# **USER MANUAL**



Model: PM4300 Series



SAVE THESE INSTRUCTIONS

For the most current manual revision, please visit our Website: www.precisionmedical.com



ONLY

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ISO 13485 Certified

## **CONTENTS**

RECEIVING / INSPECTION	1
INTENDED USE	1
READ ALL INSTRUCTIONS BEFORE USING	1
EXPLANATION OF ABBREVIATIONS	1
SAFETY INFORMATION - WARNINGS AND CAUTIONS	2
SPECIFICATIONS	4
COMPONENT DESCRIPTION	4
OPERATING INSTRUCTIONS	5
ALARM CONDITIONS	6
MAINTENANCE / CLEANING	7
RETURNS	7
DISPOSAL INSTRUCTIONS	7
REPLACEMENT PARTS	7
LIMITED WARRANTY	7

## **RECEIVING / INSPECTION**

Remove the Precision Medical, Inc. PM4300 Series Oxygen Concentrator 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. Stationary Oxygen Concentrator is intended to provide supplemental oxygen to persons requiring oxygen therapy. The device is not intended to be life supporting or life sustaining.

## READ ALL INSTRUCTIONS BEFORE USING

This manual is provided for your safety and to prevent damage to the Oxygen Concentrator. If you do not understand this manual, DO NOT USE the Concentrator and contact your Provider.

## **EXPLANATION OF ABBREVIATIONS**

LPM Liters Per Minute LED Light Emitting Diode



#### SAFETY INFORMATION - WARNINGS AND CAUTIONS



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



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.



PM4300 WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL60601-1, IEC60601-1, CAN/CSA C22.2 No. 601.1



Caution! U.S. Federal Law restricts this device to sale by or on the order of a physician.



CONSULT ACCOMPANYING DOCUMENTS

IPX1

Degree of protection against ingress of liquids



General Mandatory Action Sign



Class II Equipment



Type BF Equipment



General Alarm



Alternating Current



Power ON



Power OFF



NO SMOKING



Dangerous Voltage



NO Oil or Grease



DO NOT Disassemble



## **ADANGER**

- DO NOT smoke, allow others to smoke or have open flames near the Concentrator when in use.
- DO NOT use near any type of flame or flammable/explosive substances.
- The Concentrator is not suitable for use in an enriched environment of flammable anesthetic mixture with air, oxygen or nitrous oxide.
- **DO NOT** place any liquids on or near the Concentrator. If any liquid gets on or in the Concentrator, immediately turn "OFF" the power switch, unplug from the electrical outlet and contact your Provider.
- This product is not intended as a life-sustaining or life-supporting device.

#### TO REDUCE THE RISK OF ELECTRICAL SHOCK:

- DO NOT use, place or store the concentrator where it can fall or be pulled into water or other liquids. Unplug from wall immediately
- DO NOT remove the cover on the Concentrator. Servicing must be performed by a trained professional.
- DO NOT attempt to repair Concentrator. Any attempt could result in electrical shock.

## TO REDUCE RISK OF BURNS, ELECTROCUTION, FIRE, OR INJURY TO PERSONS:

- · Keep the Concentrator away from heat or open flame.
- DO NOT use if Concentrator has a damaged power cord or plug.
- DO NOT use if Concentrator has been dropped or damaged.
- DO NOT use oil or grease on the Concentrator.

## AWARNING

- Use the Concentrator for its "Intended Use" as described in this manual.
- In the event of an equipment audible alarm or if you are experiencing any signs of discomfort, connect to another source of oxygen and contact your Provider and/or Health Care Professional immediately.
- In certain circumstances oxygen therapy can be hazardous; any user should seek medical advice prior to using this Concentrator.
- Where the prescribing Health care professional has determined that an interruption in the supply of oxygen, for any reason, may have serious consequences to the user, an alternative source of oxygen should be available for immediate use.
- ALWAYS keep the Concentrator in an upright position.
- ALWAYS keep at least 6 in. (15.24 cm) away from walls, furniture, and especially curtains that could prevent adequate airflow to the Concentrator.
- DO NOT place the Concentrator in a small closed space such as a closet.
- **DO NOT** cover the air vents, the Concentrator requires proper ventilation.
- DO NOT use extension cords or electrical adapters.
- The Concentrator is designed to operate with a single lumen Oxygen tubing.
- Flow is available ONLY at the listed settings. There is NO FLOW between settings.
- · Flow Setting Knob does not rotate 360 degrees.
- **DO NOT** remove cover or attempt to repair. There are no user serviceable parts inside. Contact your Provider for repairs.



#### **SPECIFICATIONS**

For technical specifications call Precision Medical or visit www.precisionmedical.com.

Operating Temperature: 50°F to 95°F (10°C to 35°C)
Storage/ Transport Temperature: -29°F to 140°F (-34°C to 60°C)

Operating / Storage / Transport

Relative Humidity: Up to 95% Non-condensing

Electrical (AC Power): 115 VAC ±10%, 60 Hz, 3.2 Amps; 350 Watts

**Tubing Limitations:** 7 ft cannula with a maximum 40 ft of Crush-Proof

Tubing (47 ft total).

**Startup Time:** minimum 87% Oxygen concentration within

5 minutes

Specifications are subject to change without prior notice.

#### COMPONENT DESCRIPTION



**Back & Side View** 

Front View



#### OPERATING INSTRUCTIONS

## **AWARNING**

Additional monitoring or attention may be required for patients using this Concentrator who are unable to hear or see alarms or communicate discomfort.

- 1. Place the Concentrator in a location where room air can be drawn in without being restricted.
- 2. Plug the power cord into an electrical outlet.
- 3. Attach the Oxygen tubing
  - a. Without a bubble humidifier:

Attach the Oxygen tubing to the Oxygen Outlet.

b. With a bubble humidifier:

Attach humidifier adaptor to Oxygen Outlet, fill the bubble humidifier bottle and connect as per bubble humidifier instructions.

**NOTE:** Attach the Oxygen tubing to the bubble humidifier bottle.

 Push the Power On/Off ( I/O ) switch to "ON" ( I ) position. The Power Indicator light below the On/Off ( I/O ) switch will illuminate green when the Concentrator is powered ON.

**NOTE:** Turning the Concentrator "ON" when there is no electrical power or the device has not been plugged into an electrical outlet will cause an Audible Alarm for up to two (2) minutes.

- 5. Turn the Flow Setting Knob on the Concentrator to the prescribed flow.
- 6. Oxygen should be flowing through the Oxygen tubing. If it is not, refer to the "ALARM CONDITIONS" section.
- 7. If using a nasal cannula place over your ears and position the prongs in your nose as instructed by your Provider or cannula manufacturer.
- 8. When the Concentrator is not in use, press the power On/Off ( I/O ) switch to "OFF" ( O ) position.

## **AWARNING**

ISO 8359 (Standard for Oxygen Concentrators) highly recommends that the patient cannula that delivers gas to the patient from the oxygen concentrator should include a Fire Stop Check Valve to stop the flow of gas towards the patient in the case that the cannula becomes ignited. The Fire Stop Check Valve should be located as close to the patient as reasonably practicable.



Fire Stop Check Valve - Precision Medical Part # 507706



## **ALARM CONDITIONS**

On O₂ ⊙ On △ ⊙ Off	Oxygen level is below 83%, continue to use but contact your provider.
On On On	Oxygen level is too low; turn the concentrator "OFF", connect to another source of Oxygen and contact your provider.
On On Flashing	Flow is lower than expected; clear blocked tubing or cannula.
On On Flashing	Power ON, but temperature is too high to start compressor; wait 4 minutes for fan to cool device.
On On Flashing	Waited 4 minutes after power ON, but temperature is still too high to start compressor; turn off power, clear blocked vents, wait and try again.  or  Device was running, but temperature was too high during run; turn off power, clear blocked vents, wait and try again.
On O₂ ○ Off △ ○ On	Power ON, but pressure is too high to start compressor; wait 4 minutes to bleed pressure.
On Off	Waited 4 minutes after power ON, but pressure was too high to start compressor; turn off power, wait and try again.  or  Device was running, but pressure was abnormal during run; turn off
On On	power, wait and try again.  Power ON, but AC voltage is too low for normal operation; unit will start when AC voltage is okay.
On O2 Off  O Off	Or  Device was running, but AC voltage dropped too low for normal operation; unit will restart when AC voltage is okay.
Off O Off O Off	Power switch is ON but no AC power is present; check if power cord is connected.

**NOTE:** If alarm conditions continue, contact your provider.



#### **MAINTENANCE / CLEANING**

Cleaning for Exterior Components:

- 1. Patient should connect to an alternate Oxygen source.
- 2. Turn the Concentrator to the "OFF" ( O ) position.
- 3. Unplug the Power Cord from electrical outlet.
- Clean exterior surfaces of the Concentrator with a cloth dampened with water and mild detergent.
- 5. Wipe the Concentrator dry with a clean cloth.
- Filter should be rinsed with clean water to remove contaminants and blotted dry. Filter should be reinstalled after cleaning.
- When not in use, store the Concentrator in a clean area free from grease, oil and other sources of contamination.

#### **RETURNS**

Returned products require a Returned Goods Authorization (RGA) number, contact Precision Medical, Inc. All returns must be properly packaged to prevent shipping 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 may contain electrical components that are hazardous to the environment. DO NOT dispose device into standard trash. Contact your local waste Management for disposal of Electronic Equipment.



## REPLACEMENT PARTS

Description	Part #
Humidifier Adapter	507324
Cabinet Filter	507913
Compressor Inlet Filter	507919

#### LIMITED WARRANTY AND LIMITATION OF LIABILITY

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

Oxygen Concentrator

limited three (3) years from date of purchase

Precision Medical, Inc. is NOT responsible for normal wear and tear, or any neglect or abuse of the product.

Precision Medical, Inc. is NOT responsible for the shipping cost of the repair.

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 utilifilment 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.

