



Operating Manual & Instructions for Use

0-15 LPM R223P14 0-70 LPM R223P08



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NOTE: The $MaxFLO_2$ Mini is for use only by trained personnel. Before use, all individuals using the $MaxFLO_2$ 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 $MaxFLO_2$ Mini is designed to provide intermittent or continuous controlled flows of an air/oxygen gas mixture to infant, pediatric, and adult patients. The $MaxFLO_2$ 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 $MaxFLO_2$ 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 $MaxFLO_2$ Mini in an MRI environment.
- **DO NOT** use the $MaxFLO_2$ 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.
- \bigcirc DO NOT use the MaxFLO₂ Mini to provide mixed gas to other devices which require a pressurized gas.

\bigcirc 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 \triangle

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.
- 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%.

TABLE OF CONTENTS

INDICATIONS FOR USEII
CONTRAINDICATIONSII
WARRANTYII
NOTESV
1.0 SYSTEM OVERVIEW.11.1 Indications for Use11.2 Component Identification11.3 Component Description21.4 Symbol Guide21.5 Operational Requirements2
2.0 OPERATING INSTRUCTIONS
3.0 PERFORMANCE CHECK4
4.0 TROUBLESHOOTING
5.0 CLEANING
6.0 SERVICE AND MAINTENANCE
7.0 ABBREVIATION GUIDE6
8.0 SPECIFICATIONS

9.0 SPARE PARTS AND ACCESSORIES	7
9.1 Included with Your Unit	7
9.2 Spare Parts	7
9.3 Oxygen Diluter Specifications	7
10.0 THEORY OF OPERATION	7
10.1 Mixing Operation	7
10.2 Mixed Gas Outlet	8

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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
- 2 MEDICAL AIR FLOW ADJUSTMENT VALVE
- **3** MEDICAL AIR GAS INLET
- 4 MALE DISS FITTING (MIXED GAS OUTLET)
- **5** OXYGEN FLOW METER
- **6** OXYGEN FLOW ADJUSTMENT VALVE
- OXYGEN GAS INLET
- **8** IV POLE CLAMP

1.3 Component Description

Oxygen Flowmeter—A Thorpe tube style flowmeter with a float ball and flow graduations designed specifically for the flow of oxygen.

Medical Air Flowmeter—A Thorpe tube style flowmeter with a float ball and flow graduations designed specifically for the flow of air.

Flow Control Valve – Valve controlling the flow of gas into the flowmeter.

Mixed Gas Outlet—A diameter indexed (DISS) oxygen fitting.

Oxygen Gas Inlet—Fitting for connection of an oxygen inlet hose from the oxygen gas source.

Medical Air Gas Inlet—Fitting for connection of a medical air inlet hose from the medical air gas source. IV Pole Clamp—Clamp for securing the MaxFLO₂ Mini to a vertical pole.

1.4 Symbol Guide

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

i	Attention, consult accompanying documents	LPM	Litre per minute flow
	Manufacturer	↓	Gas Inlet
SN	Serial Number	€-	Gas Outlet
REF	Catalog Number		Maximum allowable temperature
DATEX	Latex Free	Pmax	Maximum allowable pressure
EC REP	Authorized Representative in the European Commuity	¥.	Use no oil
$R_{\!\!X}^{}$ only	Federal law (USA) restricts this device to sale by or on order of a physician	\bigcirc	Do Not
	Warning		

1.5 Operational Requirements

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

Pressurized Medical Air—For optimal performance the air source must provide clean, dry, medical grade air at a line pressure of 50 \pm 2 PSIG (345 \pm 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, see Table 1 on Pg 3.

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

TABLE 1

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

- 11.2.1 All oxygen systems should be chekced at least once per day.
- 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 $MaxFLO_2$ 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

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 $57 - 64\% O_2$.

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% O_2 .

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 $57 - 64\% O_2$.

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 $20.9 - 22\% O_2$.

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 $57 - 64\% O_2$.

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 $MaxFLO_2$ Mini. Clean the exterior surface of the $MaxFLO_2$ 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 $MaxFLO_2$ Mini's flow adjustment valves should be replaced as needed. The full $MaxFLO_2$ 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 $MaxFLO_2$ Mini prior to use. Contaminants from gas sources may compromise the function of the $MaxFLO_2$ Mini.

Store the $MaxFLO_2$ Mini in a clean, dry place when not in use.

7.0 ABBREVIATION GUIDE

FiO ₂	Fraction concentration of inspired oxygen
°C	Degrees Celsius
°F	Degrees Fahrenheit
CGA	Compressed Gas Association
DISS	Diameter indexed safety system
O ₂	Oxygen
LPM	Liters per minute
atm	Standard atmosphere
PSIG	Pounds per square inch gauge
kPaG	Kilo-pascal gauge

8.0 SPECIFICATIONS

Weight (unpackaged)	<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)
Temerpature 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

Part Number	Item
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	$MaxFLO_2$ Mini, 0-70 LPM Valve Replacement Kit
R219P33-004	MaxFLO ₂ Mini, 0-70 LPM Overhaul Kit
R219P33	MaxFLO ₂ Mini, 0-15 LPM Valve Replacement Kit
R223P14-001	MaxFLO ₂ 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 $MaxFLO_2$ Mini. For the O-70LPM $MaxFLO_2$ 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 O-15 LPM $MaxFLO_2$ 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 O-15 LPM mixer. The outlet is not intended to ever be sealed or occluded during normal operation.

