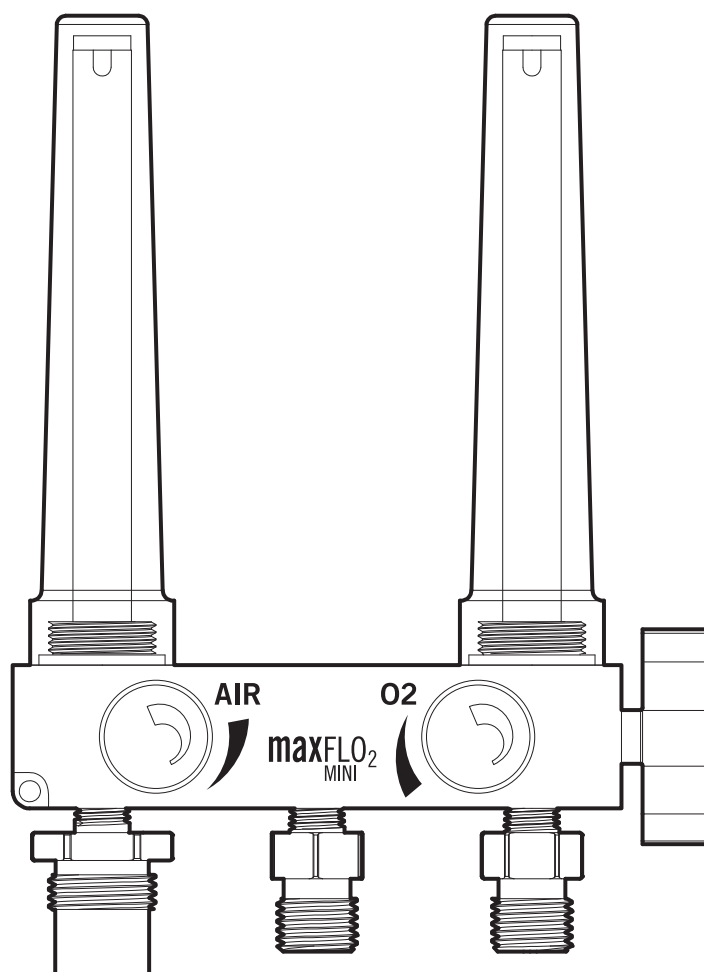




MaxFlo₂ MiniTM

Instructions for Use

ENGLISH





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CE-0123

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

NOTE: The MaxFLO2 Mini is for use only by trained personnel. Before use, all individuals using the MaxFLO2 Mini should become familiar with the information contained in this Operating Manual. Adherence to these instructions is necessary for safe, effective product performance. Thoroughly read all instructions and labelling provided with this device and any other equipment that will be used.

INDICATIONS FOR USE

The MaxFLO2 Mini is designed to provide intermittent or continuous controlled flows of an air/oxygen gas mixture to infant, pediatric, and adult patients. The MaxFLO2 Mini is a restricted medical device intended for use by qualified trained personnel under the direction of a physician in institutional environments where delivery and monitoring of air/oxygen mixtures are required.

CONTRAINDICATIONS

The MaxFLO2 Mini is not intended for use as a life support device.

WARRANTY

Under normal operating conditions, Maxtec warrants the MaxFLO2 Mini to be free from defects of workmanship or materials for a period of 3 years from the date of shipment from Maxtec, provided that the unit is properly operated and maintained in accordance with Maxtec's operating instructions. Based on Maxtec product evaluation, Maxtec's sole obligation under the foregoing warranty is limited to making replacements, repairs, or issuing credit for equipment found to be defective. This warranty extends only to the buyer purchasing the equipment directly from Maxtec or through Maxtec's designated distributors and agents as new equipment.

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 or equipment that has been subject to abuse, misuse, misapplication, alteration, negligence or accident.

These warranties are exclusive and in lieu of all other warranties, expressed or implied, including warranty of merchantability and fitness for a particular purpose.

WARNINGS

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

DO NOT use the MaxFLO2 Mini in an MRI environment.

DO NOT use the MaxFLO2 Mini as a life support device.

◆ The MaxFLO2 Mini DOES NOT CONTAIN AUDIBLE OR VISUAL ALARMS. Loss of a gas source or a drop of gas pressure below functional levels is determined visually by monitoring individual gas flows.

DO NOT use the MaxFLO2 Mini to provide mixed gas to other devices which require a pressurized gas.

DO NOT use the MaxFLO2 Mini near any type of open flame.

◆ The MaxFLO2 Mini is only for use with oxygen and medical air.

◆ Always operate the MaxFLO2 Mini with clean, dry medical grade gases. Contaminates or moisture can cause defective operation. Oxygen should have a minimum dew point of -80°F (-62°C) or moisture content less than 7.9 ppm (0.0059 mg/L). Oxygen "purity" should be at least 99.6% 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 G4.3 and G7.1 for more information. Water vapor content of medical air or oxygen supply to the MaxFLO2 Mini must not exceed 5.63 x 10³ mg/m³ H₂O of non-condensable gas.

◆ The MaxFLO2 Mini should only be used under proper supervision from a healthcare professional.

◆ Consult a physician for appropriate FiO₂ settings.

◆ The oxygen concentration selection table in this operating manual is provided only as a guideline for selecting oxygen concentration. Verify oxygen concentrations using an analyzer/monitor complying with ISO 7767 which can be calibrated.

DO NOT autoclave or expose the MaxFLO2 Mini to high temperatures >150°F (>65°C).

DO NOT use ethylene oxide sterilization.

DO NOT expose the MaxFLO2 Mini to pressures greater than 100 PSIG (689 kPaG)

DO NOT disconnect gas hoses from the MaxFLO2 Mini while the device is under pressure.

DO NOT immerse the MaxFLO2 Mini in any kind of fluid.

CAUTIONS

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

◆ Use caution when using the MaxFLO2 Mini in the presence of flammable anesthetics or in an atmosphere of flammable gases when the O₂ concentration exceeds 30%. Maxtec recommends following hospital anesthetic gas guidelines*.

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

◆ The MaxFLO2 Mini is intended for use with a gas analyzer/monitor complying with ISO 7767 for continuous or intermittent gas analysis. Maxtec recommends use of an oxygen analyzer/monitor, which can be calibrated, whenever the MaxFLO2 Mini is in use.

◆ When setting flow use center of float ball.

◆ Variations in inlet gas source pressure will alter the percent of oxygen exiting the outlet, especially when one gas source pressure is high and the other is low. Gas inlet pressure should be set to 50+/-2 PSIG (345+/-14 kPaG).

◆ Variations in inlet gas source pressure will alter total flow rate exiting the device, especially when both gas source pressures are low. Gas inlet pressure should be set to 50+/-2 PSIG (345+/-14 kPaG).

DO NOT operate the MaxFLO2 Mini with inlet gas source pressure outside of 50+/-2 PSIG.

◆ Excessive back pressure on the outlet may result in alterations to indicated gas flow but will not result in inaccurate oxygen concentration.

◆ Accuracy of flow due to variations in ambient temperature is standard accuracy +7.3%@32°F (0°C) and -3.0%@104°F (40°C)

◆ Inlet gas pressure 1.5 times greater than normal will result in inaccurate flow rates

◆ Clean the MaxFLO2 Mini as recommended in section 5 of this operating manual. Excessive cleaning can cause residue buildup on critical components which can affect the performance of the MaxFLO2 Mini.

DO NOT clean the MaxFLO2 Mini with cleaning agents that contain phenols, ammonia chloride, or chloride compounds, or that contain more than 2% glutaraldehyde. These agents may damage the plastic components.

◆ Mount the MaxFLO2 Mini vertically and securely for correct performance.

- ◆ Dropping the device may cause injury or device damage. If the MaxFLO2 Mini is dropped, follow the procedures outlined in Section 3 of this Operating Manual for a performance check before re-using the device.
- ◆ An inlet watertrap/filter is recommended for use with the MaxFLO2 Mini.
- ⚠ **DO NOT** overtighten the flow adjustment valves.
- ◆ Use only Maxtec replacement parts. Failure to do so may seriously impair the performance of the MaxFLO2 Mini. Repair or alteration of the MaxFLO2 Mini by anyone other than an authorized Maxtec service representative, could cause the product to fail to perform as designed.

*References:

1. New clinical guide to surgical fire prevention. *Health Devices*. 2009;38(10):314-332.
2. Accidents happen—an immediate action plan. The ECRI Institute website. Available at: https://www.ecri.org/Products/PatientSafetyQualityRiskManagement/CustomizedServices/Pages/Immediate_Action_Plan.aspx Accessed November 2, 2009.

NOTES

Indicates supplemental information to assist in use of the device.

- ◆ Reference section 10.2 of this Operating Manual for user servicable parts for the MaxFLO2 Mini
- ◆ The MaxFLO2 Mini is tested for compliance with ISO 11195 and meets requirements regarding reverse gas flow as delivered.
- ◆ The MaxFLO2 Mini has been cleaned and degreased for oxygen service prior to shipment. Any lubricants used are designed specifically for the application. Do not use anything other than Maxtec specified lubricants when servicing the MaxFLO2 Mini. Never use oils on the MaxFLO2 Mini.
- ◆ Users are advised to use pressure regulators set to 50 ± 2 PSIG (345 ± 14 kPaG) which display system pressure.
- ◆ All specifications assume the following standard environmental conditions unless otherwise specified: ambient and sample gas temperatures of 77°F (25°C), barometric pressure of 1 atm (101 kPaG), ambient relative humidity of 50%, sample gas relative humidity of 0%.

SYMBOL GUIDE

The following symbols and safety labels are found on the MaxFLO2 Mini:

	Follow instructions for use		Caution
	Warning		Catalog Number
	Manufacturer		Inlet
	DO NOT		Gas Outlet
	Use No Oil		Serial Number
	Authorized Representative in the European Community		Federal law (USA) restricts this device to sale by or on order of a physician.
	Lot code/Batch code		Attention, consult accompanying documents
LPM	Litre per minute flow		Latex Free
Pmax	Maximum allowable pressure		

1.0 SYSTEM OVERVIEW

1.1 Indications for Use

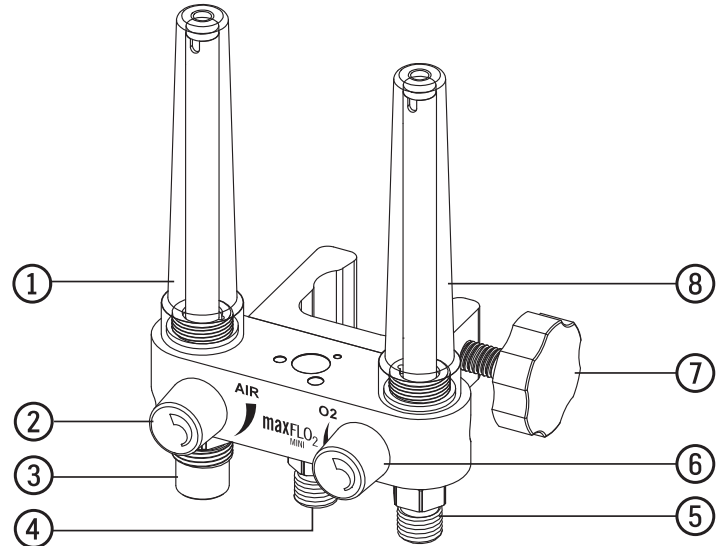
The MaxFLO2 Mini is a compact air/oxygen gas mixing device. The MaxFLO2 Mini provides precise mixing of medical grade air and oxygen through two separate gas flowmeters controlled by two separate flow control knobs. The sum of each individual gas flow yields the total flow of gas, i.e. 20 LPM of oxygen and 30 LPM of air is a total flow of 50 LPM. Resulting oxygen concentration can be determined in several ways:

- With use of an oxygen analyzer/monitor in the downstream gas mixture.
- Referencing Table 1 in Section 2.2 of this Operating Manual.

Additional features and operational benefits include:

- Durable, compact design.
- Low maintenance.

1.2 Component Identification



- ① **MEDICAL AIR FLOWMETER** — A Thorpe tube style flowmeter with a float ball and flow graduations designed specifically for the flow of air.
- ② **MEDICAL AIR FLOW ADJUSTMENT VALVE** — Valve controlling the flow of air into the flowmeter.
- ③ **MEDICAL AIR GAS INLET** — Fitting for connection of a medical air inlet hose from the medical air gas source.
- ④ **MALE MIXED GAS OUTLET** — A diameter indexed (DISS) oxygen fitting.
- ⑤ **OXYGEN GAS INLET** — Fitting for connection of an oxygen inlet hose from the oxygen gas source.
- ⑥ **OXYGEN FLOW ADJUSTMENT VALVE** — Valve controlling the flow of oxygen into the flowmeter.
- ⑦ **IV POLE CLAMP** — Clamp for securing the MaxFLO2 Mini to a vertical pole
- ⑧ **OXYGEN FLOW METER** — A Thorpe tube style flowmeter with a float ball and flow graduations designed specifically for the flow of oxygen.

1.3 Operational Requirements

Pressurized Oxygen—For optimal performance the oxygen source must provide clean, dry, medical grade oxygen at a line pressure of 50 ± 2 PSIG (345 ± 14 kPaG).

Pressurized Medical Air—For optimal performance the air source must provide clean, dry, medical grade air at a line pressure of 50 ± 2 PSIG (345 ± 14 kPaG).

NOTE: Delivered gas characteristics are affected by variations in inlet gas pressures.

2.0 OPERATING INSTRUCTIONS

2.1 Installation of MaxFLO2 Mini to an IV Pole

NOTE: Prior to placing the MaxFLO2 Mini into clinical use, the performance check described in Section 3 of this operating manual should be completed.

- Connect an appropriate tubing fitting to the male DISS fitting on the bottom of the device as seen in section 1.2 of this operating manual.
- The rear of the MaxFLO2 Mini contains a pole clamp. Mount the unit securely to the pole via the pole clamp. When mounting ensure the pole sits in the curved groove of the clamp's arm. Tighten the screw clockwise until the unit is completely secure.
- The MaxFLO2 Mini must be mounted in the vertical position for correct function of the air and oxygen flowmeters.
- Connect a pressure capable air source to the air inlet fitting and a pressure capable oxygen source to the oxygen inlet fitting.
- Connect the air and oxygen hoses to their respective gas sources.
- Connect appropriate tubing to the outlet fitting.

2.2 Setting Flow and Oxygen Concentration

- To increase the flow of air or oxygen turn the flow control knob of the desired gas counter-clockwise. Each flowmeter contains a float ball which indicates the flow rate when read against the flowmeter's scale. The float ball must be read at centerline while looking straight at the flowmeter.
- Total flow delivered to the patient is calculated by adding the air and oxygen set flows.

EXAMPLE: FiO2 delivered to the patient is based on the ratio of air to oxygen

Air LPM / O2 LPM	Approximate oxygen % exiting the MaxFLO2 Mini
.5 LPM / .5 LPM	This is a 1:1 ratio = 61% FiO2
1 LPM / 1 LPM	This is a 1:1 ratio = 61% FiO2
2 LPM / 4 LPM	This is a 1:2 ratio = 74% FiO2
4 LPM / 2 LPM	This is a 2:1 ratio = 47% FiO2

NOTE: Maxtec recommends verification of delivered gas with a calibrated oxygen analyzer in accordance with the following AARC Clinical Practice Guidelines:

1. 11.2.1 - All oxygen systems should be checked at least once per day.
2. 11.2.2 - More frequent checks by calibrated analyzers are necessary in systems. [Source: Kallstrom, Thomas J. RRT FAARC, Fairview Hospital (June, 2002). AARC Guideline: Oxygen Therapy for Adults in the Acute Care Facility. Respiratory Care, Volume 47(No 6), 717-720.]

3.0 PERFORMANCE CHECK

The MaxFLO2 Mini is designed for low maintenance operation. However, the following functional tests should be performed periodically in order to ensure proper function.

- Install the MaxFLO2 Mini according to section 2.1 of this operating manual in order to conduct the performance check.
- Conduct the performance check on Pg 4 of this Operating Manual.

⚠ WARNING: If the MaxFLO2 Mini does not function as described in the following tests discontinue use of the device pending service by trained technicians or contact your Maxtec Distributor or Maxtec at: 2305 South 1070 West, Salt Lake City, UT 84119 (801) 266-5300 or (800) 748-5355

3.1 Gas Supply Functional Testing

Procedure:

1. Place a calibrated Analyzer/Monitor in the downstream mixed gas stream and adjust both flowmeters to flow at 10 LPM. Observe gas flowing from mixed gas outlet and that the Analyzer/monitor reads 57 - 67% O2.
2. Maintain both flowmeters at 10 LPM and disconnect 50 PSIG (345 kPaG) air source from the wall or regulator. Observe gas flowing from mixed gas outlet and that the Analyzer/Monitor reads 95 - 100% O2.
3. Reconnect 50 PSIG (345 kPaG) air source to the wall or regulator. Observe gas flowing from mixed gas outlet and that the Analyzer/Monitor reads 57 - 64% O2.
4. Maintain both flowmeters at 10 LPM and disconnect 50 PSIG (345 kPaG) oxygen source from the wall or regulator. Observe gas flowing from mixed gas outlet and that the Analyzer/Monitor reads 20.9 - 22% O2.

5. Reconnect 50 PSIG (345 kPaG) oxygen source to wall or regulator. Observe gas flowing from mixed gas outlet and that the Analyzer/Monitor reads 57 - 64% O2.

3.2 Reverse Flow functional testing procedure:

1. Using air and oxygen cylinders with regulators, adjust both air and oxygen cylinder regulators to zero (0) PSIG (0 kPaG).
2. Cover and seal the male DISS fitting (Mixed Gas Outlet).
3. Remove air inlet hose at air cylinder regulator and insert end into beaker of water.
4. Fully open MaxFLO2 Mini air and oxygen valves.
5. Slowly raise pressure of oxygen cylinder regulator to 50 PSIG (345 kPaG) and return back to zero (0) PSIG (0 kPaG) while watching air hose end in beaker. Observe that no bubbles are escaping from submerged end of air hose during test.
6. Ensure air inlet hose is completely dry and re-attach to air cylinder regulator.
7. Remove oxygen inlet hose at oxygen cylinder regulator and insert end into beaker of water.
8. Slowly raise pressure of air cylinder regulator to 50 PSIG (345 kPaG) and back to zero (0) (0 kPaG) while watching oxygen hose end in beaker. Observe that no bubbles are escaping from submerged end of oxygen hose during test.
9. Ensure oxygen inlet hose is completely dry and re-attach to oxygen cylinder regulator.
10. Uncover the DISS fitting (Mixed Gas Outlet).

4.0 TROUBLESHOOTING

PROBLEM: Gas leaking past flow control valve even though valve is closed.

POTENTIAL CAUSES AND SOLUTIONS:

- Flow valve knob is over-tightened or the valve's internal stem may not be seated correctly. Turn the valve counter-clockwise to allow some flow then re-close the valve without undue force.
- Flow valve is contaminated or internal o-rings are worn or damaged. Contact your Maxtec distributor or Maxtec for repair.

PROBLEM: Float ball is not stable and bobbles up and down.

POTENTIAL CAUSES AND SOLUTIONS:

- Flow rate is outside flowmeter specifications. Reduce flow rate. (Occasional and intermittent bobbling is normal at flow rates between 80% and 100% of full scale.)

PROBLEM: Flow or oxygen concentration exiting the MaxFLO2 Mini measures incorrectly.

POTENTIAL CAUSES AND SOLUTIONS:

- Verify gas inlet pressures are set correctly to 50+/-2 PSIG (345+/-14 kPaG)
- Float ball is contaminated. Contact your Maxtec distributor or Maxtec for repair.

5.0 CLEANING

Use caution to prevent any fluid from entering the MaxFLO2 Mini. Clean the exterior surface of the MaxFLO2 Mini in accordance with institutional cleaning protocols. Dry completely before re-use.

⊘ **DO NOT** soak or immerse the MaxFLO2 Mini in fluid.

⊘ **DO NOT** allow any fluid to enter the MaxFLO2 Mini.

⊘ **DO NOT** autoclave or expose the MaxFLO2 Mini to ethylene oxide sterilization.

⊘ **DO NOT** use any solvent based cleaners on the MaxFLO2 Mini or it's labels.

6.0 SERVICE AND MAINTENANCE

Maxtec recommends the performance check listed in section 3 of this operating manual be conducted prior to placing the MaxFLO2 Mini into clinical use and periodically thereafter. **IF THE MAXFLO2 MINI DOES NOT FUNCTION AS DESCRIBED IN THE PERFORMANCE CHECK, DISCONTINUE USE OF THE DEVICE PENDING SERVICE BY TRAINED TECHNICIANS OR CONTACT YOUR MAXTEC DISTRIBUTOR OR MAXTEC AT**

2305 South 1070 West, Salt Lake City, UT 84119 (801) 266-5300 or (800) 748-5355

The MaxFLO2 Mini's flow adjustment valves should be replaced as needed. The full MaxFLO2 Mini device should be overhauled and serviced a minimum of every four (4) years to replace all o-rings and valves. See section 9.2 of this Operating Manual for spare part numbers.

When using a medical grade air source, an inlet watertrap/filter is recommended to be attached to the air inlet of the MaxFLO2 Mini prior to use. Contaminants from gas sources may compromise the function of the MaxFLO2 Mini.

Store the MaxFLO2 Mini in a clean, dry place when not in use.

7.0 ABBREVIATION GUIDE

FiO2	Fraction concentration of inspired oxygen
°C	Degrees Celsius
°F	Degrees Fahrenheit
CGA	Compressed Gas Association
DISS	Diameter indexed safety system
O2	Oxygen
LPM	Liters per minute
atm	Standard atmosphere
PSIG	Pounds per square inch gauge
kPaG	Kilo-pascal gauge

8.0 SPECIFICATIONS

Weight (unpacked)	<1.5 lbs (0.7 kg)
Internal Filter (air and O2 inlet)	45-90 µm particulate
O2 Concentration Adjustment Range	21% - 100% O2
Gas Supply Pressure	50 +/- 2 PSIG (345 +/- 14kPaG)
Outlet Flow Range	10 LPM (at 20.9% O2 and 100% O2) to 140 LPM (at 60% O2) for 0-70 lpm mixer 0.5 LPM (at 20.9% O2 and 100% O2) to 30 LPM (at 60% O2) for 0-15 LPM mixer
Optimal Working Pressure	50 PSIG (345 kPaG)
Maximum Allowable Pressure	100 PSIG (689 kPaG)
Temperature Range	59°F - 104°F (15°C - 40°C)
Maximum Allowable Temperature	150°F (60°C)
Relative Humidity Range	0 - 95% non-condensing
Ambient Storage Conditions Temperature Range	5°F - 122°F (-15°C - 50°C)

9.0 SPARE PARTS AND ACCESSORIES

9.1 Included with Your Unit

R223P08	MaxFLO2 Mini, 0-70 LPM, or
R223P14	MaxFLO2 Mini, 0-15 LPM
R223M08	Operating Manual and Instructions for Use

Spare Parts

Part Number	Item
R219P33-001	MaxFLO2 Mini, 0-70 LPM Valve Replacement Kit
R219P33-004	MaxFLO2 Mini, 0-70 LPM Overhaul Kit
R219P33	MaxFLO2 Mini, 0-15 LPM Valve Replacement Kit
R223P14-001	MaxFLO2 Mini, 0-15 LPM Overhaul Kit

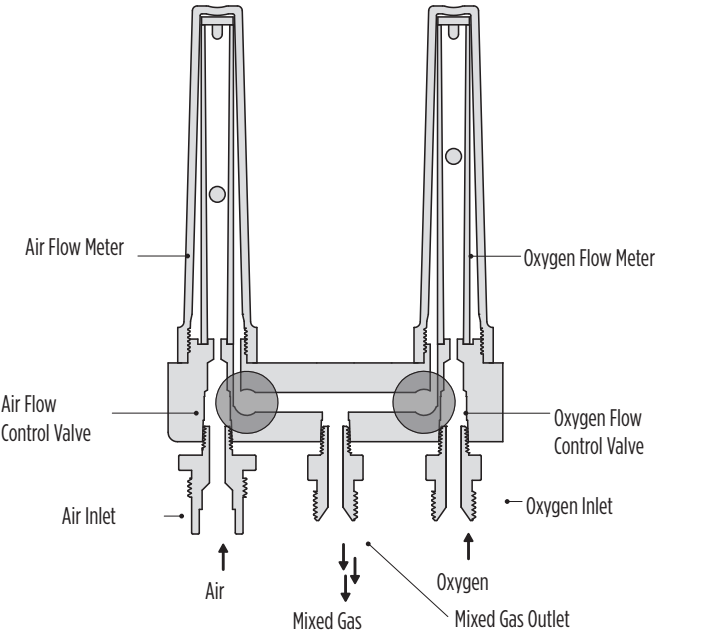
9.2 Oxygen Diluter Specifications

Part Number	Item
R219P32	22mm Male/15mm Female Conical Fitting, High Flow
R129P01	Dual Blender Hose, Air/Oxygen
R100P49-001	SmartStack I.V. Stand (Single, Premium)

10.0 THEORY OF OPERATION

10.1 Mixing Operation

The MaxFLO2 Mini is designed to utilize two 50 PSIG (345 kPaG) gas sources - medical grade air and oxygen (Figure 1, for reference only). The two gases enter through the air and oxygen inlet connectors located on the left and right side of the MaxFLO2 Mini respectively. Each inlet connector incorporates a one-way check valve which prevents reverse gas flow from either the air or oxygen supply system in the event of a loss of pressure from either gas source. The check valves are followed by a 45-90 micron particulate filter. Once through the filters, each gas passes through a pressure compensated flowmeter. The pressure compensated flowmeters display flow correctly by means of a float, regardless back pressure. **Inlet pressures over 100 PSIG (690 kPaG) risk damaging the mixer and/or causing injury and should never be surpassed.** Variations in inlet gas pressure will alter O2 concentrations of the delivered gas. The amount of the variation determines the magnitude of the alteration in O2 concentration. The MaxFLO2 Mini should always receive 50+/-2 PSIG (345+/-14 kPaG) of inlet gas pressure for optimum performance for both flow and O2 concentration accuracy.



10.2 Mixed Gas Outlet

A single gas outlet is located at the bottom of the MaxFLO2 Mini. For the 0-70LPM MaxFLO2 Mini, the outlet is capable of delivering metered flows of 10 LPM (at 20.9% or 100% O2) to 140 LPM (at 60% O2) of mixed gas. For the 0-15 LPM MaxFLO2 Mini, the outlet is capable of delivering metered flows of 0.5 LPM (at 20.9% O2 and 100% O2) to 30 LPM (at 60% O2) for 0-15 LPM mixer. The outlet is not intended to ever be sealed or occluded during normal operation.



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