BIRD® MicroBlender

LOW AND HIGH FLOW AIR-OXYGEN BLENDER

Instructions for Use

ENGLISH

maxtec

R200M04 REV. A

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

SYMBOL GUIDE

The symbols defined below may appear in this document and on the equipment label or labels:

	Warning	IPX0	Ingress protection rating
	Caution		Consult instructions for use
	Do Not	Rx only	Federal law (USA) restricts this device to sale by or on order of physician
	Manufacturer	O_2 %	Oxygen percent
	Date of manufacture	UDI	Unique device identifier
LOT	Batch code	REF	Catalog number
SN	Serial Number		Temperature limit
MD	Medical device		Humidity limitation

INTENDED USE

The Maxtec BIRD® MicroBlender products provide an accurate air/oxygen mixture of gas directly to a patient by way of a mask or cannulas or to a ventilator for subsequent delivery to the patient. They are used to treat patients who suffer a wide array of diseases and clinical conditions among the neonatal, pediatric, and adult patient populations that require the use of supplemental oxygen. The MicroBlender does not come into contact with any human tissues or bodily fluids, but oxygen delivery devices such as a mask, nasal cannula, or endotracheal tube that are used in conjunction with blenders do. MicroBlenders are intended to be used in hospital/clinical settings operated by trained, qualified medical personnel under the direct supervision of a licensed physician.

1 INTRODUCTION

The MicroBlender is a lightweight, compact, air-oxygen blender that provides precise mixing of medical-grade air and oxygen.

The MicroBlender provides oxygen concentrations from two gas-outlet ports.

LOW FLOW MICROBLENDER

HIGH FLOW MICROBLENDER

The MicroBlender can be used in conjunction with:

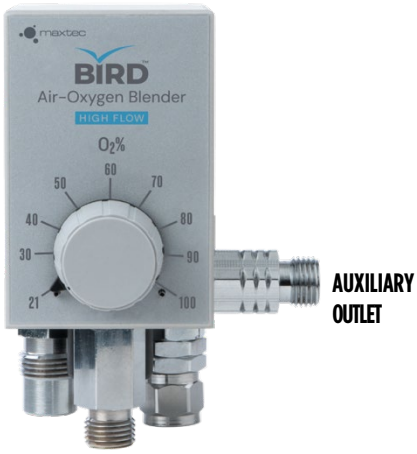
- Oxygen hoods
- Resuscitation bags
- Masks
- Transports
- Nasal cannulas
- Treatments

2 OPERATION OVERVIEW

The MicroBlender provides a selection of oxygen concentrations by means of a single control knob located on the front of the unit. Oxygen concentrations ranging from 21 to 100% are available.

	OUTLET	FLOW RANGE	BLEED FLOW
Low Flow MicroBlender	Primary, Left Side	3–30 LPM	No Bleed Flow
	Auxiliary, Right Side	0–30 LPM	2.5–3.5 LPM
High Flow MicroBlender	Primary, Bottom	15–120 LPM	No Bleed Flow
	Auxiliary, Right Side	2–100 LPM	10–12 LPM

LOW FLOW MICROBLENDER OUTLETS



PRIMARY OUTLET

HIGH FLOW MICROBLENDER OUTLETS

2.1 Gas Inlets

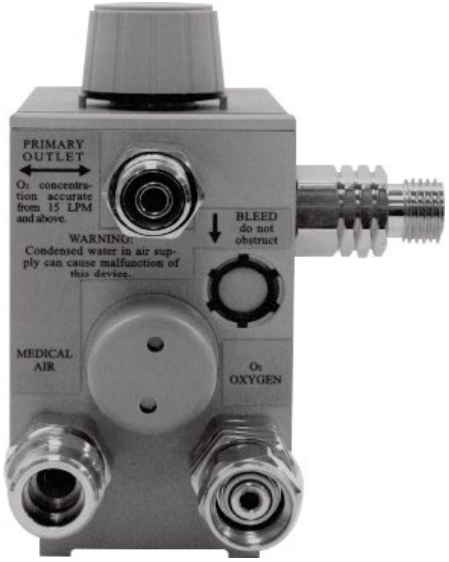
The ports located on either side of the unit allow flexibility for the clinician. The MicroBlender operates by using two 30–75 PSI gas sources that enter the device through DISS or NIST connectors located on the bottom the unit.

LOW FLOW MICROBLENDER 30–75 PSI INLET CONNECTORS

Air and oxygen hoses are connected directly onto the MicroBlender gas inlets.

Each inlet connector incorporates a 30 micron particulate filter. After passing through the filter, the gases travel through duckbill check valves that prevent reverse gas flow from either the air or oxygen supply systems.

The MicroBlender is tested for compliance with ISO 11195 (1995), clause 6, regarding reverse-gas flow as delivered.



HIGH FLOW MICROBLENDER 30–75 PSI INLET CONNECTORS

2.2 Balance Module

The gases then enter the balance modules, which equalize the operating pressures of the air and oxygen. The diaphragm in the balance module responds to a difference in pressure and directs the movement (stroke) of each poppet contained within the air and oxygen chambers. The movement of each poppet adjusts the amount of gas flowing through the balance module, equalizing the air and oxygen pressures.

2.3 Proportioning Module

From the balance module, the gases flow into the proportioning module and mix according to the oxygen percentage selected with the MicroBlender control knob. This module consists of a double-ended poppet positioned between two valve seats.

One valve seat controls the passage of air and the other valve seat controls the passage of oxygen into the MicroBlender outlets. At this point, the two gases have been blended according to the oxygen percentage selected by the control knob.

2.4 Alarm/Bypass

The alarm feature provides for an audible alarm if source pressures differ by 20 ±2 PSI or more. The primary purpose of the alarm is to audibly warn the operator of an excessive pressure drop or depletion of either source gas. The alarm will also activate when there is an elevation of either source gas resulting in a 20 ±2 PSI difference. Should both gas pressures (oxygen or medical air) increase or decrease simultaneously, and a 20 ±2 PSI differential is not seen, there will not be an audible alarm. If either source gas pressure drops, the output pressure of the blender will drop similarly, since the source gases are always balanced to that of the lower pressure.

The bypass function operates in unison with the alarm. The alarm bypass poppet communicates directly with the air supply on one end and the oxygen supply on the other.

When the two source gases are near equal in pressure, the alarm bypass poppet is positioned over the bypass channel, blocking the flow of both gases. The poppet will remain seated for unequal pressures up to 20 ±2 PSI. Once a 20 ±2 PSI difference occurs, the higher gas pressure will overcome the spring force and pressure of the poppet at its opposite end, thus creating a path (air or oxygen) to flow into the alarm channel.

The gas with the higher pressure will also flow directly to the blender outlet port bypassing the Balance and Proportioning Modules. The gas is also directed to the bottom of the unit to the reed alarm, thus creating an audible warning. The oxygen concentration will be that of the gas at the higher pressure. The blender in the alarm/bypass mode will deliver oxygen (100%) or medical air (21%) until the pressure has been restored to a differential of approximately 6 PSI.

If the blender is set at 21% and the OXYGEN source pressure is reduced enough to produce a 20 ±2 PSI or greater differential, the unit may not alarm because it will continue to deliver 21% concentration according to the setting. If the control is moved slightly from the 21% setting, the alarm will sound.

Similarly, if the blender is set to deliver 100% concentration and AIR source pressure is reduced or lost, the unit may not alarm because it will continue to deliver the selected 100% concentration.

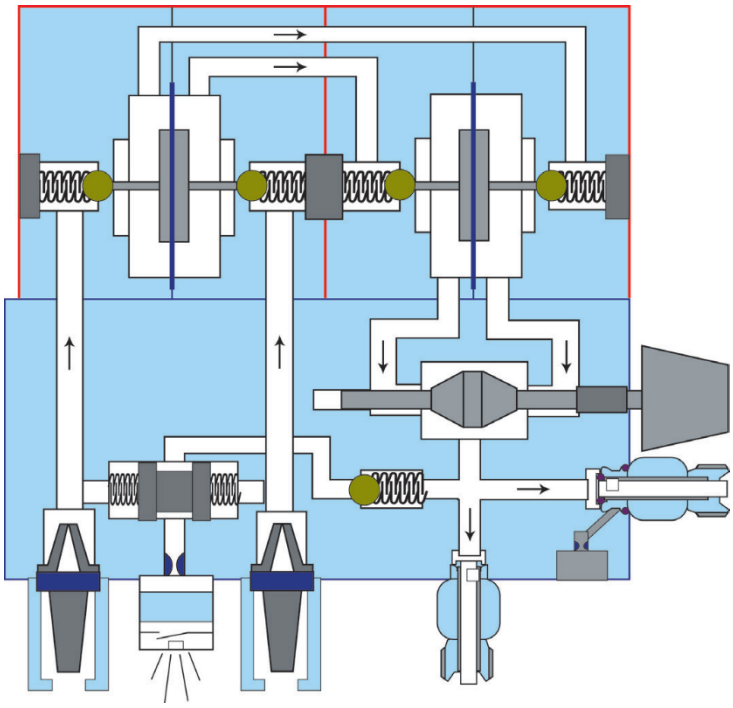
If the blender is left connected to source gases but is not being used (i.e., no output flow or bleed flow) the unit will not alarm if a 20 ±2 PSI or greater pressure differential develops. If the blender is not in use, an alarm under these conditions will be an unnecessary distraction or nuisance.

2.5 Outlet Ports

On the Low Flow MicroBlender, two outlet ports are located on the right and left sides of the MicroBlender and allow low ranges from 0–30 LPM with bleed and 3–30 LPM without bleed respectively. On the High Flow MicroBlender, the primary outlet port is located on the bottom of the MicroBlender, and the auxiliary outlet is located on the right side of the MicroBlender, allowing ranges from 15 to 120 LPM without bleed and 2 to 100 LPM with bleed respectively.

2.6 Bleed Outlet

For the Low Flow MicroBlender, when a connection is made to the right side outlet port, for example, when a flow meter is attached, a bleed flow of 2.5–3.5 LPM is achieved. For the High Flow MicroBlender, when a connection is made to the right side outlet port, a bleed flow of 10–12 LPM is achieved. For both Blenders, the bleed flow exits the unit through a muffler port located on the bottom of the MicroBlender.



HIGH FLOW MICROBLENDER

3 WARNINGS, CAUTIONS, AND NOTES

The MicroBlender should be operated by trained, qualified medical personnel under the direct supervision of a licensed physician. Before clinical application, the following **WARNINGS**, **CAUTIONS** and **NOTES** should be read and understood.

NOTES

- Users are advised to use inlet pressure regulators with the MicroBlender to display system pressure.
- Allow equilibration time for FiO_2 changes before analyzing gas.

⚠ CAUTIONS

- Always operate air/oxygen blenders with clean and dry medical grade gasses. Contaminant or moisture can cause defective operation. Air used for medical purposes must meet USP compressed air and/or CGA G7.1-2018 grade N, and water vapor content must not exceed a blender's dew point of 5°F below the lowest ambient temperature to which the delivery system is exposed. Particulate content must not exceed that which would be downstream of a 15 micron absolute filter.
- Water vapor content of medical air or O_2 supply to the MicroBlender must not exceed 5.63 grams H_2O per cubic meter of non-condensable gas.
- Always disconnect the gas sources from the blender when the blender is not in use.

⚠ WARNINGS

- If either the air or oxygen gas source fails, the MicroBlender alarm sounds, alerting the clinician that a condition has occurred that may significantly alter the FiO_2 and flow output from the MicroBlender.
- If either the air or oxygen gas source pressure is reduced or increased creating a pressure differential of 20 ±2 PSI, the MicroBlender alarm sounds. This condition significantly alters the FiO_2 and flow output from the MicroBlender.
- Always operate the MicroBlender with clean and dry medical grade gases.
- Air Inlet Filter/Water Trap (P/N RP05P08) is recommended for use with the MicroBlender especially when the air source is known or suspected to contain contaminants. Introduction of water or particulate matter into the MicroBlender may lead to inaccuracies in the desired oxygen concentration or malfunction of the device.
- The patient gas must be monitored with an oxygen analyzer.

⊘ **DO NOT** steam clean, autoclave, or otherwise subject the MicroBlender to temperatures above 145°F (62°C).

⊘ **DO NOT** immerse the assembled MicroBlender in liquid decontamination agents.

- Consult a physician for appropriate FiO_2 setting.

⊘ **DO NOT** tape, obstruct, or remove the reed alarm outlet at any time.

⊘ **DO NOT** occlude or obstruct the bleed port or muffler on the bottom of the MicroBlender.

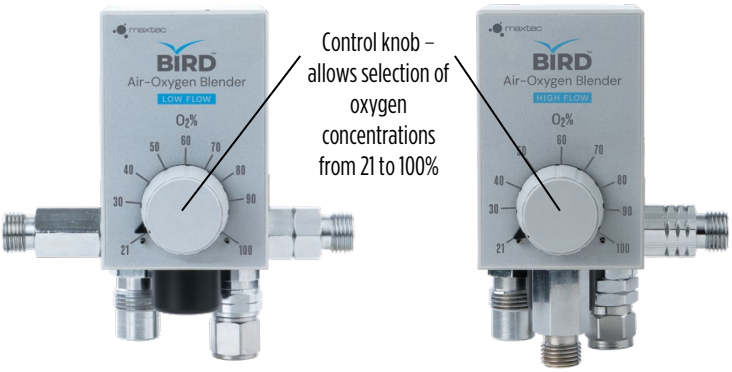
- Adjustment of the oxygen concentration must be verified using an oxygen analyzer.
- The MicroBlender is not suitable for use with Oxygen 93.

The following symbol may be referenced on the blender or in the accompanying documentation.

SYMBOL	SOURCE/COMPLIANCE	MEANING
	Symbol #5.4.3 ISO 15223-1	Indicates the need for the user to consult the instructions for use

4 CONTROLS AND ALARMS

The MicroBlender delivers selected oxygen concentrations through two outlet ports. The outlet ports, although similar in appearance, have different flow range specifications. The two outlet ports provide a choice of flow ranges based on the application desired. Both outlets may be used simultaneously, provided the combined flows do not exceed the rated maximum flow capability of the MicroBlender. The use of a flow meter attached to either or both of the outlet ports may be used to control the flow of mixed gas.



LOW FLOW MICROBLENDER **HIGH FLOW MICROBLENDER**

(Front View)

An audible alarm indicates a differential of 20 PSI has been reached between air and oxygen inlet gas pressures.

5 PERFORMANCE CHECKS

⚠ **Warning:** If the MicroBlender does not function as described below, contact Maxtec (refer to the company information at the beginning of this manual).

⊘ **DO NOT** use the MicroBlender until correct performance is verified.

5.1 MicroBlender Alarm/ Bypass Check

ADJUSTMENT	RESPONSE
1. Connect the 50 ±5 PSIG** air/ oxygen source gases. Adjust the control knob to 60%. Connect the flow meter to the auxiliary outlet and set the flow to 2 LPM.	1. Alarm/Bypass* should not activate (if gases are within 20 PSI of each other).
2. Disconnect the 50 PSIG air source from the MicroBlender.	2. Audible alarm, bypass* gas flow starts.
3. Reconnect the 50 PSIG** air source to the MicroBlender.	3. Audible alarm stops; bypass* gas flow stops flowing.
4. Disconnect the 50 PSIG** oxygen source from the MicroBlender.	4. Audible alarm, bypass* gas flow starts.
5. Reconnect the 50 PSIG** oxygen source to the MicroBlender.	5. Audible alarm stops; bypass* gas flow stops flowing.
6. Verify that the oxygen flow meter is set at 2 LPM.	6. Oxygen analyzer should read 60 ±3% when measured from the flow meter outlet.

* Bypass flow should occur whenever the alarm sounds, but this condition can only be verified by measuring O_2 concentrations with an oxygen analyzer.

** Gas supply pressures of 50 PSIG provide optimal performance.

5.2 Reverse Flow Check

1. Connect both gas supply hoses to the inlet connectors.
2. Connect the oxygen hose to an oxygen pressure regulator and submerge the free end of the air hose in a container of water. Do not make a connection to either blender outlet (so that they remain closed).
3. Slowly adjust the oxygen pressure regulator to increase pressure from 0 to 50 PSIG* while looking for bubbles to rise from the submerged air hose connector.
4. The presence of bubbles indicates leakage of the one-way valve and the need for repair.
5. If there is no leakage, disconnect the oxygen from the regulator and sub-merge the end of the hose in water.
6. Connect the air hose to an air pressure regulator and repeat the procedure. Repair if bubbles are present.

* Gas supply pressures of 50 PSIG provide optimal performance.

6 TROUBLESHOOTING GUIDE

PROBLEM	POTENTIAL CAUSE	CORRECTIVE ACTION
Oxygen concentration discrepancy between MicroBlender settings and analyzer	1. Analyzer out of calibration.	1. Calibrate the analyzer
	2. Flow requirements are below the specified LPM range.	2. Correct the flow. Verify that the correct outlet port is being used. Each outlet port has a different flow range.
	3. Gas supply is contaminated.	3. Correct the contaminated gas supply. If repair is needed, contact Maxtec
	4. MicroBlender is out of calibration.	4. Contact Maxtec for repair.
	5. Bleed filter is obstructed, causing reduction of bleed.	5. Contact Maxtec
	6. Air entrained into circuit by ventilator or accessory device.	6. Correct
Alarm sounding	1. Inlet pressure difference greater than 20 PSI.	1. Correct the pressure difference.
	2. Alarm module is not calibrated properly.	2. Contact Maxtec for repair.
	3. Inlet gas contamination, alarm module malfunction.	3. Contact Maxtec for repair.
MicroBlender in bypass – no alarm.	Reed plate improperly installed or damaged.	Contact Maxtec for repair.
MicroBlender is accurate only when inlet gas pressures are equal.	1. Balance module not functioning properly.	1. Contact Maxtec for repair.
	2. Both air and oxygen gas sources are below 30 PSIG.	2. Correct the low pressure condition.

7 CLEANING

- Use 17.2% isopropanol disposable wipes (CaviWipes™ or chemically equivalent composition) to clean the exterior surfaces. Allow the surfaces to dry before using the device.

⊘ Do not steam autoclave or otherwise subject the MicroBlender to temperatures over 63°C (145°F).

⊘ Do not immerse the assembled Low Flow MicroBlender in liquid decontamination agents.

⊘ Do not use any strong solvent cleaners on labels or markings.

8 MAINTENANCE AND SERVICE

⚠ **Caution:** The MicroBlender should only be serviced or calibrated by the Maxtec service department or in accordance with the service manual.

Maxtec equipment is designed to provide the maximum amount of utilization with a minimum amount of maintenance. When determining the desired frequency of complete overhaul intervals, three variables must be considered:

- Frequency of use
- Cleanliness of compressed air source
- Use of an air inlet filter/water trap

The MicroBlender, like other pieces of health care equipment, will require routine maintenance over a period of time. Maxtec recommends a complete overhaul be performed at least every two (2) years. The Maxtec approved maintenance kit (P/N 10003) includes all necessary components for overhauling the MicroBlender. Before placing the MicroBlender into clinical use, follow the performance-check guidelines outlined in Section 5. Visually inspect all device labeling at least every two (2) years to verify legibility and check for peeling. Contact Maxtec for replacement labels if required.

When using the MicroBlender with a compressed air source, an air inlet filter/water trap (RP05P08) is recommended. Contaminants from hospital air lines may compromise the function of the MicroBlender.

⚠ **Caution:** If the MicroBlender does not function as outlined in Section 5, contact Maxtec for service.

Applicable parts used in the MicroBlender have been cleaned and de-greased for oxygen service. All lubricants used during assembly are designed for use in an oxygen enriched environment. Use only Maxtec specified lubricants (Fluorolube T-80) when servicing this device.

Elastomer components, such as diaphragms and O-rings, are designed to function satisfactorily for a minimum of two years. The need for cleaning and replacement depends on gas line conditions and is indicated by the MicroBlender not meeting its specified performance.

9 PARTS AND ACCESSORIES

9.1 MicroBlender Brackets

PART NUMBER	DESCRIPTION
R100P26	Blender Bracket, Rail/Pole Mount
RP05P07	Blender Bracket, Wall Mount Small
RP05P09	Blender Bracket, Wall Mount Large

9.2 Parts & Accessories

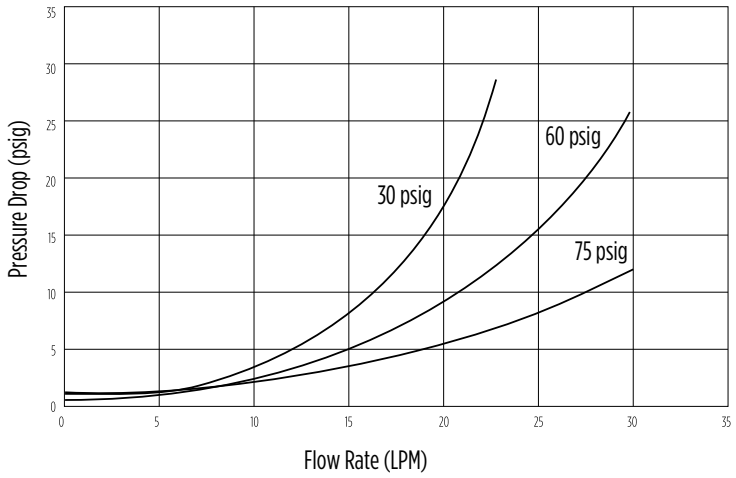
PART NUMBER	DESCRIPTION
10003	BIRD® MicroBlender Maintenance Kit (Low/High Flow), Domestic
10003V2	Blender Maintenance Kit (Low/High Flow), International
R219P50	2-in-1 Muffled Adapter
R219P32	2-in-1 Adapter
RP11P20	1.5" 90 Degree DISS Elbow
RP05P08	Air Inlet Filter/Water Trap

10 EXPLANATION OF ABBREVIATIONS

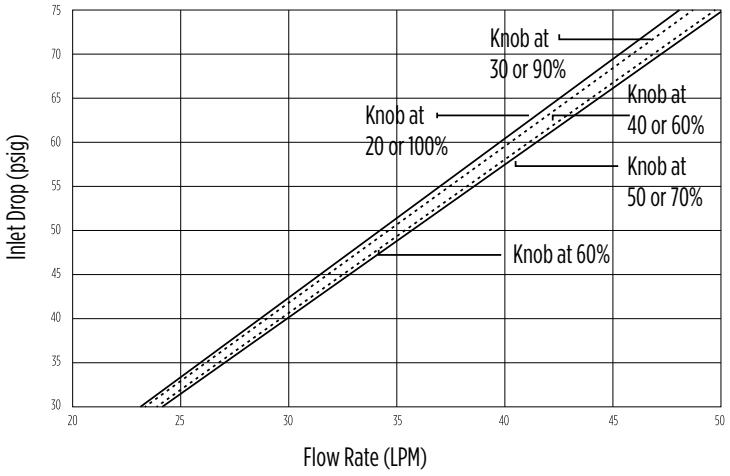
Air/O_2	Mixture of Compressed Air and Oxygen
°C	Degrees Centigrade
CGA	Compressed Gas Association
DISS	Diameter Indexed Safety System
°F	Degrees Fahrenheit
FiO_2	Fractional Concentration of Inspired Oxygen
O_2	Oxygen
LPM	Liter Per Minute
P/N	Part Number
psi	Pounds Per Square Inch
psig	Pounds Per Square Inch Gauge

⊘ Do not operate the MicroBlender outside the supply pressure range (30–75 PSIG). Gas supply pressures of 50 PSIG provide optimal performance. The graphs on the following page illustrate typical flow performance characteristics of a representative sample for the Low Flow MicroBlender. The graphs are typical of a representative sample; slight variations among units should be expected.

11 SPECIFICATIONS



OUTLET PRESSURE DROP AT FLOW



AVERAGE OUTLET FLOW AT VARIOUS INLET PRESSURES

NOTE: The graphs are typical of a representative sample; slight variations among units should be expected.

Gas Inlet Supply Pressure	Low Flow	30–75 psig
	High Flow	30–75 psig. Output flow rate will be diminished if either supply pressure is below 50 psig; output flow will increase if both supply pressures are above 50 psig.
Oxygen Concentration Control	Low Flow and High Flow	21 to 100%
Auxiliary Outlet Flow Range	Low Flow	Right Side Outlet 0–30 LPM (Bleed 2.5–3.5 LPM)[1]
	High Flow	Right Side Outlet 2–100 LPM (Bleed 10–12 LPM)
Primary Outlet Flow Range	Low Flow	Left Side Outlet 3–30 LPM (No Bleed)[1]
	High Flow	Bottom Port 15–120 LPM (No Bleed)
Maximum available flow at 60% setting with 50 psig both inlets	Low Flow	>30 LPM
	High Flow	>120 LPM
Accuracy	Low Flow and High Flow	The accuracy is ±3% FIO_2 at any set-point, provided the inlet supply pressures are between 30 and 75 psig and the difference between them does not exceed 20 psi.
Stability	Low Flow and High Flow	O_2 concentration shall not vary from a set-point by more than ±3% if either the inlet supply pressure or the output flow rate is changed within its range specified herein.
Alarm/Bypass Activation	Low Flow and High Flow	When inlet gas pressures differ by 20 ±2 psi.
Alarm Sound Generator	Low Flow	Reed Alarm
	High Flow	
Alarm Sound Intensity	Low Flow	80 dB minimum at 1 foot
	High Flow	80 dB minimum at 1 foot
Alarm/Bypass Reset	Low Flow	When inlet gas pressure differential is 10 psi or less
	High Flow	When inlet gas pressure differential is 6 psi or less
Pressure Drop	Low Flow	Less than 6 psi at 50 psig inlet pressures and 10 LPM flow rate
	High Flow	Less than 6 psi at 50 psig inlet pressures and 40 LPM flow rate
Weight	Low Flow	2.75 lb. (1.25kg)
	High Flow	
Dimensions (Excluding Fittings)	Low Flow	Height: 3 ½ in. (8.9 cm) Width: 2 ¼ in. (5.8 cm) Depth: 4 ½ in. (11.5 cm)
	High Flow	Height: 3 ½ in. (8.9 cm) Width: 2 ¼ in. (5.8 cm) Depth: 4 ½ in. (11.5 cm)
Storage Conditions	Low Flow	Temperature: –15 to 50°C (5 - 122°F) Relative Humidity 15 to 95%
	High Flow	
Operating Conditions	Low Flow	Temperature: 15 to 40°C (59 - 104°F) Relative Humidity 15 to 95%
	High Flow	

[1] For supply pressures less than 50 psig, the maximum flow rate may drop as low as 20 LPM.

NOTE: Product specifications are subject to change without notice.

12 WARRANTY

The MicroBlender is designed for air/oxygen delivery. Under normal operating conditions, Maxtec warrants the MicroBlender to be free from defects of workmanship or materials for a period of two years from the date of dispatch, 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 repairs, or issuing credit, or replacement for equipment found to be defective. This warranty extends only to buyers purchasing new equipment directly from Maxtec, or through Maxtec's designated distributors and agents. Routine maintenance items are excluded from warranty. Maxtec, and any other subsidiaries, shall not be liable to the purchaser or other persons for incidental or consequential damages to equipment that has been subject to abuse, misuse, misapplication, alteration, negligence, or accident. **THESE WARRANTIES ARE EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WARRANTY OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE**.

NOTE: In order to obtain optimum performance from your MicroBlender, all operation and maintenance must be performed in accordance with this manual. Please read the manual thoroughly before using the MicroBlender, 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 device.

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