USER MANUAL

HELIO2
HELIUM-OXYGEN BLENDER

(DISS and NIST Connections)

Model No. PM5400 Series (shown)
PM5500 Series

SAVE THESE INSTRUCTIONS

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

PRECISION MEDICAL®

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RECEIVING / INSPECTION

Remove the Precision Medical, Inc. *HELIO₂* (Helium-Oxygen) *Blender* from the packaging and inspect for damage. If there is any damage, DO NOT USE and contact your Provider.

INTENDED USE

The Precision Medical, Inc. Helium and Oxygen Blender is designed to dispense a continuous and precise blend of Medical Helium and Oxygen via outlet ports to infant, pediatric and adult patients. The exact F_{IO_2} blend of gases corresponds to the dialed in Fractional Concentration of Oxygen (F_{IO_2}) setting indicated by the control face. Oxygen concentrations can be dialed in from 20% to 100% for heliox tank mixtures of 20% oxygen / 80% helium, and 30% to 100% for heliox tank mixtures of 30% oxygen / 70% helium. The Helium and Oxygen Blender is a restricted medical device intended for use by qualified and trained personnel under the direction of a physician in institutional environments where delivery and monitoring of helium/oxygen mixture is required.
The Blender is not intended as a life supporting device.

READ ALL INSTRUCTIONS BEFORE USING

This manual instructs a Professional to install and operate the *HeliO₂ Blender*. This is provided for your safety and to prevent damage to the *HeliO₂ Blender*. If you do not understand this manual, DO NOT USE the *HeliO₂ Blender* and contact your Provider.

⚠DANGER

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

EXPLANATION OF ABBREVIATIONS

$F_{IHe\text{-}O_2}$	Fractional Concentration of Inspired Helium-Oxygen
F_{IO_2}	Fractional Concentration of Inspired Oxygen
Heliox	Helium-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

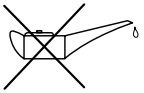
⚠DANGER Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

⚠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)**

℞ ONLY

Prescription Required

⚠WARNING

- Only trained, qualified medical personnel under the direct supervision of a licensed physician should operate the *HELIO₂ Blender*.
- Use this *HELIO₂ Blender* only for its Intended Use as described in this manual.
- Confirm prescribed dose before administering to patient. Monitor on a frequent basis. Continuous Monitoring with an alarmed Oxygen Monitor / Analyzer is recommended.
- The *HELIO₂ Blender* shall be serviced by a qualified service technician.
- Always follow ANSI and CGA standards for Medical Gas Products, Flowmeters and Oxygen Handling.
- The clinician must verify the Heliox tank concentration prior to utilizing the Blender.
- An alarmed Oxygen Monitor / Analyzer 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 beyond the endpoint settings will damage the Blender.

⚠CAUTION

- Turn off gas supplies when *HELIO₂ Blender* is not in use.
- Store the *HELIO₂ Blender* in a clean, dry area when not in use.
- The *HELIO₂ 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 *HELIO₂ 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 the *HELIO₂* Blender must match inlet pressure of F_{IO_2} Blender.

SPECIFICATIONS

	High Flow		Low Flow	
Model	**PM5580:** 80/20 heliox **PM5570:** 70/30 heliox		**PM5480:** 80/20 heliox **PM5470:** 70/30 heliox	
Primary Outlet Flow Range	15 - 120 lpm		3 - 30 lpm	
	With both supply pressures at 50 psi (3.4 bar) with BLEED *Closed*			
Auxiliary Outlet Flow Range	2 - 100 lpm		0 - 30 lpm	
	With both supply pressures at 50 psi (3.4 bar) with BLEED *Open*			
Bleed Flow @ 100% F_{IO_2}	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 Helium 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:	**PM5480** **PM5580**	20 - 100%	**PM5470** **PM5570**	30 - 100%
Gas Supply Pressure:	30 - 75 psi (2.1 - 5.2 bar) Heliox & Oxygen within 10 psi (0.69 bar) of each other			
Mixed Gas Stability:	±1% Oxygen			
Connection Types:	DISS Type - Heliox & Oxygen Inlets & Outlets and / or NIST Type - Heliox & Oxygen Inlets			

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:	2.9 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
F_{IO_2} Accuracy:*	± 3% of full scale @ 50 psi (3.4 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% F_{IO_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% F_{IO_2}.

The Helium-Oxygen Blender has been cleaned for Oxygen Service prior to delivery.

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

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

Dryness and Composition for inlet gases:

Heliox:	Medical grade 80/20 or 70/30 is required.
Oxygen:	Oxygen supply must meet all requirements of USP Medical Oxygen.
Dew Point: (ONLY for CE requirements)	Both inlets should remain 10°F (-12.2°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 F_{IO_2} will be affected if bleed flow is not engaged at low flows. (At or below 3 lpm for Low Flow and 15 lpm for High Flow).

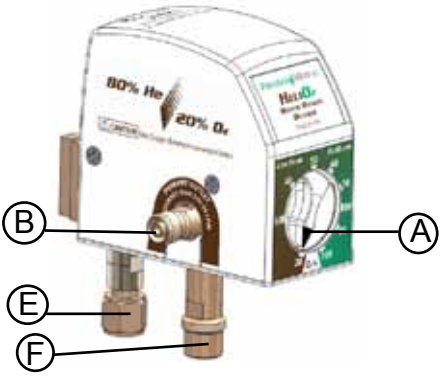
* When Heliox tank pressure and oxygen outlet pressures are unbalanced, bleed may need to be engaged at a higher liter flow to maintain accuracy.

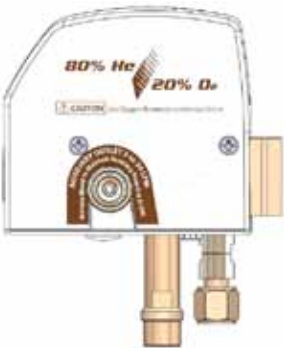
Specifications are subject to change without prior notice.

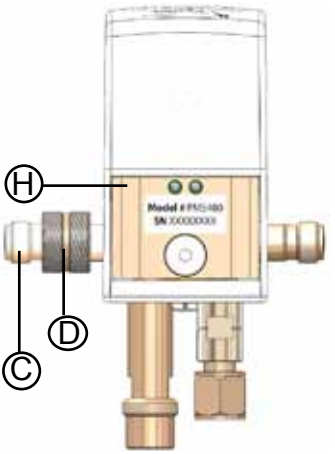
DIAGRAMS

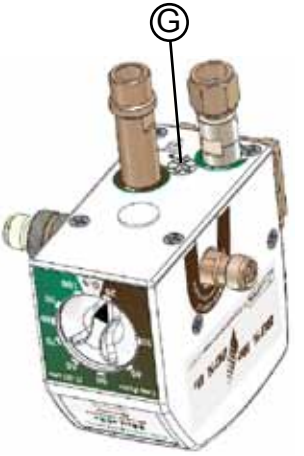
⚠CAUTION
Missing or illegible labels must be replaced, contact Precision Medical, Inc.

PM5400 and PM5500 Models









COMPONENT DESCRIPTION

ITEM	DESCRIPTION
A	**Oxygen Concentration Dial** A dial used for selecting oxygen concentrations between 20% -100% or 30% -100%. The F_{IO_2} scale is used for reference only. **The actual F_{IO_2} must be verified with an Alarmed Oxygen Monitor / Analyzer.** **This Dial does not rotate 360°.** The dial starts at 20% or 30% 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 F_{IO_2} Concentration below 15 lpm for the High Flow and $\leq$ 3 lpm for the Low Flow. To activate the bleed, slide and rotate the knurled collar back until it contacts the cover. To deactivate the bleed, pull and rotate collar away from cover until bleed flow valve is closed.
E	**Oxygen Inlet Fitting** A female DISS or NIST oxygen fitting with one way valve that is used to connect an oxygen supply hose.
F	**Heliox Inlet Fitting** A male DISS or NIST heliox fitting with one way valve that is used to connect a heliox supply hose.
G	**Alarm** An audible alarm that sounds due to an excessive pressure drop or deletion of either gas supply.
H	**Rear Slide Mount** with dove tail.

PRE-USE TESTING

⚠WARNING

- Read this User Manual before installing or operating the *HeliO₂ Blender*.
- Confirm the concentration of heliox with an alarmed Oxygen Monitor / Analyzer.
- Confirm contents of heliox cylinder prior to use.

CAUTION

Inspect the *HeliO₂ Blender* for visual damage before use, DO NOT USE if damaged.

NOTE: The tests listed below should be performed prior to placing the *HeliO₂ Blender* in service.

Pre-Use Testing consists of:

- Alarm Test
- Reverse Gas Flow Procedure

1. Secure the *HeliO₂ Blender* to a wall or pole bracket in an upright position.
2. Connect the heliox and oxygen supply lines to the appropriate inlet fittings on the bottom of the *HeliO₂ Blender*.
3. Attach a flowmeter, or other metering device to one of the outlet ports and verify F_{IO_2} range for accuracy with an alarmed Oxygen Monitor / Analyzer.

   Primary Outlets Flow capacity:

   - High Flow Blender (PM 5500 Model) 15 lpm to 120 lpm
   - Low Flow Blender (PM 5400 Model) 3 lpm to 30 lpm

   Auxiliary Outlet Use:

   The auxiliary flow outlet maintains the same flow capacity and F_{IO_2} accuracy as the Primary Outlets with Bleed Valve not engaged. When the bleed flow is activated, some of the heliox mixture will vent to atmosphere to maintain F_{IO_2} concentration accuracy at the low flow settings.

   - High Flow Blender (PM 5500 Model) 15 lpm or less
   - Low Flow Blender (PM 5400 Model) 3 lpm or less
4. Attach a supply line to the outlet port of the flowmeter.

ALARM TEST

1. Connect the *HeliO₂ Blender* to respective heliox and oxygen sources, pressurize the Blender and turn “ON” the flowmeter.
2. Set Oxygen Concentration Dial to 50% F_{IO_2}.
3. Disconnect or turn “OFF” the heliox supply line to the *HeliO₂ Blender*. The Blender should alarm with a loud whistle noise. The whistle indicates the alarm is operating correctly.
4. Reconnect and activate the heliox supply line to the Blender, the alarm should stop whistling.
5. Disconnect or turn “OFF” the oxygen supply line to the *HeliO₂ Blender*. 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. Assure bleed flow valve is not engaged. Disconnect the oxygen hose from the gas source. Remove all outlet connections from the *HeliO₂ 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 heliox 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 leakage is >100 ml/min. Reference *HeliO₂ Blender* Service Manual (P/N 506124).
4. Repeat steps 1-3 to check for leakage past the heliox inlet check valve.

OPERATING INSTRUCTIONS

CAUTION
Inspect the *HeliO₂ Blender* for visual damage before use, DO NOT USE if damaged.

1. Secure Blender to wall or pole mount bracket.
2. Connect heliox and oxygen supply lines from *HeliO₂ Blende*r to heliox cylinder and oxygen supply.
3. Connect oxygen flowmeter to Blender outlet.
4. Adjust the Oxygen Concentration Dial to the prescribed concentration. The balance of the concentration will be helium exiting the flowmeter.

   NOTE: The Oxygen Concentration Dial does not rotate 360°. **DO NOT** force dial beyond the oxygen concentration endpoints as this will damage the Blender.

5. Confirm the flow of heliox mixture to the patient.
6. Actual heliox concentration to the patient may vary due to entrainment of room air via the patient interface device.

⚠CAUTION
• Refer to “Oxygen Flowmeter Conversion Chart” for corrected heliox flows. • An oxygen flowmeter should be used on the outlets of the *HeliO₂ Blender* along with the corresponding flow conversion chart. • Actual flow from an oxygen flowmeter utilized to deliver heliox are higher than read on the flowmeter.

7. Confirm the concentration of heliox with an Oxygen Monitor / Analyzer. If necessary activate the bleed flow valve to maintain F_{IO_2} accuracy.
8. To activate the bleed, turn and rotate the knurled collar back until it contacts the cover.
9. To deactivate the bleed, pull and rotate the collar away from the cover until bleed flow valve is closed.
10. Turn “OFF” the heliox and oxygen supply or disconnect when the *HeliO₂ Blender* is not in use.

CLEANING

CAUTION
• **DO NOT** steam autoclave. • **DO NOT** immerse the *HeliO₂* 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.

MAINTENANCE

The following maintenance on the *HeliO₂ 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 506124), and available on the Internet; www.precisionmedical.com
- Every 2 years the *HeliO₂ Blender* should be serviced.
  PM5400 (P/N 506125) **PM5500** (P/N 506212)
- Refer to the *HeliO₂ Blender* Service Manual (P/N 506124) for complete details regarding further maintenance and testing.

OXYGEN FLOWMETER CONVERSIONS

Oxygen Flowmeter Setting	Corrected Heliox Flow (LPM) at Various FIO_2 Settings								
	20%	30%	40%	50%	60%	70%	80%	90%	100%
1	1.8	1.6	1.4	1.3	1.2	1.18	1.15	1.02	1.0
2	3.6	3.2	2.8	2.6	2.4	2.4	2.3	2.0	2.0
3	5.4	4.8	4.2	3.9	3.6	3.5	3.5	3.1	3.0
4	7.2	6.4	5.6	5.2	4.8	4.7	4.6	4.1	4.0
5	9.0	8.0	7.0	6.5	6.0	5.9	5.8	5.1	5.0
6	10.8	9.6	8.4	7.8	7.2	7.1	6.9	6.1	6.0
7	12.6	11.2	9.8	9.1	8.4	8.3	8.1	7.1	7.0
8	14.4	12.8	11.2	10.4	9.6	9.4	9.2	8.2	8.0
9	16.2	14.4	12.6	11.7	10.8	10.6	10.4	9.2	9.0
10	18.0	16.0	14.0	13.0	12.0	11.8	11.5	10.2	10.0
11	19.8	17.6	15.4	14.3	13.2	13.0	12.7	11.2	11.0
12	21.6	19.2	16.8	15.6	14.4	14.2	13.8	12.2	12.0
13	23.4	20.8	18.2	16.9	15.6	15.3	15.0	13.3	13.0
14	25.2	22.4	19.6	18.2	16.8	16.5	16.1	14.3	14.0
15	27.0	24.0	21.0	19.5	18.0	17.7	17.3	15.3	15.0
16	28.8	25.6	22.4	20.8	19.2	18.9	18.4	16.3	16.0
17	30.6	27.2	23.8	22.1	20.4	20.1	19.6	17.3	17.0
18	32.4	28.8	25.2	23.4	21.6	21.2	20.7	18.4	18.0
19	34.2	30.4	26.6	24.7	22.8	22.4	21.9	19.4	19.0
20	36.0	32.0	28.0	26.0	24.0	23.6	23.0	20.4	20.0
21	37.8	33.6	29.4	27.3	25.2	24.8	24.2	21.4	21.0
22	39.6	35.2	30.8	28.6	26.4	26.0	25.3	22.4	22.0
23	41.4	36.8	32.2	29.9	27.6	27.1	26.5	23.5	23.0
24	43.2	38.4	33.6	31.2	28.8	28.3	27.6	24.5	24.0
25	45.0	40.0	35.0	32.5	30.0	29.5	28.8	25.5	25.0
26	46.8	41.6	36.4	33.8	31.2	30.7	29.9	26.5	26.0
27	48.6	43.2	37.8	35.1	32.4	31.9	31.1	27.5	27.0
28	50.4	44.8	39.2	36.4	33.6	33.0	32.2	28.6	28.0
29	52.2	46.4	40.6	37.7	34.8	34.2	33.4	29.6	29.0
30	54.0	48.0	42.0	39.0	36.0	35.4	34.5	30.6	30.0
31	55.8	49.6	43.4	40.3	37.2	36.6	35.7	31.6	31.0
32	57.6	51.2	44.8	41.6	38.4	37.8	36.8	32.6	32.0
33	59.4	52.8	46.2	42.9	39.6	38.9	38.0	33.7	33.0
34	61.2	54.4	47.6	44.2	40.8	40.1	39.1	34.7	34.0
35	63.0	56.0	49.0	45.5	42.0	41.3	40.3	35.7	35.0
36	64.8	57.6	50.4	46.8	43.2	42.5	41.4	36.7	36.0
37	66.6	59.2	51.8	48.1	44.4	43.7	42.6	37.7	37.0
38	68.4	60.8	53.2	49.4	45.6	44.8	43.7	38.8	38.0
39	70.2	62.4	54.6	50.7	46.8	46.0	44.9	39.8	39.0
40	72.0	64.0	56.0	52.0	48.0	47.2	46.0	40.8	40.0

TECHNICAL DESCRIPTION

For a complete Technical Description of the *HeliO₂ Blender* and list of Replacement Parts, reference the *HeliO₂ Blender* Service Manual (P/N 506124) available on the Internet; www.precisionmedical.com.

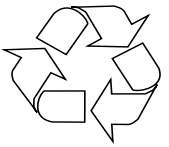
RETURNS

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 *HeliO₂ Blender* fails to function, consult the Troubleshooting Guide below.

If problem cannot be solved by using Troubleshooting Guide, refer to the *HeliO₂ Blender* Service Manual (P/N 506124) available on the Internet; www.precisionmedical.com or consult your Provider.

Problem	Probable Cause	Remedy
Oxygen concentration discrepancy between Blender setting and alarmed Oxygen Monitor / Analyzer (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. Alarmed Oxygen Monitor / Analyzer inaccurate	2. Recalibrate alarmed Oxygen Monitor / Analyzer or Verify with second alarmed Oxygen Monitor / Analyzer
	3. Low flow bleed obstructed	3. Remove obstruction
	4. Gas supply contaminated or heliox concentration incorrect	4. Check gas sources with calibrated alarmed Oxygen Monitor / Analyzer to confirm oxygen is 100% and verify heliox tank content
	5. Downstream device causing back flow or restricted flow	5. Isolate Blender. Check oxygen concentration at Blender Outlets
	6. Supply pressure imbalanced	6. Assure heliox and oxygen inlets pressures are within 10 psi
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 heliox inlet pressures greater than specified	1. Correct pressure difference until heliox and oxygen pressures are within specification

LIMITED WARRANTY
AND
LIMITATION OF LIABILITY

Precision Medical, Inc. warrants that the *HeliO₂ 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 (European Office) Molenstraat 15 2513 BH, The Hague The Netherlands Phone: +31 (0) 70.345.8570 Fax: +31 (0) 70.346.7299
Product:	Gas Mixers for Medical Use (Blender)
Model(s):	PM5470EN, PM5480EN, PM5570EN, PM5580EN
MDD Class:	IIb
Classification criteria:	Clause 3.2 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	Edition
EN 980	2008
EN 1041	2008
ISO 11198	1995
ISO 14971	2007 2nd Ed
ISO 15001	2004
ISO 7000	2004

Notified Body: TÜV Rheinland Products Safety GmbH CE 0197

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