



AIR-OXYGEN BLENDER

(DISS and NIST Connections)

Model No. PM5200 Series PM5300 Series (shown)



SAVE THESE INSTRUCTIONS

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

PRECISION MEDICAL.

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CONTENTS

RECEIVING / INSPECTION	2
INTENDED USE	2
READ ALL INSTRUCTIONS BEFORE USING	2
EXPLANATION OF ABBREVIATIONS	2
SAFETY INFORMATION - WARNINGS AND CAUTIONS	3
SPECIFICATIONS	5
DIAGRAMS	7
COMPONENT DESCRIPTION	8
PRE-USE TESTING	9
ALARM TEST	10
REVERSE GAS FLOW PROCEDURE	10
OPERATING INSTRUCTIONS	11
CLEANING	11
MAINTENANCE	12
TECHNICAL DESCRIPTION	12
RETURNS	12
DISPOSAL INSTRUCTIONS	12
TROUBLESHOOTING	13
LIMITED WARRANTY	14
DECLARATION OF CONFORMITY	15

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.

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

EXPLANATION OF ABBREVIATIONS

- FIO2 Fractional Concentration of Inspired Oxygen
- DISS Diameter Indexed Safety System
- NIST Non-Interchangeable Screw Thread
- psi Pounds Per Square Inch
- I/min Liters Per Minute

SAFETY INFORMATION - WARNINGS AND CAUTIONS

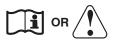
Indicates an	imminent	ly hazardou	us situation
^l which, if not	avoided,	will result	in death or
serious injury			

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

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"



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)

- 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.

- 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 I/min for the High Flow Blender, and 3 I/min for the Low Flow Blender.
- **DO NOT** obstruct the alarm.
- DO NOT 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.

- 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 Oxide.
- **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.
- Inlet pressure of device used in conjunction with Blender must match inlet pressure of Blender.
- When using a bottled high pressure gas source, always use a pressure reducing regulator set within 30-75 psi (2.1-5.2 bar).

SPECIFICATIONS

Model	PM5200 High Flow		PM5300 Low Flow	
Primary Outlet	15 - 120 l/min		3 - 30 I/min	
Flow Range	With both	supply press with BLEE	•	osi (3.4 bar)
Auxiliary Outlet	2 - 10	0 l/min	0 - 30 l/min	
Flow Range	With both	supply press with BLE		osi (3.4 bar)
Bleed Flow	13 I/min or less at 50 psi (3.4 bar)			n or less i (3.4 bar)
Maximum Combined Flow (All Outlets)	≥ 120 I/min		≥ 30	l/min
Bypass Flow (Loss of Air or Oxygen supply)	> 85 l/min		> 45 l/min	
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.			s 6 psi	
Alarm Sound Leve	l: ≥ to 8	0 db at 1 ft ((0.3 m)	
Oxygen Concentra Adjustment Range	Z = 1	00%		
Gas Supply Pressu	Air an	: 30 - 75 psi (2.1 - 5.2 bar) Air and Oxygen within 10 psi (0.69 bar) of each other		
Mixed Gas Stability: ±1% Oxygen				
Connection Types:		Type - Air & (or NIST Type		

Note: All flow-rate values are as measured from an Oxygen flowmeter (uncorrected).

SPECIFICATIONS continued

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:		2.29 lbs	(1.04 kg)
Shipping We	eight:	2.95 lbs	(1.34 kg)
Operating Te	emperature Range:	59°F to 10	4°F (15°C to 40°C)
Transport	/ Storage Require	ements	
Temperatur	e Range: -10°F to	0 140°F (-23°	°C to 60°C)
Humidity: Max 95% Noncondensing			ensing
FIO ₂ Accura	cy:* ± 3% of	full scale	
Pressure D	Drop:		
Low Flow:	 ≤ 2 psi (0.14 bar) at inlet pressures from 30-90 psi (2.1- 6.2 bar) and at 10 I/min flow rate at 60% FIO2. 		
High Flow:	• •	· ·	sures from 30-90 psi flow rate at 60% FIO2
The Air-Oxygen I	Blender has been cleaned	for Oxygen Se	rvice prior to delivery.
The Air-Oxygen	Blender reverse gas flow	complies with	clause 6 of ISO 11195
The Oxygen An	alyzer should comply with	n ISO 21647.	
Dryness a	nd Composition	for inlet g	ases:
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 Grade Oxygen.		
Dew Point: (ONLY for CE requirements)	Both inlets should r below the lowest t distribution system temperature of 25°I 90 psi (6.33 kg/cm ²) t	emperature equipment = (-3.9°C)	to which the air is exposed. At a and a pressure of

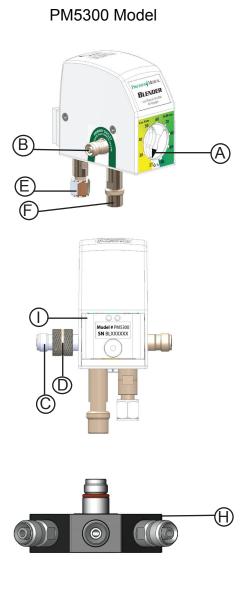
* Accuracy of oxygen concentration will be affected if bleed is not activated at flow settings below 15 l/min for the high flow Blender, and 3 l/min for the low flow Blender.

Specifications are subject to change without prior notice.

ACAUTION

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

Depending on model, your fittings and/or labels may differ from these diagrams.





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%.
В	Primary Outlet Port A male DISS oxygen fitting with check valve that delivers flow when engaged to any controlling device, such as a flowmeter.
С	Auxiliary Outlet PortA male DISS oxygen fitting with check valve that deliversflow when engaged to any controlling device, such asa flowmeter. This outlet is equipped with a bleed valvethat allows the user to control if the bleed is ON or OFF.With the bleed in the ON position, this outlet deliversaccurate oxygen concentrations in the following flows:ModelFlow RangeHigh Flow $2 - 100$ l/minLow Flow $0 - 30$ l/min
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 I/min for the High Flow and ≤ 3 I/min for the Low Flow. To activate the bleed, slide and rotate (if applicable) the knurled collar back until it contacts the cover. To deactivate the bleed, pull and rotate (if applicable) collar away from cover until it reaches a positive stop.
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 continued

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.
Н	Manifold Outlet (Optional) Manifold with 3 primary outlets.
I	Rear Slide Mount with dove tail.

PRE-USE TESTING

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

CAUTION

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

NOTE: The tests listed below should be performed prior to placing the Blender in service.

Pre-Use Testing consists of:

- Alarm Test
- Reverse Gas Flow Procedure
- 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 and verify FIO₂ range for accuracy with an oxygen analyzer.

Primary Outlets Flow capacity:

- High Flow Blender (PM 5200 Model) 15 I/min to 120 I/min
- Low Flow Blender (PM 5300 Model) 3 I/min to 30 I/min

Auxiliary Outlet:

The auxiliary flow outlet maintains the same flow capacity and FIO₂ accuracy as the Primary Outlets with Bleed Valve not engaged. When bleed flow is activated, some of the air/ oxygen mixture will vent to atmosphere to maintain FIO₂ concentration accuracy at the Low Flow settings.

- High Flow Blender (PM 5200 Model) 15 I/min or less
- Low Flow Blender (PM 5300 Model) 3 I/min or less
- 5. Attach a supply line to the outlet port of the flowmeter.

ALARM TEST

- 1. Connect the Air-Oxygen Blender to air and oxygen sources, pressurize the Blender and turn "ON" the flowmeter.
- 2. Set Oxygen Concentration Dial to 60% FIO2.
- 3. Disconnect or turn "OFF" the air supply to the Air-Oxygen Blender. The Blender should alarm with a loud whistle noise. The whistle indicates the alarm is operating correctly.
- 4. Reconnect and activate the air supply line to the Blender, the alarm should stop whistling.
- 5. Disconnect or turn "OFF" the oxygen supply line to the Blender. 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

- 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. 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.
- Replace the Duckbill Check Valve in the oxygen inlet if leakage is > 100 ml/min. 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. Secure Blender to wall or pole mount bracket.
- 2. Connect Air and Oxygen supply lines from Blender to wall outlets.
- 3. Connect flowmeter to Blender outlet.
- 4. Adjust the Oxygen Concentration Dial to the prescribed concentration.

- 5. Confirm the flow of air and/or oxygen mixture to the patient.
- 6. Confirm the concentration of air/oxygen with an Oxygen Analyzer/Monitor. If necessary activate bleed flow valve to maintain FIO₂ accuracy.
- 7. To activate the bleed, turn and rotate the knurled collar back until it contacts the cover.
- 8. To deactivate the bleed, pull and rotate the collar away from the cover until bleed flow valve is closed.
- 9. Turn "OFF" gas supplies when Air-Oxygen Blender is not in use.

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 Oxide.
- **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.

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.

MAINTENANCE

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

- The alarm should be tested prior to being placed into clinical service and periodically there after.
- Every year conduct the Operational Verification Procedure (OVP).
 * A detailed description of the OVP tests can be found in the Blender Service Manual (P/N 504827), available on the Internet; www.precisionmedical.com
- 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.

Manuals available on our Website; 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	1. High Flow model, flow requirement below 15 I/min. Low Flow model, flow requirement below 3 I/min.	1. Use auxiliary outlet & engage bleed
(greater than 3%)	2. Analyzer/Monitor inaccurate	2. Recalibrate Analyzer/Monitor or Verify with second Analyzer/Monitor
	 Low flow bleed obstructed 	3. Remove obstruction
	4. Gas supply contaminated	 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	 Gas sources turned "OFF" Gas sources not connected 	 Turn gas sources "ON" 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







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Classification:

Classification criteria: Clause 3.2 Rule 11 of Annex IX of MDD

llb

We hereby declare that an examination of the under mentioned production quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II, 3 of the Directive 93/42/EEC and Directive 2007/47/EC on medical devices.

We certify that the production quality system conforms to the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0473 marking on those products listed above.

Applied Standards: EN 1041, ISO 11195, EN ISO 13485, EN ISO 14971, EN ISO 15001, EN ISO 15223-1

Notified Body: Address:	Intertek AMTAC Certification Services Limited C€ 0473 Davy Avenue Knowlhill Milton Keynes MK5 8NL, UK
Certification Registration No's:	1126 CE Date of Expiry: 03 August 2017
Devices already manufactured: Validity of DOC:	S/N traceability Device History Records 04 August 2012 to Date of Expiry
Manufacture Representative:	Quality Manager
Position:	Quality Systems/ISO Representative
Date of Issue:	04 August 2012

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Salvia Lifetec alpha

Aerolife

Mediline / RI₂

Aeroplus

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SERVICE LEISTUNGEN / Services

Service- und Wartungsarbeiten

Die Firma HVS Hörnla bietet Ihnen flächendeckend für Deutschland, Österreich und die Schweiz Vor-Ort-Services für Reparaturen, Wartungs- und Instandhaltungsarbeiten an.

Vor-Ort-Service

Die Vorteile sind:

- » Keine höheren Kosten für den Kunden
- » Ein Ansprechpartner vor Ort
- » Auf Wunsch Einweisung nach MPBetreibV
- » Entlastung des medizinischen Personals sowie der technischen Abteilung Ihrer Einrichtung
- » Kein aufwendiger Versand der Geräte
- » Bereitstellung eines Überbrückungsgerätes während der Durchführung der Servicearbeiten -Dadurch wird eine unterbrechungsfreie Versorgung in Ihrer Einrichtung sichergestellt
- » Kostentransparenz durch unsere preiswerten Servicepauschalen

Sie benötigen eine Sonderlösung? – Sprechen Sie uns an. Wir helfen Ihnen gerne weiter!

Service and Maintenance works

The company HVS Hörnla offers a comprehensive on-site service in Germany, Austria and Switzerland for repair, maintenance and service works.

On-Site Service

The advantages are:

- » No higher costs for the customer
- » One contact person on-site
- » On request instruction according to German medical regulations
- » Relieve the medical staff and the technical department of your facility
- » No expensive shipping of devices
- » Provision of a bridging device during the service work execution to ensure an uninterrupted supply in your facility
- » Cost transparency through our low-cost service flat rate

Do you need a special solution? - Contact us. We're here to help!



Your contact for sales and service:



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