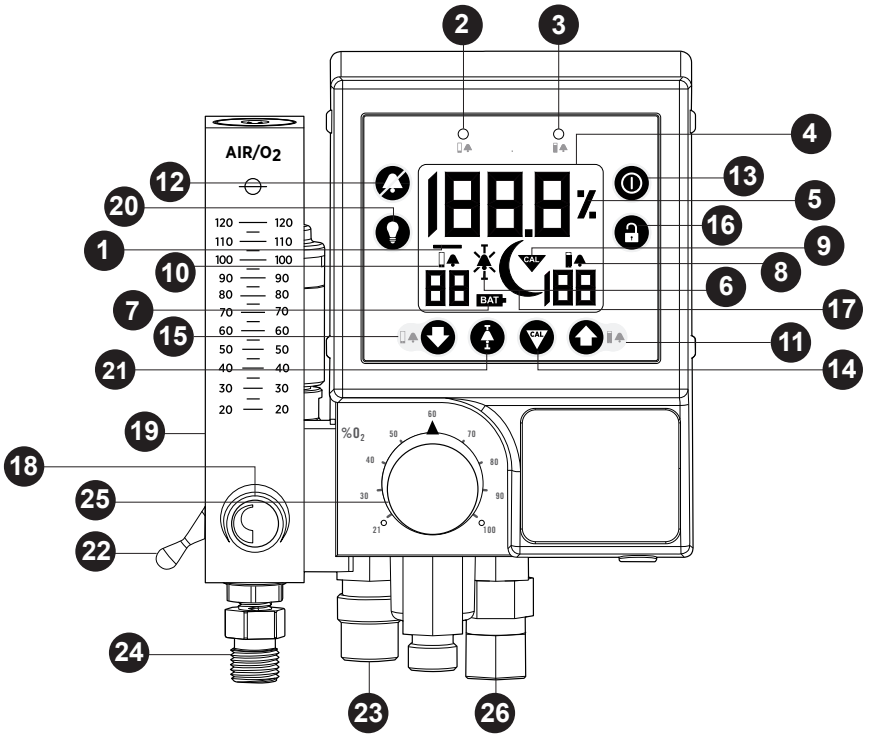
Power Supply Meets CEC Tier 3 and EU Phase 2 Standards


Conforms to EU requirements


For use in dry indoor locations



Combined UL / CSA Mark




### 1.4 Component Identification

① **<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 2.3.1 for setting this low alarm condition.

② **Low Alarm LED -** In a low alarm condition, the red "LOW ALARM" LED will flash twice a second, accompanied by the audio buzzer.

③ **High Alarm LED -** In a high alarm condition, the red "HIGH ALARM" LED will flash twice a second accompanied by the audio buzzer.

④ **3 1/2-Digit Display -** The 3 1/2 digit liquid crystal display (LCD) provides direct readout of oxygen concentrations. The digits also display error codes, alarm set modes and calibration codes as necessary.

⑤ **% Symbol -** The "%" sign is located to the right of the concentration number and is present during normal operation.

⑥ **Alarm Silence/Smart Alarm Indicator -** When the Silent key is pressed the indicator will display with cross bars to alert condition. When Smart Alarm key is pressed the indicator will display with T-bars to alert condition.

⑦ **Low Battery Indicator -** BAT The low battery indicator is located at the middle of the display and is only activated when the voltage on the batteries is below a normal operating level.

⑧ **High Alarm Indicator -** The high alarm setting is displayed at all times just below the "HIGH" icon on the LCD readout. The indicated value represents the oxygen percentage at which the high alarm will be activated.

⑨ **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.

⑩ **Low Alarm Indicator -** The low alarm setting is displayed at all times just below the "LOW" icon on the LCD readout. The indicated value represents the oxygen percentage at which the low alarm will be activated.

⑪ **Up (Alarm High) Key -** The up key is used in setting the high $FiO_2$ alarm limit. The device must be in the unlocked state for the key to operate. See section 2.3.2 for instructions on setting the high $FiO_2$ alarm limit.

⑫ **Silent Key -** In an alarm condition, pressing the SILENT key will deactivate the audio alarm for 2 minutes.

⑬ **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.

⑭ **Calibration Key -** This key is used to calibrate the device. The device must be in the un-locked state for the key to operate. See section 2.8 for instructions on calibrating.

⑮ **Down (Alarm Low) Key -** The down key is used in setting the low $FiO_2$ alarm limit. The device must be in the unlocked state for the key to operate. See section 2.3.1 for instructions on setting the low $FiO_2$ alarm limit.

⑯ **Un-lock Key -** The un-lock key is used to unlock and lock the instrument.

⑰ **Sleep Mode Indicator -** The sleep mode indicator is used to help with battery consumption.

⑱ **Flow Control Knob -** The flow control knob controls the flow of gas exiting the flowmeter.

⑲ **Oxygen Flowmeter -** Measures the flow of mixed gas exiting the flowmeter outlet.

⑳ **Backlight Key -** The backlight key will manually activate the backlight for 30 seconds. See section 2.6 for more information on backlighting operation.

㉑ **Smart Alarm Key -** The Smart Alarm key is used to help set the High-Low Alarm window quickly. See section 2.3.3 for instructions on using the Smart Alarm setting.

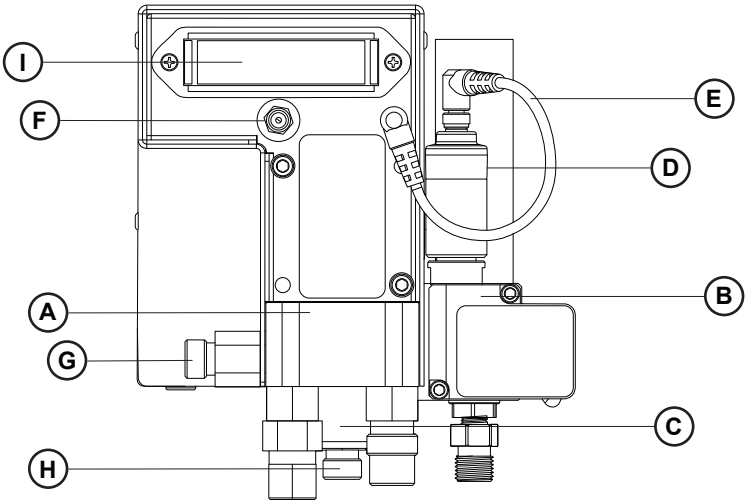
㉒ **Bleed Toggle Switch -** Turns on the auxiliary bleed. The bleed must be turned on whenever the total flow delivered to the patient is less than 15 LPM for high flow model, or less than 3 LPM for low flow model.

(23) **Medical Air Inlet Connector -** An air fitting for connection to an air inlet hose from the air gas source.

(24) **Flowmeter Outlet -** A fitting for connection to the patient delivery tubing.

(25) **Oxygen Concentration Selector Control -** A knob which allows for selections of mixed oxygen concentrations from 21% to 100%.

(26) **$O_2$ Inlet Fitting -** An $O_2$ fitting for connection to the $O_2$ inlet hose from the gas source.




**1.5 Back View**

(A) **Mount Adapter -** An adapter which allows the MAXBlend2 to be mounted onto a mating bracket for mounting to a rail or ventilator system.

(B) **$O_2$ Sensor Port -** A sampling port for the oxygen sensor. It allows mixed gas from the blender to flow over the sensor membrane.

(C) **Pressure Differential Reed Alarm -** An audible alarm which, when activated, indicates that an unacceptable pressure differential exists between the two gas source pressures.

(D) **Sensor with Diverter -** The sensor with flow diverter is designed to fit into a port behind the flow meter.

(E) **Sensor Cable -** The cable connects the MAXBlend2**,** to the MAX-550E Sensor.

(F) **External Power Supply Port -** The port provides connection for the external power adapter. See section 2.7 for more information on the power supply.

(G) **Auxiliary Mixed Gas Outlet -** Can be used to add additional flowmeters.

(H) **Auxiliary Mixed Gas Outlet** - Can be used as power take off.

(I) **Battery Compartment -** powered by four, AA, alkaline batteries.

### 1.6 What You Will Need to Operate the Blender

All operator-detachable inlet pressure hoses supplied with the gas mixer comply with ASTM/ISO 5359.

**Pressurized Oxygen:** The compressed oxygen source must provide clean, dry, medical grade oxygen at the pressure specified in Section 8.0.

**Pressurized Air:** The compressed air source must provide clean, dry, medical grade air at the pressure specified in Section 8.0.

## 2.0 OPERATING PROCEDURES

### 2.1 Setup and Installation

#### 2.1.1 Battery Installation

All MAXBlend2 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 service personnel. Use only brand name batteries. Replace with four AA batteries and insert per orientation marked inside the battery box.

**To install the batteries:**

Open the battery drawer by squeezing inward on both tabs as shown in figure below. If you have difficulty squeezing the tabs in with your fingers, use two flat screwdrivers or two coins. Remove the battery drawer completely from the MaxBlend2. Install four new, AA, alkaline batteries in the unit, observing the orientation shown on the plastic inside the drawer. Slide the drawer back in with the batteries facing upward. Press in on the drawer until both tabs latch into place.

⚠ **WARNING:** Battery replacement by inadequately trained personnel could result in a safety hazard.

⚠ **WARNING:** Electrical shock or damage to the equipment may occur if an inappropriate external power supply is used. Maxtec recommends using only the Maxtec MAXBlend2 External Power Supply - R230P10.


### 2.1.2 MAXBlend2 Setup

1. Connect the pressurized air source to the air inlet fitting (see page 3 for location).
2. Connect the pressurized oxygen source to the oxygen fitting (see page 3 for location).
3. Flush gas at the highest possible flow rate through the blender for at least one minute to eliminate any particulate that may have been introduced into the system during handling and installation.

### 2.1.3 Sensor Installation

1. Plug the sensor cable into the cable port on the sensor. Thread and tighten the locking shroud to lock the cable in place.
2. Press the ON/OFF key. Insert the sensor into the sensor port on the left side of the MAXBlend2 behind the flowmeter.
3. Allow adequate time for the sensor to equilibrate to ambient temperature.
4. Follow the desired calibration procedure in section 2.8.

### 2.2 Monitoring

Before use on a patient, the oxygen concentration of the delivered gas should be checked at the setting intended for use.

To begin monitoring, press the ON/OFF key located on the front panel (if necessary). Monitoring will begin immediately.

Should oxygen level exceed either the HIGH or LOW alarm set points, the red alarm indicator on the front panel will illuminate indicating either a high or low oxygen condition within limits or the limits are adjusted.

To conclude monitoring, press the ON/OFF key located on the front panel.

This will place the MAXBlend2 in a standby mode in which the display and alarm circuits are not functional, but the gas blender supply hoses will continue to supply mixed gas if the inlet hoses have not been disconnected.

### 2.3 Alarm Setting Procedure

### 2.3.1 Low Alarm Setting

To adjust the low alarm setting:

1. Press the Un-lock 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 high alarm setting 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 Un-lock key to accept the low alarm setting and return to normal operation.

**NOTE:** The default low alarm setting is 18% $O_2$. Removing the batteries or shutting the unit OFF will reset the low alarm limit to 18% if it is set to <18%.

### 2.3.2 High Alarm Setting

To adjust the high alarm setting:

1. Press the Un-lock 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% 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% 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 Un-lock key again to accept the high alarm setting and return to normal operation.

**NOTE:** The default high alarm setting is 50% $O_2$. Removing the batteries will reset the high alarm limit to 50%.

### 2.3.3 Smart Alarm Mode

1. Press the Un-lock key to Un-lock 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 equal to the current oxygen reading +3% (rounded to the nearest integer). The low alarm will now be set equal to the current oxygen reading -3% (rounded to the nearest integer but never lower than 18%).

3. Pressing of 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%.
4. Once the desired alarm settings are attained, press the Un-lock 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.

### 2.4 Basic Operation

To check the oxygen concentration of the delivered gas:

1. Ensure the sensor is connected to the flow diverter and inserted completely in the sensor port behind the flow meter.
2. Set the oxygen blender control knob to the desired oxygen setting.
3. Using the ON/OFF key, make sure the unit is in the power on mode.
4. Allow the oxygen reading to stabilize.
5. Adjust the flow meter to the desired flow rate. Read the flow rate at the center of the float ball.

**CAUTION:** The outlets of this device are capable of delivering pressure as high as the inlet pressure. Ensure that the devices that carry the gas from the blender to the patient prevent excessive pressure to the patient.

### 2.5 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 | Alarm Priority | Low Alarm LED (add symbol) | High Alarm LED (add symbol) | 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 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 oxygen alarm setting | Medium | Off | Pulsing Yellow | 3 Pulses | Every 25 Sec. |
| Oxygen level below the low oxygen 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. |

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 actual concentration is 0.1% lower than the high alarm setting.

To help differentiate the level of severity, the Monitor provides three unique sound bursts.

### 2.6 Backlight Operation

To turn on the backlighting:

1. When the unit is on, pressing the Backlight button 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, any button press will activate the backlight.

**CAUTION:** Excessive use of the back light can reduce the life of the batteries.

### 2.7 External Power Supply Operation

To extend the life of the batteries an external Maxtec approved 7.5V DC external power supply can be purchased. Once connected to the unit, total power is supplied by the 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 external power supply called out in section 10.0.

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

### 2.8 Calibration Procedures

#### 2.8.1 Calibration to 100% Oxygen

The MAXBlend2 should be calibrated before being placed into clinical use. Thereafter, Maxtec recommends calibration of the unit on a weekly basis. Frequent calibration will have no adverse effect on the performance of the MAXBlend2.

Calibration should also be performed upon replacement of a sensor. The sensor is best calibrated while mounted in the MAXBlend2 sensor port. As in normal operation, the oxygen sensor responds best when installed in a vertical position with the sensor facing down.

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).

It is best to calibrate the MAXBlend2 using the sensor port, and with a technical grade oxygen standard (99.0% or better). Calibration of the unit with room air is less accurate over the full $FiO_2$ operating range.

1. Connect the oxygen supply line **(Pressure differential alarm may sound).** Verify the sensor is plugged into the $O_2$ sensor port and connected to the sensor cable. **DO NOT** connect air supply line at this time.
2. Using the ON/OFF key, make sure the MAXBlend2 is in the power on mode.
3. Rotate the $FiO_2$ control knob to the 100% stop. Allow a few minutes for the reading to stabilize.
4. Press the Un-lock 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.

### 2.8.2 Calibration to Room Air

The MAXBlend2 can quickly be calibrated to room air (20.9%)

To use this function:

1. Connect the air supply line **(Pressure differential alarm may sound).** Verify the sensor is plugged into the $O_2$ sensor port and connected to the sensor cable. **DO NOT** connect oxygen supply line at this time.
2. Using the ON/OFF key, make sure the MAXBlend2 is in the power on mode.
3. Rotate the $FiO_2$ control knob to the 21% stop. Allow a few minutes for the reading to stabilize.
4. Press the Un-lock 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.

## 3.0 PERFORMANCE CHECK

Prior to placing the MAXBlend2 into clinical use, perform the following tests.

**WARNING:** If the MAXBlend2 does not function as described on the next page, contact your Maxtec Distributor or contact a Maxtec Certified Service Technician at:

Maxtec
2305 South 1070 West
Salt Lake City, UT 84119
(385) 549-8000 or (800) 748-5355

**DO NOT** use the MAXBlend2 until correct performance has been verified.

### 3.1 Blender Safety Check

**NOTE:** Before proceeding, ensure that the high alarm set point control is OFF [display reads (--)] and that the low alarm set point control is below 20%.

| PROCEDURE | MAXBlend2 RESPONSE |
|---|---|
| 1. Adjust the oxygen concentration such that the display reads 60% $O_2$ ±3%. | No response. |
| 2. Disconnect the 50 PSIG AIR source from the MAXBlend2. | Audible alarm sounds. Display reads 100% +/-3%. |
| 3. Reconnect 50 PSIG AIR source to the MAXBlend2. | Audible Alarm stops. Verify that display panel reads 60% ±5%. |
| 4. Disconnect 50 PSIG OXYGEN source from the MAXBlend2. | Audible alarm sounds. Display reads 20.9% +/-3%. |
| 5. Reconnect 50 PSIG OXYGEN to the MAXBlend2. | Audible alarm stops. Verify that display panel reads 60% ±5%. |
| 6. Adjust both air and oxygen inlet regulators to 0 PSIG. | No response. |
| 7. Remove air inlet hose at regulator and insert end into beaker of water. | No response. |
| 8. Slowly raise pressure of oxygen regulator to 50 PSIG and back to 0 PSIG while observing air hose end in beaker. | No bubbles should be observed. Audible alarm sounds. |
| 9. Dry and reattach air inlet hose to regulator. | No response. |
| 10. Remove oxygen inlet hose at regulator, and insert end into beaker of water. | No response. |
| 11. Slowly raise pressure of air regulator to 50 PSIG and back to 0 PSIG while observing oxygen hose end in beaker. | No bubbles should be observed. Audible alarm sounds. |
| 12. Dry and reattach oxygen inlet hose to regulator. | No response. |

## 4.0 TROUBLESHOOTING

### 4.1 Problem Troubleshooting

**Problem:** Oxygen concentration discrepancy between oxygen concentration selection knob and actual reading on display.

**Potential Causes and Solutions:**

» Monitor out of calibration. Calibrate. Refer to section 2.8, Calibration Procedure.
» Sensor exhausted. Replace sensor. Refer to section 6.2.
» Gas supply contaminated. Contact Maxtec for repair of the MAXBlend2.
» MAXBlend2 blender out of calibration. Contact Maxtec for repair.

**Problem:** Pressure differential alarm sounding
**Potential Causes and Solutions:**
» Inlet pressure differences of 20 PSI or more. Correct pressure difference.
» Pressure alarm not calibrated properly. Contact Maxtec for repair.
» MAXBlend2 blender operation out of calibration. Contact Maxtec for repair.

**Problem:** Inlet pressure has supply loss, no audible pressure differential alarm.
**Potential Causes and Solutions:**
» Reed alarm cap damaged or defective. Contact Maxtec for repair.

**Problem:** Selected oxygen concentration accurate only when gas pressures are equal.
**Potential Causes and Solutions:**
» MAXBlend2 balance module not functioning properly. Contact Maxtec for repair.

**Problem:** Blank display.
**Potential Causes and Solutions:**
» Battery not installed. Install batteries. Refer to section 2.1.1.
» Battery completely dead. Replace batteries. Refer to section 2.1.1.
» Monitor defective. Contact Maxtec for repair.

**Problem:** Partial or distorted display.
**Potential Causes and Solutions:**
» Monitor damaged. Contact Maxtec for repair.

**Problem:** Sensor will not calibrate.
**Potential Causes and Solutions:**
» Sensor cell exhausted. Replace sensor. Refer to section 6.2.
» Sensor cable defective. Return to Maxtec.
» Monitor defective. Contact Maxtec for repair.

**Problem:** Sensor will calibrate, but takes too long to return to 21% ±2% oxygen in air (2 to 5 minutes) when performing calibration.
**Potential Causes and Solutions:**
» Disposable oxygen sensor damaged or defective. Replace sensor. Refer to section 6.2.

**Problem:** Sensor will calibrate, but does not return to 21% ±2% oxygen in air (2 to 5 minutes) when performing calibration.
**Potential Causes and Solutions:**
» Disposable oxygen sensor damaged or defective. Replace sensor. Refer to section 6.2

**Problem:** Sensor will calibrate, but reading at any constant level drifts more than ±3% over a 24 hour period.
**Potential Causes and Solutions:**
» Barometric pressure change since last calibration. Recalibrate.
» Room or gas temperature went below 59°F (15°C) or above 104°F (40°C). Correct temperature and recalibrate.

**Problem:** Low battery icon.
**Potential Causes and Solutions:**
» If the low battery icon is displayed on the LCD readout at any time, the batteries should be replaced as quickly as possible.

**Problem:** E01: Sensor voltage is too low to perform a valid calibration.
**Potential Causes and Solutions:**

» Manually attempt a new calibration.
» If unit repeats this error more than three times, contact Maxtec's Customer Service Department for possible sensor replacement.

**Problem:** E02: No sensor attached.
**Potential Causes and Solutions:**

» Disconnect and reconnect external sensor.
» Unit should perform an auto calibration, and should read 20.9%.
» If not, contact Maxtec's Customer Service Department for possible sensor replacement or cable replacement.

**Problem:** E03: No valid calibration data available.
**Potential Causes and Solutions:**

» Make sure unit has reached thermal equilibrium and perform a calibration routine.

**Problem:** E04: Battery below minimum operating voltage.
**Potential Causes and Solutions:**

» Replace batteries. A medium priority alarm will sound every 25 seconds until the batteries are replaced or become too dead to sound the alarm.

**Problem:** E05: Sensor voltage is too high to perform a valid calibration.
**Potential Causes and Solutions:**

» Manually attempt a new calibration.
» If unit repeats this error more than three times, contact Maxtec's Customer Service Department for possible sensor replacement.

**Problem:** E06: Non-compatible oxygen sensor.
**Potential Causes and Solutions:**

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 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.

**Problem:** E07: Sensor signal is not stable enough to perform a valid calibration.
**Potential Causes and Solutions:**

» Wait for displayed oxygen reading to stabilize, when calibrating the device at 100% oxygen.
» Wait for unit to reach thermal equilibrium. Please note that this can take up to one half hour, if the device is stored in temperatures outside the specified operating temperature range.

**Problem:** E08: Battery voltage is too low to perform a valid calibration.
**Potential Causes and Solutions:**

» Replace batteries.

**NOTE:** Use only a Maxtec approved Max-550E sensor called out in section 9.0 of the Spare Parts List. The Max550E sensor is equipped with an authentication chip to ensure the monitor is used with an approved sensor.

**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.

## 5.0 CLEANING AND DISINFECTING THE MAXBLEND2

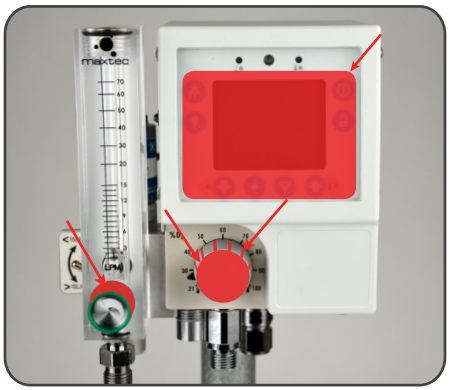
The external surfaces of the device and its accessories can be cleaned and disinfected using the process detailed below. Under normal use conditions, the sensing surfaces of the sensor should not become contaminated. If you suspect that the sensing face of the sensor or internal surfaces of the flow diverter have become contaminated, these items should be discarded and replaced. Store the device in a clean, dry location when not in use.

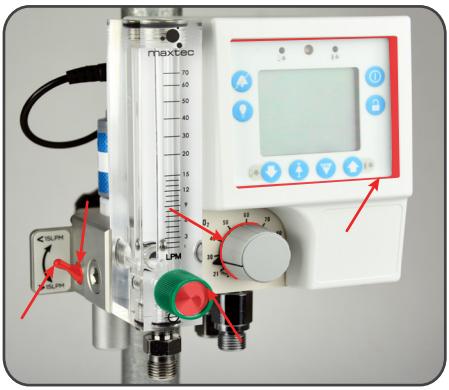
1. Ensure battery drawer is closed and sensor/diverter are inserted into their port.
2. Using Super Sani-Cloth germicidal disposable wipes (medical grade 2-in- 1 cleaning / disinfecting wipes) remove all visible contamination from the external surfaces of the device and its accessories. Be sure to closely inspect and remove contamination from seams and recesses on the device that may trap contaminants. Wipe with clean paper towel to remove debris and bioburden.
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 completely.
5. Visually inspect the device for visible contamination. Repeat cleaning/disinfection process if visible soil remains.

⦸ **DO NOT** allow the liquid or spray to penetrate the device.
⦸ **DO NOT** spray cleaning solution directly onto the sensor port, bleed muffler or buzzer openings.

Be sure to thoroughly clean and disinfect the areas depicted in the images below. These regions are contacted during normal use and may contribute to cross-contamination if not disinfected properly.

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



- **DO NOT** immerse the device 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 device with steam, ethylene oxide or irradiation.

## 6.0 SERVICE AND MAINTENANCE

### 6.1 Maintenance

Prior to placing the MAXBlend2 into clinical use, follow the performance check guidelines listed in section 3.

When using the MAXBlend2 with a medical grade compressed air source, an air inlet watertrap/filter is recommended to be attached to the air inlet of the MAXBlend2 prior to use. Contaminants from hospital air lines may compromise the function of the MAXBlend2.

Elastomer components such as O-rings are designed to function satisfactorily for a minimum of two years. Maxtec recommends that the MAXBlend2 be overhauled and serviced at a minimum of every two years.

Repair of this equipment must be preformed by a Maxtec Certified Service Technician experienced in repair of this device.

### 6.2 Replacing $O_2$ Sensor

The oxygen sensor is designed to operate for two years under normal use conditions. The oxygen sensor should be replaced whenever any of the problems listed in section, 4.0 Troubleshooting dictate the need to do so.

1. Remove the sensor from the sensor monitor port.
2. Remove the sensor from the sensor cable.
3. Install a new $O_2$ sensor with flow diverter, taking care not to use excessive force when plugging and/or threading the locking shroud into the $O_2$ sensor.
4. Calibrate the sensor following the instructions for calibration listed in section 2.8.

### 6.3 Alarm Testing

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.

## 7.0 ABBREVIATION GUIDE

| Term | Description |
|---|---|
| Air/$O_2$ | Mixture of compressed air and oxygen |
| °C | Degrees celsius |
| CGA | Compressed Gas Association |
| DISS | Diameter Indexed Safety System |
| °F | Degrees fahrenheit |
| $FiO_2$ | Fractional Concentration of Inspired Oxygen |
| $O_2$ | Oxygen |
| LPM | Liters Per Minute |
| PSIG | Pounds Per Square Inch Gauge |

## 8.0 SPECIFICATIONS

### 8.1 Instrument Specifications

Weight (unpackaged) . . . . . 5.3 lbs. (2.4 kg.)
Power Source. . . . . Four AA alkaline batteries, 1.5 V each
Battery Life . . . . . 5000 hours (continuous operation, no alarming)
Oxygen Measurement Range . . . . . 0% to 100% oxygen
Display Resolution . . . . . 0.1% oxygen
$O_2$ Concentration Adjustment Range . . . . . 21% to 100% $O_2$
Gas Supply Pressure . . . . . The gas supplies must provide clean, dry, medical grade air and oxygen at a pressure of 30 to 75 PSIG (2.0 to 5.2 BAR). Air and oxygen must be within 20 PSI (1.3 BAR). Optimal performance is achieved at 50 PSIG inlet pressures.
Pressure Drop . . . . . Less than 6 PSIG (0.4 BAR) @ 50 PSIG (3.4 BAR) supply pressures and 10 LPM flow rate
Sensor Bleed Flow . . . . . 0.1LPM LPM @ 50 PSIG (3.4 BAR)
Bleed Flow (toggle ON) . . . . . 3 LPM for low flow blender (R229P01) and 13 LPM for high flow blender (R229P02)
Outlet Flow Range . . . . . 0-30 LPM for low flow blender (R229P01) and 2-100 LPM for high flow blender (R229P02) with inlet pressures at 50 PSIG (3.4 BAR)
Mixed Gas Stability* Ambient Operating Conditions . . . . . ±1% oxygen
Operating Temperature Range . . . . . 59°F to 104°F (15°C to 40°C)
Relative Humidity Range . . . . . 0-95%, non-condensing
Ambient Storage Conditions Temperature Range . . . . . 5°F to 122°F (-15°C to 50°C)
Flowmeter accuracy** . . . . . +/-10% of indicated value or 0.5 LPM whichever is greater, with inlet pressure set to 50PSIG.

*The delivered oxygen concentration will remain constant within ±1% of the set point value with constant inlet pressures. The displayed value may vary more than this due to sensor accuracy, age, environmental conditions and length of time since last sensor calibration.

**Position the device such that the flow meters are vertical to ensure accuracy.

### 8.2 Alarm Specifications

Pressure Diffential Alarm Activation . . . . . When supply pressures differ by 20 PSI (1.3 BAR) or more alarm is activated
Low Oxygen Alarm Range: . . . . . 15%-99% (>1% lower than high alarm)
High Oxygen Alarm Range: . . . . . 16%-100% (>1% higher than low alarm)
(according to IEC 60601-1-8 Audible Alarms in Medical Equipment)

### 8.3 $O_2$ Sensor Specifications

Total accuracy*:. . . . . .±3% actual oxygen level over full operating temp range
Oxygen Measurement Accuracy. . . . . ±1% oxygen
Linearity. . . . . ± 1% at constant temperature and pressure
Error Over Operating Temp Range . . . . . ±3% oxygen, maximum
Response Time to 90% of Final Reading*. . . . . @ 77°F (25°C) ≤20 seconds
Storage Temperature Range. . . . . 5°F to 122°F (-15°C to 50°C)
Expected Useful Life . . . . . 1,500,000 $O_2$% hours (approx. 2 years average use)

*The accuracy of the oxygen monitor is not affected by supply gas inlet pressure to the blender, however, pressures below 50 PSIG may result in a longer response time.

**Note:** All specifications assume the following standard environmental conditions unless specified otherwise.

» Ambient and sample gas temperatures of 77°F (25°C)
» Barometric pressure of 30 inHg (102 kPa)
» Ambient relative humidity of 50%
» Sample gas relative humidity of 0%

## 9.0 FACTORS INFLUENCING CALIBRATION

### 9.1 Temperature Effect

The MAXBlend2 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. For best results, perform the calibration procedure at a temperature close to the temperature where analysis will occur.

### 9.2 Pressure Effect

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 30kPa to 29kPa, the reading will drop to: 50% x (29/30) = 48.3%. Maxtec recommends that you re-calibrate after changing point-of-use elevation by more than 500 feet (150m).

### 9.3 Humidity Effect

Humidity in the sample gas will affect the oxygen reading. Maxtec recommends that the gas delivered to the MaxBlend Lite be medical grade, clean and dry. Refer to ISO 7396-1 for further details.

### 9.4 Exposure to Anesthetic Gases

Because of the unique chemistry of the oxygen sensors provided with the MAXBlend2, 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 $O_2$% |
|---|---|---|
| Nitrous Oxide | 60%, balance $O_2$ | <1.5% |
| Halothane | 4% | <1.5% |
| Enflurane | 5% | <1.5% |
| Isoflurane | 5% | <1.5% |
| Helium | 50%, balance $O_2$ | <1.5% |
| Sevoflurane | 5% | <1.5% |
| Desflurane | 15% | <1.5% |

**NOTE:** Balance mixture 30% $O_2$/70%$N_2O$, unless otherwise specified.

## 10.0 SPARE PARTS AND ACCESSORIES

| DESCRIPTION | PART NUMBER |
|---|---|
| MAX550E Oxygen Sensor | R140P02-001 |

**ACCESSORIES:**

| DESCRIPTION | PART NUMBER |
|---|---|
| Monitor Cable | R228P49 |
| Rail Mount Bracket | R100P09 |
| Adjustable Pole Mount Bracket | R100P22 |
| Pole Mount Bracket | R100P26 |
| Accessory Hook | R200P03 |
| Compact Wall Mount | RP05P07 |
| Maxtec Approved Power Supply | R230P10 |
| Wall Mount Large Bracket | RP05P09 |
| 10' Dual Blender hose (DISS) | R129P01 |

Repair of this equipment must be preformed by a Maxtec Certified Service Technician experienced in repair of this device.

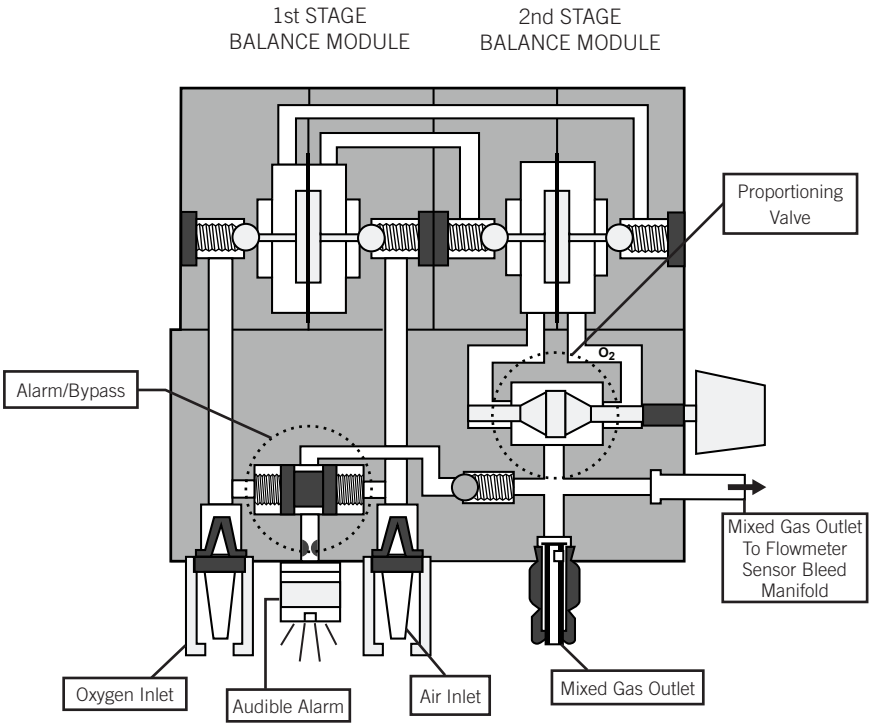
Equipment in need of repair shall be sent to:

Maxtec
Service Department
2305 South 1070 West
Salt Lake City, Ut 84119
1.800.748.5355
(Include RMA number issued by Customer Service)

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

# 11.0 THEORY OF OPERATION

## 11.1 Operational Diagram




## 11.2 Mixing Operation

The MAXBlend2 is designed to utilize two 50 PSIG (3.4 BAR) gas sources. The two gas sources enter through the air and oxygen inlet connectors located on the bottom of the MAXBlend2. Each inlet connector incorporates a 30 micron particulate filter. Once through the filters, each gas passes through a duckbill check valve, which prevents possible reverse gas flow from either the air or the oxygen supply systems.

The two gases then pass through a two-stage balance regulator. The purpose of this regulator is to equalize the operating pressures of the air and oxygen gas sources. Once these pressures have been balanced, the gases are proportioned according to the oxygen concentration selected on the oxygen concentration selection knob. The oxygen concentration knob allows the clinician to select a desired oxygen concentration from 21% to 100% $O_2$. From this point, the mixed gas flows to the outlet port.

### 11.3 Gas Outlet

There are three gas outlets on the MAXBlend2. One is a fixed acrylic flow meter, the other two are auxiliary ports (one on the bottom of the unit and one on the right side). These outlets are capable of delivering combined metered flows of 0-30 LPM for the low flow model (R229P01) and 0-100 LPM for the high flow model (R229P02). The auxiliary outlet ports are fitted with an automatic shut off valve. The flow of gas from either outlet port is automatically initiated by attaching a pneumatic device (such as a flow meter) to the outlet port.

Regardless of whether or not the outlet has any device connected to it, a minimal gas bleed flow of 0.1 LPM flows form the MAXBlend2 sensor port on the left side of the blender. It is from this bleed flow that the gas is analyzed by the oxygen sensor. In addition a toggle switch is provided allowing the user to activate an additional gas bleed which ensures the blender has sufficient flow to function accurately when the total flow delivered to the patient is below a certain minimum threshold. For a low flow model (R229P01) this additional bleed should be activated if the total flow delivered to the patient is less than 3 LPM.

For a high flow model (R229P02) the additional bleed should be activated if the total flow delivered to the patient is less than 15 LPM. At delivered flows greater than these limits, the bleed toggle can be deactivated to conserve oxygen.

**CAUTION:** Failure to activate the bleed as described above may result in significant drift in the oxygen concentration delivered to the patient.

### 11.4 Alarm/Bypass Function

The MAXBlend2 includes a pressure differential alarm which provides an audible alarm if gas source pressures differ by 20 PSI (1.3 BAR) (nominal) or more, or if there is a gas supply failure of one of the source gases. This alarm is generated by a reed alarm located in a cap on the bottom of the MAXBlend2.

The primary purpose of the alarm is to audibly warn the operator of an excessive pressure drop or depletion of either source gas pressure. Should both gas pressures increase or decrease simultaneously, an alarm will not activate. If either source gas pressure drops, the outlet pressure will drop similarly as the mixed gas is always balanced to that of the lower gas source.

The gas bypass function operates in unison with the alarm. Once the pressure alarm is activated, the bypass function is actuated and the gas with the higher pressure flows directly to the outlet port, bypassing the mixing function of the MAXBlend2. The oxygen concentration flowing out of the MAXBlend2 will be that of the gas with the higher pressure. In the alarm/bypass mode, the blender will deliver oxygen (100%) or medical air (21%) until pressures have been restored to a differential of 6 PSI or less (0.4 BAR).

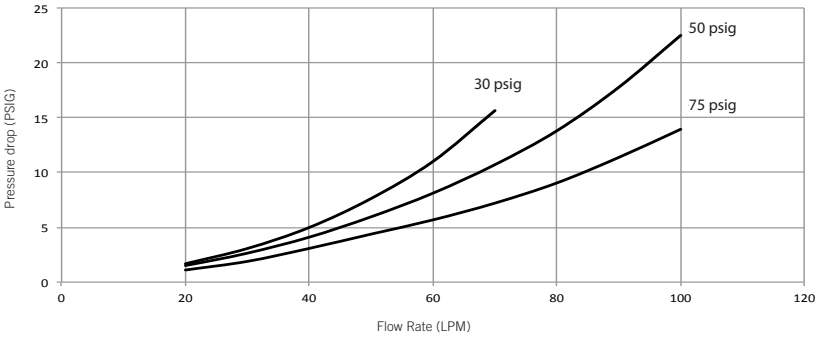
If the MAXBlend2 is set to deliver 21% and the OXYGEN source pressure is reduced enough to produce a 20 PSI (1.3 BAR) differential, the unit may not alarm because it will continue to deliver 21% concentration according to the setting. If the setting is moved slightly from 21%, the pressure differential alarm will sound. Similarly, if the MAXBlend2 is set to deliver 100% and the AIR source pressure is reduced or lost, the unit may not alarm because it will continue to deliver 100% concentration.

## 12.0 FLOW CHARACTERISTICS

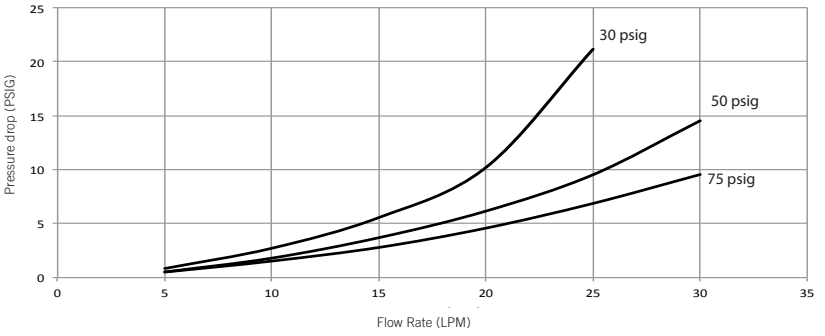
The outlet pressure of the MAXBlend2 decreases as the total flow rate increase. The total flow rate is the measurement of the total flow from all outlet ports. The charts below indicate the pressure drop that occurs for both low flow and high flow models at 3 inlet pressure settings; 30 PSIG (2.07 BAR), 50 PSIG (3.45 BAR), and 75 PSIG (5.17 BAR).

The fixed acrylic flow meter on the left side of the MaxBlend2 has been pressure compensated to accommodate for the pressure loss through the blender at each flow rate, using an inlet pressure of 50 PSIG."

**Flow Rate -vs- Pressure Drop**
(For High Flow Blender)




**Flow Rate -vs- Pressure Drop**
(For Low Flow Blender)



## 13.0 Electromagnetic Compatibility

The information contained in this section (such as separation distances) is in general specifically written with regard to the MaxBlend2 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.

<table>
<tr><th colspan="3">ELECTROMAGNETIC EMISSIONS</th></tr>
<tr><td colspan="3">This equipment is intended for use in the electromagnetic environment specified below.<br>The user of this equipment should assure that is used in such an environment.</td></tr>
<tr><th>EMISSIONS</th><th>COMPLIANCE ACCORDING TO</th><th>ELECTROMAGNETITC ENVIRONMENT</th></tr>
<tr><td>RF emissions (CISPR 11)</td><td>Group 1</td><td>The MaxO2ME 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.*</td></tr>
<tr><td>CISPR Emissions Classification</td><td>Class A</td><td rowspan="3">The MaxO2ME 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.</td></tr>
<tr><td>Harmonic emissions (IEC 61000-3-2)</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations / flicker (IEC 61000-3-3)</td><td>Complies</td></tr>
</table>

## ELECTROMAGNETIC IMMUNITY

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

| IMMUNITY AGAINST | IEC 60601-1-2 TEST LEVEL | COMPLIANCE LEVEL (OF THIS DEVICE) | ELECTROMAGNETITC ENVIRONMENT |
|---|---|---|---|
| electrostatic discharge, ESD (IEC 61000-4-2) | contact discharge: ± 6 kV<br>air discharge: ± 8 kV | ± 6 kV<br>± 8 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. |
| electrical fast transients / bursts (IEC 61000-4-4) | power supply lines: ± 2 kV<br>longer input / output lines: ± 1 kV | ± 2 kV<br>± 1 kV | Mains power quality should be that of a typical commercial or hospital environment. |
| surges on AC mains lines (IEC 61000-4-5) | Common mode: ± 2 kV<br>differential mode: ± 1 kV | ± 2 kV<br>± 1 kV | Mains power quality should be that of a typical commercial or hospital environment. |
| power frequency magnetic field 50/60 Hz (IEC 61000-4-8) | 3 A/m | 3 A/m | Equipment which emits high levels of power line magnetic fields (in excess of 3A/m) should be kept at a distance to reduce the likelihood of interference. |
| voltage dips and short interruptions on AC mains input lines (IEC 61000-4-11) | dip >95%, 0.5 periods<br>dip 60%, 5 periods<br>dip 30%, 25 periods<br>dip >95%, 5 seconds | >95%, 0.5 per.<br>60%, 5 per.<br>30%, 25 per.<br>>95%, 5 sec. | Mains power should be that of a typical commercial or hospital environment. If user requires continued operation during power mains interruptions insure that batteries are installed and charged. Insure that battery life exceeds longest anticipated power outages or provide and additional uninterruptible power source. |

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 – 80 MHz d=1.2/V1]√P | 80 MHz to 800MHz d=1.2/V1]√P | 800 MHz 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 propagation 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 should assure that it is used in such an environment.

| IMMUNITY TEST | IEC 60601 TEST LEVEL | COMPLIANCE LEVEL | ELECTROMAGNETIC ENVIRONMENT – GUIDANCE |
|---|---|---|---|
| | | | Portable and mobile RF communications equipment should be used no closer to any part of the, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter as below. **Recommended separation distance** |
| Conducted RF<br>rf coupled into lines<br>(IEC 61000-4-6) | 150 kHz to 80 MHz<br>outside ISM bandsa | 3 Vrms | d=1.2√P |
| Radiated rf<br>(IEC 61000-4-3) | 3 V/m<br>80 MHz – 2.5 GHz | 3 V/m | d=1.2/√P 80 MHz to 800 MHz<br><br>d=2.3√P 800 MHz to 2.5 GHz<br><br>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).<br><br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site surveya, should be less than the compliance level in each frequency rangeb.<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br><br>(((•))) |

[a] 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.

[a] 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.