USER MANUAL

AIR-OXYGEN BLENDER

(DISS and NIST Connections)

Model No. PM5200 Series
PM5300 Series (shown)

SAVE THESE INSTRUCTIONS

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

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RECEIVING / INSPECTION

Remove the Precision Medical, Inc. Air-Oxygen Blender from the packaging and inspect for damage. If there is any damage, DO NOT USE and contact your Provider.

INTENDED USE

Precision Medical, Inc. Air-Oxygen Blender dispenses a continuous and precise blend of medical air and USP oxygen via outlet ports to infant, pediatric and adult patients. The exact Fractional Concentration of Inspired Oxygen (FiO_2) blend of gases corresponds to the dialed in FiO_2 setting indicated by the control knob (dial).

READ ALL INSTRUCTIONS BEFORE USING

This manual instructs a Professional to install and operate the Air-Oxygen Blender. This is provided for your safety and to prevent damage to the Air-Oxygen Blender. If you do not understand this manual, DO NOT USE the Air-Oxygen Blender and contact your Provider.

⚠ DANGER

This product is not intended as a life-sustaining or life-supporting device.

EXPLANATION OF ABBREVIATIONS

FiO_2	Fractional Concentration of Inspired Oxygen
DISS	Diameter Indexed Safety System
NIST	Non-Interchangeable Screw Thread
psi	Pounds Per Square Inch
lpm	Liters Per Minute

SAFETY INFORMATION - WARNINGS AND CAUTIONS

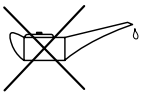
⚠DANGER Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

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

⚠CAUTION Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.

CAUTION Used without the safety alert symbol indicates a potentially hazardous situation which, if not avoided, may result in property damage.

CONSULT ACCOMPANYING DOCUMENTS



Symbol for “USE NO OIL”

CE
0197

Symbol indicates the device complies with the requirements of Directive 93/42/EEC concerning medical devices and all applicable International Standards. **(On CE marked Devices ONLY)**

⚠WARNING

- Only trained, qualified medical personnel under the direct supervision of a licensed physician should operate the Air-Oxygen Blender .
- Use this Air-Oxygen Blender only for its Intended Use as described in this manual.
- Confirm prescribed dose before administering to patient. Monitor on a frequent basis.
- The Air-Oxygen Blender shall be serviced by a qualified service technician.
- Always follow ANSI and CGA standards for Medical Gas Products, Flowmeters and Oxygen Handling.

⚠WARNING

- An Oxygen Analyzer/Monitor must be used to verify oxygen concentration.
- Accuracy of oxygen concentration will be affected if bleed is not activated at flow settings below 15 lpm for the High Flow Blender, and 3 lpm for the Low Flow Blender.
- **DO NOT** obstruct the alarm.
- **DO NO**T use Blender when alarm is sounding.
- **DO NOT** use oil in or around the Blender.
- **DO NOT** occlude or obstruct the bleed port on the auxiliary outlet of the Blender.
- **DO NOT** use near any type of flame or flammable/ explosive substances, vapors or atmosphere.
- **Oxygen Concentration Dial does not rotate 360 degrees.** Rotating the dial less than 21% or over 100% oxygen will damage the Blender.

⚠CAUTION

- Turn off gas supplies when Air-Oxygen Blender is not in use.
- Store the Air-Oxygen Blender in a clean, dry area when not in use.
- The Air-Oxygen Blender contains magnetic, ferrous material that may affect the results of an MRI.
- Ensure all connections are tight and leak free.
- Avoid excessive pressure surges greater than 100 psi (6.9 bar) when pressuring the Blender inlets.
- **DO NOT** steam autoclave.
- **DO NOT** immerse Air-Oxygen Blender into any liquid.
- **DO NOT** gas sterilize with (ETO) Ethylene Trioxide.
- **DO NOT** use if dirt or contaminants are present on or around the Blender or connecting devices.
- **DO NOT** smoke in an area where oxygen is being administered.
- **DO NOT** clean with aromatic hydrocarbons.

SPECIFICATIONS

Model	**PM5200** High Flow		**PM5300** Low Flow	
Primary Outlet Flow Range	15 - 120 lpm		3 - 30 lpm	
	With both supply pressures at 50 psi (3.4 bar) with NO BLEED			
Auxiliary Outlet Flow Range	2 - 100 lpm		0 - 30 lpm	
	With both supply pressures at 50 psi (3.4 bar) with BLEED			
Bleed Flow	13 lpm or less at 50 psi (3.4 bar)		3 lpm or less at 50 psi (3.4 bar)	
Maximum Combined Flow (All Outlets)	≥ 120 lpm		≥ 30 lpm	
Bypass Flow (Loss of Air or Oxygen supply)	> 85 lpm		> 45 lpm	
Bypass Alarm Activation	**50 psi** (3.45 bar)	**60 psi** (4.14 bar)	**50 psi** (3.45 bar)	**60 psi** (4.14 bar)
	13-25 psi	16-24 psi	18-22 psi	16-24 psi
	0.9-1.7 bar	1.1-1.65 bar	1.2-1.5 bar	1.1-1.65 bar

Alarm Reset:	When pressure differential is 6 psi (0.4 bar) or less.
Alarm Sound Level:	≥ to 80 db at 1 ft (0.3 m)
Oxygen Concentration Adjustment Range:	21 - 100%
Gas Supply Pressure:	30 - 75 psi (2.1 - 5.2 bar) Air and Oxygen within 10 psi (0.67 bar) of each other
Mixed Gas Stability:	±1% Oxygen
Connection Types:	DISS Type - Air & Oxygen Inlets & Outlets and / or NIST Type - Air & Oxygen Inlets

Dimensions: (without fittings)			
	Depth:	4.9 in	(12.5 cm)
	Width:	2.3 in	(5.7 cm)
	Height:	4.1 in	(10.4 cm)
Weight:		2.9 lbs	(1.3 kg)
Shipping Weight:		3.5 lbs	(1.6 kg)
Operating Temperature Range:		59°F to 104°F (15°C to 40°C)	

Transport / Storage Requirements

Temperature Range:	-10°F to 140°F (-23°C to 60°C)
Humidity:	Max 95% Noncondensing
FiO_2 Accuracy:*	± 3% of full scale @ 50 psi (3.4 bar)
	± 4% of full scale @ 60 psi (4.14 bar)

Pressure Drop:

Low Flow:	≤ 2 psi (0.14 bar) at inlet pressures from 30-90 psi (2.1- 6.2 bar) and at 10 lpm flow rate at 60% FiO_2.
High Flow:	≤ 3 psi (0.21 bar) at inlet pressures from 30-90 psi (2.1- 6.2 bar) and at 30 lpm flow rate at 60% FiO_2.

The Air-Oxygen Blender has been degreased for Oxygen Service prior to delivery.

The Air-Oxygen Blender reverse gas flow complies with clause 6 of ISO 11195.

The Oxygen Analyzer should comply with ISO 7767 to meet CE requirement.

Dryness and Composition for inlet gases:

Air:	Medical Air supply should meet the requirements of ANSI Z86.1 - 1973 commodity specification for Air, type 1 grade D or better.
Oxygen:	Oxygen supply must meet all requirements of USP Medical Oxygen Grade N.
Dew Point: (ONLY for CE requirements)	Both inlets should remain 10°F (5.5°C) or more below the lowest temperature to which the air distribution system equipment is exposed. At a temperature of 25°F (-3.9°C) and a pressure of 90 psi (6.33 kg/cm^2) this equates to 2000 mg/m^3.

* Accuracy of oxygen concentration will be affected if bleed is not activated at flow settings below 15 lpm for the high flow Blender, and 3 lpm for the low flow Blender.

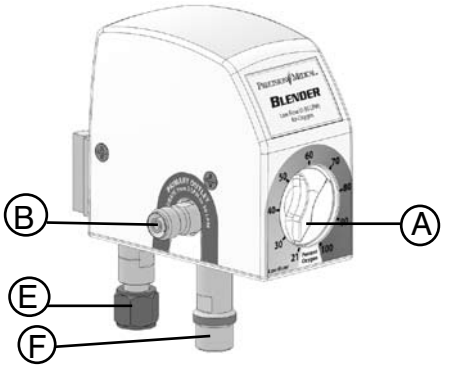
Specifications are subject to change without prior notice.

DIAGRAMS

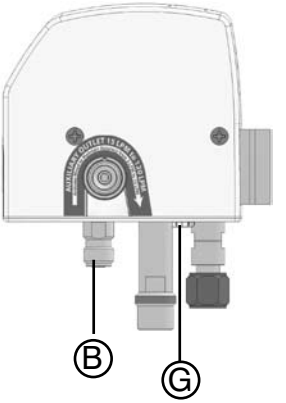
⚠CAUTION
Missing or illegible labels must be replaced, contact Precision Medical, Inc.

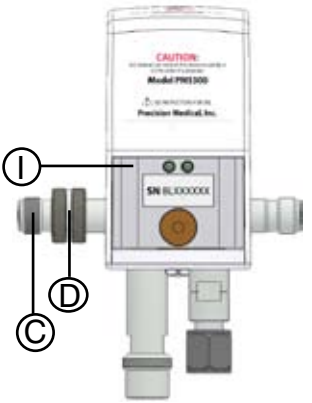
Depending on model, your fittings may differ from these diagrams.

PM5300 Model



PM5200 Model





COMPONENT DESCRIPTION

ITEM	DESCRIPTION
A	**Oxygen Concentration Dial** A dial used for selecting oxygen concentrations between 21%-100%. The FiO_2 scale is used for reference only. **This Dial does not rotate 360°.** The dial starts at 21% and ends at 100%.
B	**Primary Outlet Port** A male DISS oxygen fitting with check valve that delivers flow when engaged to any controlling device, such as a flowmeter.
C	**Auxiliary Outlet Port** A male DISS oxygen fitting with check valve that delivers flow when engaged to any controlling device, such as a flowmeter. This outlet is equipped with a bleed valve that allows the user to control if the bleed is ON or OFF. With the bleed in the ON position, this outlet delivers accurate oxygen concentrations in the following flows: **Model** — **Flow Range** High Flow — 2 – 100 lpm Low Flow — 0 – 30 lpm
D	**Auxiliary Bleed Collar** The collar is used to engage and disengage the bleed. The bleed is necessary to maintain accurate FiO_2 Concentration below 15 lpm for the High Flow and 3 lpm for the Low Flow. This collar is designed to prevent accidental disengagement of the bleed. To activate the bleed, turn the knurled collar until the bleed pin is engaged. Slide collar back until it contacts the cover. To deactivate the bleed, pull collar away from cover while rotating until the collar slot engages the pin, turn additional 1/4 turn to lock in place.
E	**Oxygen Inlet Fitting** A female DISS or NIST oxygen fitting with one way valve that is used to connect an oxygen supply hose.

COMPONENT DESCRIPTION

ITEM	DESCRIPTION
F	**Air Inlet Fitting** A male DISS or NIST air fitting with one way valve that is used to connect an air supply hose.
G	**Alarm** An audible alarm that sounds due to an excessive pressure drop or deletion of either gas supply.
H	**Manifold Outlet** (Optional) Manifold with 3 primary outlets.
I	**Rear Slide Mount** with dove tail.

INSTALLATION

⚠WARNING

- Read this User Manual before installing or operating the Air-Oxygen Blender.
- Confirm the concentration of air/oxygen with an Oxygen Analyzer/Monitor.

1. Secure the Air-Oxygen Blender to a wall or pole bracket in an upright position.
2. It is recommended to install a condensation trap in the air supply line.
3. Connect the air and oxygen supply lines to the appropriate inlet fittings on the bottom of the Blender.
4. Attach a flowmeter, or other metering device to one of the outlet ports.

   Primary Outlets Flow capacity:
   - High Flow Blender (PM 5200 Model) 15 lpm to 120 lpm
   - Low Flow Blender (PM 5300 Model) 3 lpm to 30 lpm

   Auxiliary Outlet:
   This will bleed off some of the air/oxygen mixture to maintain concentration accuracy at the Low Flow setting.
   - High Flow Blender (PM 5200 Model) 15 lpm or less
   - Low Flow Blender (PM 5300 Model) 3 lpm or less
5. Attach a supply line to the outlet port of the flowmeter.

ALARM TEST

1. The Air-Oxygen Blender is installed and the flowmeter is turned on. Disconnect or turn off the air supply line to the Air-Oxygen Blender.
2. The Blender should alarm with a loud whistle noise. The whistle indicates the alarm is operating correctly.
3. Reconnect and activate the air supply line to the Blender, the alarm should stop whistling.
4. Disconnect or turn off the oxygen supply line to the Blender.
5. The Blender should alarm with a loud whistle noise. The whistle indicates the alarm is operating correctly.
6. Reconnect and activate the oxygen supply line to the Blender, the alarm should stop whistling.
7. If alarm fails to function properly, DO NOT USE.

REVERSE GAS FLOW PROCEDURE

(CE Requirements ONLY)

1. Disconnect the oxygen hose from the gas source. Remove all outlet connections from the Blender to ensure that there is no outlet flow.
2. Place the free end of the oxygen supply hose under water. While gradually increasing the air supply pressure from 30-75 psi (2.07-5.17 bar) check for leakage past the oxygen inlet check valve.
3. Replace the Duckbill Check Valve in the oxygen inlet if bubbles indicate leakage. Reference Air-Oxygen Blender Service Manual (P/N 504827.)
4. Repeat steps 1-3 to check for leakage past the air inlet check valve.

OPERATING INSTRUCTIONS

CAUTION
Inspect the Air-Oxygen Blender for visual damage before use, DO NOT USE if damaged.

1. Turn “ON” the Air and Oxygen supply.
2. Adjust the Oxygen Concentration Dial to the prescribed concentration.

   NOTE: The Oxygen Concentration Dial does not rotate 360°. **DO NOT** force dial less than 21% or over 100% oxygen, this will damage the Blender.

3. To activate the bleed, turn the knurled collar until the bleed pin is engaged. Then slide the collar back until it contacts the cover.
4. Confirm the concentration of air/oxygen with an Oxygen Analyzer/Monitor.
5. Confirm the flow of air and/or oxygen mixture to the patient.
6. Turn "OFF" the Air and Oxygen supply when deactivating the Auxiliary bleed, and no device is attached to the outlet port.
7. To deactivate the bleed, pull the collar out away from the cover while rotating the collar until the slot engages the pin. Then slide the collar past the pin and turn an additional 1/4 turn to lock in place.

   NOTE: This Procedure is completed with ease when all gas supplies to the Blender are turned "OFF".
8. Turn "OFF" the Air and Oxygen supply or disconnect when the Blender is not in use.
9. Operational Verification listed below should be done before the Blender is placed in service.

   Verification consists of:
   - Alarm Test
   - Verify FiO_2 Concentration with a Oxygen Analyzer/Monitor
   - Reverse Gas Flow Procedure

PERFORMANCE CHECK

A detailed description of the tests listed below can be found in the Blender Service Manual (P/N 504827), available on the Internet; www.precisionmedical.com

- Reverse Gas Flow Procedure
- Operational Verification Procedure (OVP)

CLEANING

CAUTION
• **DO NOT** steam autoclave. • **DO NOT** immerse the Air-Oxygen Blender into any liquid. • **DO NOT** use any strong solvent or abrasive cleaners. • **DO NOT** gas sterilize with (ETO) Ethylene Trioxide. • **DO NOT** clean with aromatic hydrocarbons.

1. Disconnect all gas connections and equipment before cleaning.
2. Clean exterior surfaces with a cloth dampened with mild detergent and water.
3. Wipe dry with a clean cloth.

MAINTENANCE

The following maintenance on the Air-Oxygen Blender must be performed by a trained service technician:

- Every month verify proper functioning of alarm.
- Every year conduct the Operational Verification Procedure (OVP).
- Every 2 years the Air-Oxygen Blender should be serviced. **PM5200** (P/N 505407) **PM5300** (P/N 504932)
- Refer to the Air-Oxygen Blender Service Manual (P/N 504827) for complete details regarding further maintenance and testing.

TECHNICAL DESCRIPTION

For a complete Technical Description of the Air-Oxygen Blender and list of Replacement Parts, reference the Air-Oxygen Blender Service Manual (P/N 504827) available on the Internet; www.precisionmedical.com.

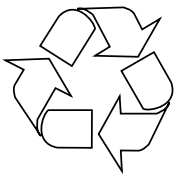
RETURNS

Returned products require a Returned Goods Authorization (RGA) number, contact Precision Medical, Inc. All returns must be packaged in sealed containers to prevent damage. Precision Medical, Inc. will not be responsible for goods damaged in transit. Refer to Precision Medical, Inc. Return Policy available on the Internet; www.precisionmedical.com.

DISPOSAL INSTRUCTIONS

This device and its packaging contain no hazardous materials. No special precautions need to be taken when disposing the device and/or its packaging.

Please Recycle



TROUBLESHOOTING

If the Air-Oxygen Blender fails to function, consult the Troubleshooting Guide below.

If problem cannot be solved by using Troubleshooting Guide refer to the Air-Oxygen Blender Service Manual (P/N 504827) available on the Internet; www.precisionmedical.com or consult your Provider.

Problem	Probable Cause	Remedy
Oxygen concentration discrepancy between Blender setting and Analyzer/Monitor (greater than 3%)	1. High Flow model, flow requirement below 15 lpm. Low Flow model, flow requirement below 3 lpm.	1. Use auxiliary outlet & engage bleed
	2. Analyzer/Monitor inaccurate	2. Recalibrate Analyzer/Monitor or Verify with second Analyzer/Monitor
	3. Low flow bleed obstructed	3. Remove obstruction
	4. Gas supply contaminated	4. Check gas sources with calibrated Oxygen Analyzer/ Monitor to confirm Oxygen is 100% and Air is 21%
	5. Downstream device causing back flow or restricted flow	5. Isolate Blender. Check oxygen concentration at Blender Outlets
No flow at Blender outlets	1. Gas sources turned “OFF”	1. Turn gas sources “ON”
	2. Gas sources not connected	2. Connect gas sources
Alarm sounding	1. Difference between Oxygen and air inlet pressures greater than specified	1. Correct pressure difference until Air and Oxygen pressures are within specification

LIMITED WARRANTY
AND
LIMITATION OF LIABILITY

Precision Medical, Inc. warrants that the Blender, (the Product), will be free of defects in workmanship and/or material for the following period:

Two (2) years from shipment

Should any failure to conform to this warranty appear within the applicable period, Precision Medical, Inc. shall, upon written notification thereof and substantiation that the goods have been stored, installed, maintained and operated in accordance with Precision Medical, Inc.'s instructions and standard industry practice, and that no modifications, substitutions, or alterations have been made to the goods, correct such defect by suitable repair or replacement at its own expense.

ORAL STATEMENTS DO NOT CONSTITUTE WARRANTIES.

The representatives of Precision Medical, Inc. or any retailers are not authorized to make oral warranties about the merchandise described in this contract, and any such statements shall not be relied upon and are not part of the contract for sale. Thus, this writing is a final, complete and exclusive statement of the terms of that contract.

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OTHER WARRANTY OF QUALITY, WHETHER EXPRESS OR IMPLIED.

Precision Medical, Inc. shall not under any circumstances be liable for special, incidental or consequential damages including but not limited to lost profits, lost sales, or injury to person or property. Correction of non-conformities as provided above shall constitute fulfillment of all liabilities of Precision Medical, Inc. whether based on contract, negligence, strict tort or otherwise. Precision Medical, Inc. reserves the right to discontinue manufacture of any product or change product materials, designs, or specifications without notice.

Precision Medical, Inc. reserves the right to correct clerical or typographical errors without penalty.

DECLARATION OF CONFORMITY

Manufacturer:	Precision Medical, Inc. 300 Held Drive, Northampton, PA 18067, USA CONTACT: Quality Manager Phone: 610-262-6090
Authorized European Representative:	Emergo Europe Molenstraat 15 2513 BH, The Hague The Netherlands
Product:	Gas Mixers for Medical Use
Model(s):	PM5200EN, PM5200MEN, PM5300EN, PM5300MEN
MDD Class:	IIb
Classification criteria:	Clause 3.1 Rule 11 of Annex IX of MDD

As delivered, the object of the declaration described above is in conformity with the requirements of MDD 93/42/EEC Annex II.3 and the following documents:

Document	Title	Edition
ISO 14971	Medical Devices - Application of Risk Management to Medical Devices	2000+A1:2003
EN 980	Graphical Symbols for Use in the Labeling of Medical Devices	2003
EN 1041	Information supplied by the Manufacturer with Medical Devices	1998
ISO 11195	Gas mixers for medical use - stand alone gas mixers	1995
ISO 15001	Anesthetic and respiratory equipment -- Compatibility with oxygen	2004

Notified Body: TÜV Rheinland Products Safety GmbH CE 0197

EC Certificate No.: HD600119110 0001

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ISO 13485 Certified

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