USER MANUAL



PORTABLE OXYGEN CONCENTRATOR

Model: PM4150 Series



SAVE THESE INSTRUCTIONS

ACAUTION

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. *EasyPulse* Portable Oxygen Concentrator (POC) from the packaging and inspect for damage. If there is any damage, DO NOT USE and contact your Provider.

INTENDED USE

The Precision Medical *EasyPulse POC* (model PM4150) is intended to provide supplemental oxygen to persons requiring oxygen therapy. The Precision Medical POC can be used in a home, institution, vehicle and for transportable use.

READ ALL INSTRUCTIONS BEFORE USING

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

ADANGER

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

EXPLANATION OF ABBREVIATIONS

mL/min Milliliters Per Minute LED Light Emitting Diode

POC Portable Oxygen Concentrator

SAFETY INFORMATION - WARNINGS AND CAUTIONS

A DANGER

Indicates an imminently hazardous situation 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.

ACAUTION

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.



PM4150 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



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.



Excessive Heat Warning



Class II Equipment



Type BF Equipment



General Alarm



Direct Current



Power OFF



Drip Proof Equipment



NO SMOKING



DO NOT Disassemble



NO Oil or Grease

A DANGER

- DO NOT smoke, allow others to smoke or have open flames near the POC when in use.
- **DO NOT** use near any type of flame or flammable/explosive substances.
- DO NOT allow POC to exceed "Operating or Storage Temperature Specifications".
- · Excessive heating of the Carry Bag can occur if intake vents are blocked.
- Equipment not suitable for use in the presence of flammable anesthetic.

TO REDUCE THE RISK OF ELECTRICAL SHOCK:

- DO NOT use while bathing.
- **DO NOT** reach for the POC that has fallen into water. Unplug immediately.
- **DO NOT** attempt to repair POC. Any attempt could result in electrical shock.

AWARNING

- · Use the POC for its "Intended Use" as described in this manual.
- This POC contains magnetic, ferrous material that may affect the results of an MRI.
- In the event of an equipment 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 POC.
- 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 POC in an upright position during operation.
- ALWAYS keep at least 6 in. (15.24 cm) away from walls, furniture, and especially
 curtains that could prevent adequate airflow to the POC.
- DO NOT place the POC in a small closed space such as a closet.
- DO NOT use extension cords or electrical adapters.
- The POC is designed to operate with a single lumen, adult cannula with a maximum length of 7 ft (2.1 m).
- The Setting Knob does not rotate 360°. Rotating the knob less than the "OFF (O) position" or over "setting 5" will damage the Concentrator.
- DO NOT use Components / Accessories not recommended by Precision Medical, see "ACCESSORIES / REPLACEMENT PARTS".

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

- · Keep away from heat or open flame.
- DO NOT use an AC or DC Power Adapter with a damaged power cord or plug.
- **DO NOT** use if POC has been dropped or damaged.
- DO NOT use oil or grease on the POC.
- DO NOT cover the air vents, the POC requires proper ventilation.
- DO NOT remove the cover on the POC. Servicing must be performed by a trained professional.

A CAUTION

- The POC is designed to be used indoors or outdoors, in the outdoors environment the POC should be used in a "dry location" with Battery only.
- POC is designed to be used in dry conditions, the POC is not to be submerged or operated under water.

CAUTION

DO NOT place any liquids on or near the POC. If any liquid gets on the POC, immediately turn "OFF" the power switch and unplug from the electrical outlet.

SPECIFICATIONS

Dimensions: Height: 10.1 in (25.7 cm)

Width: 6.5 in (16.5 cm)
Depth: 4.5 in (11.4 cm)
6.8 lbs (3.08 kg)

 Weight:
 6.8 lbs (3.08 kg)

 Shipping Weight:
 13.1 lbs (5.94 kg)

 Altitude:
 Sea level to 9000 ft (2743 m)

Operating Temperature: 41°F to 104°F (5°C to 40°C)
Storage / Transport Temperature: -4°F to 140°F (-20°C to 60°C)

Operating / Storage / Transport

Relative Humidity: Up to 95% Non-Condensing

Oxygen Concentration: 87% to 95%

 Start Up Time
 87% O₂ Concentration ≤ 10 min

 Oxygen Minute Volume*:
 Setting 1: 240 +/-15% mL/min

 Setting 2: 380 +/-15% mL/min

 Setting 3:
 520 +/-15% mL/min

 Setting 4:
 660 +/-15% mL/min

 Setting 5:
 780 +/-15% mL/min

Mode of Delivery:Pulsed Dose onlyTrigger Sensitivity:0.50 cmH2O maximumTrigger Delay:0.11 seconds typical

Power: AC Power Adapter: 100-240 VAC (1.0 A @ 120 VAC)

DC Power Adapter: 11-16 VDC (5.0 A @ 12 VDC)

 Battery Duration:
 Setting 1:
 4.5 hrs

 (Approximate)
 Setting 2:
 3.2 hrs

 Setting 3:
 2.5 hrs

 Setting 4:
 1.8 hrs

 Setting 5:
 1.5 hrs

Sound (@ Setting 2): 44 dBA

Cannula: Maximum 7 ft (2.1 m) long standard adult single lumen nasal cannula.

Equipment Classification:

Class II - with respect to protection from electrical shock
Type BF - degree of protection against electrical shock
IPX1 - degree of protection against ingress of liquids

Mode of Operation - Continuous

Volatile Organic Compound (VOC) and Particulate Requirements:

The oxygen delivered from the EasyPulse POC meets the following requirements for particulate levels, VOC levels, carbon monoxide levels, carbon dioxide levels and ozone levels.

EPA PM_{2.5} Particulate Matter ASTM D5466 Ozone Levels

21 CFR 801.415 Carbon Monoxide Levels EPA NAAQS - Carbon Monoxide Carbon Dioxide Levels

OSHA Permissible Exposure Limits

Standard Test Method for Determination of Volatile Organic Chemicals in Atmospheres (Canister Sampling Methodology)

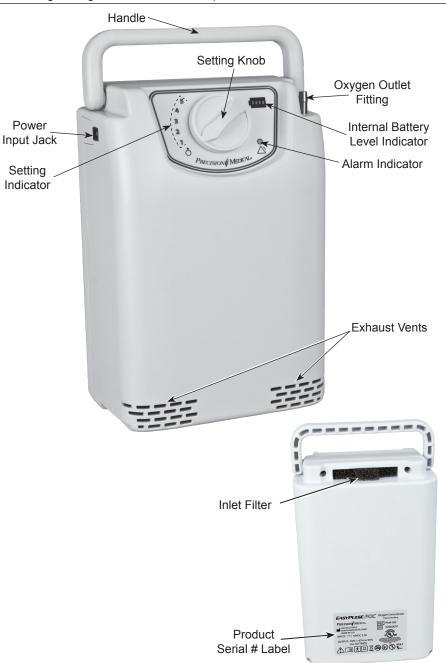
Specifications are subject to change without prior notice.

^{*} At Sea level

COMPONENT DESCRIPTION

ACAUTION

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



OPERATING INSTRUCTIONS

AWARNING

- · Read this User Manual before operating the POC.
- The POC shall be used by an adult or supervised by an adult when being used by a child.
- Additional monitoring or attention may be required for patients using this POC who are unable to hear or see alarms or communicate discomfort.
- The Setting Knob does not rotate 360°. Rotating the knob less than the "OFF (O) position" or over "setting 5" will damage the Concentrator.

ACAUTION

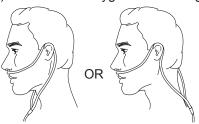
- For Proper Oxygen Flow, be sure that cannula is not kinked or obstructed before or during use.
- DO NOT use humidifier bottles with the POC.
- DO NOT use pediatric, low flow nasal cannulas or oxygen masks with the POC.

CAUTION

- · Inspect the POC for visual damage before use, DO NOT USE if damaged.
- To prevent damage to the POC, DO NOT operate the POC without the inlet filter or while the inlet filter is wet.

Using the EasyPulse POC

- 1. Connect the end of a standard adult single lumen oxygen nasal cannula with a maximum length of 7 feet (2.1 m) to the POC's oxygen outlet fitting.
- 2. Place the cannula over your ears and position the prongs in your nose as instructed by your Equipment Provider or cannula manufacturer.



- Prior to operation, ensure the inlet and exhaust vents on the POC are clear. Any blockage of the vents can inhibit performance.
- 4. Choose one of the 3 power options: AC Power Adapter, DC Power Adapter or Internal Battery (Refer to the "POWER SUPPLY" section of the user manual for details on these 3 options).
- 5. Turn "ON" the POC by rotating the setting knob *clockwise* until the knob points to your prescribed flow setting number and the number is illuminated green.
- 6. Breathe normally through your nose. A measured pulse of oxygen will be delivered each time the POC senses an inhalation. To show the POC is triggering properly the illuminated setting number will turn off briefly each time it senses an inhalation.
- 7. To turn "OFF" the POC, rotate the setting knob *counterclockwise* to the "OFF" (O) position.

Operating Position

The POC can be operated in an upright position with or without the carry bag as shown below.



The POC can be operated lying on its back ONLY while in the carry bag as shown below.



Using the Carry Bag

The carry bag is intended to make the POC easier to transport, prevent movement due to vibration and protect the device from minor mishaps.

CAUTION

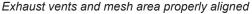
The carry bag is not intended to make the POC waterproof, or to protect the device from major falls or accidents/abuse.

When inserting the POC into the carry bag make sure of the following:

- Before placing POC inside bag make sure bag is clean and empty.
- Make sure the control knob and control panel are aligned with the clear window on the bag.
- Make sure bottom exhaust vents are aligned with the mesh opening along the bottom of the bag.

Control panel and clear window properly aligned







Proper carrying position

AWARNING

- The mesh on the carry bag must be aligned with the exhaust vents on the POC to keep the POC cool and operating properly.
- Be sure the exhaust vents are facing away from body while being carried.



- If the outside of the bag feels hot or causes any discomfort, set the POC down and check to be sure all vents are unobstructed.
- **DO NOT** cover Air Vents, the POC requires proper ventilation.
- **DO NOT** allow the POC to come in direct contact with skin while in the carry bag.

The carry handle can be placed in either of the positions below with the flap secured.





POWER SUPPLY

AC Power Adapter:

The AC power adapter connects the POC to a 100-240 VAC, 50/60 Hz wall outlet. The power adapter converts AC voltage to DC voltage in order to power the POC. The AC adapter will power the POC and simultaneously charge the internal battery.

Connection: To connect the AC Power Adapter to the POC, insert the DC plug connector into the power input jack on the POC and insert the AC wall plug into a wall socket.



DC Power Adapter:

The DC power adapter connects the POC to an automobile's 12 VDC outlet. The DC adapter will power the POC and simultaneously charge the internal battery.

Connection: To connect the AC Power Adapter to the POC, insert the DC plug connector into the power input jack on the POC and insert the other end into your automobile's 12 V accessory jack.



Internal Battery Pack:

The POC contains an internal rechargeable lithium ion battery pack. When fully charged, the battery will power the POC for up to 4.5 hours dependent upon setting. The Battery Level Indicator in the upper right corner of the control panel continuously displays the charge level of the internal battery while the POC is on. When the battery charge level drops to 15%, the last LED will turn solid red and a brief audible beep will be emitted once every minute. When the battery charge level drops to 5% the last LED starts to flash red and a brief audible beep is emitted once every 20 seconds to signal that the battery is almost depleted and you will need to connect the POC to another power source.

Charging: The internal battery can be charged by connecting either the AC Power Adapter or DC Power Adapter to the POC. The internal battery will begin charging as soon as power is connected. You will also be able to run the POC while the internal battery charges.

ACCESSORIES / REPLACEMENT PARTS

Precision Medical, Inc. recommends that only the items listed below be used with the POC.

Description	Part #
Inlet Filter	505847
AC Power Supply	506629
DC Power Supply	506750
Carry Bag	506707
Cannula	504833

Other Power Cord / Plug combination for the AC Power Adapter available thru Precision Medical, Inc. ONLY.

ALARM / INDICATORS / TROUBLESHOOTING

The Audible Alarm and LED Indicators are listed in the chart.

Visual Indicator/ Problem	Audible Alarm	Probable Cause	Remedy
The last LED on the internal Battery Level Indicator turns red	Repetitive beep	Internal battery has dropped below 15% charge remaining	Connect the POC to the AC Power Adapter, DC Power Adapter, or external battery pack
The last LED on the internal Battery Level Indicator flashes red	Repetitive beep	Internal battery has dropped below 5% charge remaining	Connect the POC to the AC Power Adapter, DC Power Adapter, or external battery pack Change to alternate oxygen source if power source is not available
Amber alarm indicator is illuminated and setting number is not flashing during inhalation to signal a detected breath	Repetitive beep	No breath detected for 1 minute	Verify the cannula is not kinked Verify the cannula is properly connected to oxygen outlet Verify the cannula is properly positioned in the nose
Red alarm indicator is illuminated and setting number is not flashing during inhalation to signal a detected breath	Repetitive beep	No breath detected for 2 minutes	Verify the cannula is not kinked Verify the cannula is properly connected to oxygen outlet Verify the cannula is properly positioned in the nose If alarm persists change to alternate oxygen source and contact your Equipment Provider
Amber alarm indicator is illuminated	Repetitive beep	Breath rate exceeding 35 breaths / minute	Reduce level of activity to allow breath rate to slow
Red alarm indicator is illuminated	Repetitive beep	Breath rate exceeding 35 breaths / minute for longer than 1 minute	Reduce level of activity to allow breath rate to slow If alarm persists, change to alternate oxygen source and contact your Equipment Provider
Red alarm indicator is illuminated, unit is not running and setting numbers 1 & 2 are flashing	Repetitive beep	Abnormal compressor operation detected	Turn the POC to the "OFF" position Turn the POC back "ON" to prescribed setting If alarm persists, change to alternate oxygen source and contact your Equipment Provider

Visual Indicator/ Problem	Audible Alarm	Probable Cause	Remedy
Red alarm indicator is illuminated, unit is not running and setting numbers 1 & 3 are flashing	Repetitive beep	Internal battery is outside its operating temperature range	1. Turn off the POC and disconnect any power supplies 2. Check that the inlet filter is clean 3. Ensure inlet and exhaust vents are not blocked in any way 4. Verify you are operating the POC within the specified operating temperature range. 5. It may be necessary to allow the POC to warm up or cool before turning back on
Red alarm indicator is illuminated, unit is not running and setting numbers 1 & 4 are flashing	Repetitive beep	Motor is above it's maximum operating temperature	Turn off the POC Check that the inlet filter is clean Ensure inlet and exhaust vents are not blocked in any way Verify you are operating the POC within the specified operating temperature range It may be necessary to allow the POC to cool before turning back "ON"
Red alarm indicator is illuminated, unit is not running and setting numbers 1 & 5 are flashing	Repetitive beep	Pressure outside of normal operation	Turn the POC to the "OFF" position Turn the POC back "ON" to prescribed setting If alarm persists, change to alternate oxygen source and contact your Equipment Provider
Red alarm indicator is illuminated, unit is not running and setting numbers 2 & 3 are flashing	Repetitive beep	Fan malfunction	Turn the POC to the "OFF" position Turn the POC back "ON" to prescribed setting If alarm persists, change to alternate oxygen source and contact your Equipment Provider
Red alarm indicator is illuminated, unit is not running and setting numbers 2 & 4 are flashing	Repetitive beep	Failed electrical connection	Turn the POC to the "OFF" position Turn the POC back "ON" to prescribed setting If alarm persists, change to alternate oxygen source and contact your Equipment Provider
Amber alarm indicator is flashing and unit is running	NA	Service Needed	Continue to use POC Contact Equipment Provider
Red alarm indicator is flashing and unit is running	NA	Service Needed	Switch to another source of oxygen Contact Equipment Provider

MAINTENANCE / CLEANING

AWARNING

- Prior to cleaning, ensure the POC is turned off and unplug any external power sources.
- **DO NOT** disassemble or attempt to repair. There are no user serviceable parts inside. Contact your Equipment Provider for service.
- DO NOT spray or apply any cleaners directly onto the case.
- DO NOT allow any liquids to drip inside any case openings.

Perform cleaning as required.

Cabinet:

- 1. The patient should connect to an alternate Oxygen source.
- 2. Turn the POC to the "OFF" (O) position.
- 3. Unplug the external power source before cleaning.
- 4. Clean exterior surfaces of the POC with a cloth dampened with disinfectant solution. *Example: Sporicidin*[®] *Brand Disinfectant Solution*.
- 5. Allow POC to air dry.
- 6. DO NOT place inside carry bag or run the POC until it is thoroughly dry.
- 7. When not in use, store the POC in a clean area free from grease, oil and other sources of contamination.

Inlet Filter:

- 1. Remove the inlet filter by pulling on the protruding tab.
- 2. Wash filter with mild detergent. Rinse thoroughly with water and allow to dry completely.
- 3. Once filter is dry, push the filter back into the case so only the small tab is protruding.



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 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.



LIMITED WARRANTY AND LIMITATION OF LIABILITY

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

Portable Oxygen Concentrator three (3) years from date of shipment Battery 90 days from date of shipment

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 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)

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Product: Portable Concentrator

Model(s): PM4150
MDD Class: Ilb

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 Directive 2007/47/EC of The European Parliament and the following documents:

BS EN 60601-1, BS EN 60601-1-2, BS EN 60601-1-8, EN 980, EN 1041, IEC 60601-1-4, IEC 60601-1-6, ISO 3744, IEC 62366, ISO 3744, ISO 8359, ISO 14971, ISO 15001, ISO 15223-1

Notified Body for Product Safety:

TUV Rheinland Products Safety GmbH € 0197

Certification Registration No's: HD 60019110 0001

Date of Expiry: 03/08/2012



ISO 13485 Certified

Precision Medical, Inc. 300 Held Drive Northampton, PA 18067 USA

