

USER MANUAL

EASYPULSE POC

PORTABLE OXYGEN CONCENTRATOR

Model: PM4130 Series



SAVE THESE INSTRUCTIONS

R_x ONLY

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 PM4130) 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.

EXPLANATION OF ABBREVIATIONS

mL/min	Milliliters Per Minute
LED	Light Emitting Diode
POC	Portable Oxygen Concentrator

<i>Indicator light Colors and Meaning</i>	
Red	Warning - Immediate response by the OPERATOR is required
Amber	Caution - Prompt response by the OPERATOR is required
Green	Ready for use

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.



PM4130 WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005, 3rd ed), CAN/CSAC22.2 No. 60601-1 (2008) 62NA



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



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.



Symbol indicates the device complies with the requirements of Directive 93/42/EEC concerning medical devices and all applicable International Standards.
















Authorized by FAA for Use Onboard Aircraft
Docket #: FAA-2012-0928



The patient cannula is intended for single patient use only. Use on more than one patient may cause cross contamination.

SAFETY INFORMATION - WARNINGS AND CAUTIONS

(continued)

	General Warning Sign		NO SMOKING
	Follow Instructions for Use		DO NOT Disassemble
	General Mandatory Action Sign		NO Oil or Grease
	The PM4130 Oxygen Concentrator, gas pathways, components and accessories do not contain any natural rubber latex.		
IP21	Protected from touch by fingers and objects greater than 12 millimeters. \ Protected from condensation.		
	Class II Equipment		Type BF Equipment
	General Alarm		Direct Current
	Power OFF		Excessive Heat Warning

DANGER

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

- **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.
- POC is designed to be used in dry conditions, the POC is not to be submerged, operated under water or used while swimming.

WARNING

- 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.
- Place the POC on a secure flat surface when not transporting to avoid accidental damage to the POC.
- **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).
- **DO NOT** use Components / Accessories not approved by Precision Medical, see “ACCESSORIES / REPLACEMENT PARTS”.
- The POC delivers oxygen in a concentrated form when a breath is taken. An oxygen enrichment of the surrounding area is unlikely.

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.
- Use only water-based lotions or salves that are oxygen-compatible before and during oxygen therapy. Never use petroleum or oil-based lotions or salves to avoid the risk of fire and burns.
- Do not lubricate fittings, connections, tubing, or other accessories of the oxygen concentrator to avoid the risk of fire and burns.

WARNING (continued)

- Use only spare parts recommended by Precision Medical to ensure proper function and to avoid the risk of fire and burns.
- Use of this device at an altitude above or below sea level to 9000 ft (2743 m) or outside a temperature of 41°F to 104°F (5°C to 40°C) or a relative humidity above 95% Non-Condensing is expected to adversely affect the flowrate and the percentage of oxygen and consequently the quality of the therapy.
- Geriatric, pediatric or any other patient unable to communicate discomfort can require additional monitoring and or a distributed alarm system to convey the information about the discomfort and or the medical urgency to the responsible care giver to avoid harm.
- Smoking during oxygen therapy is dangerous and is likely to result in facial burns or death. Do not allow smoking within the same room where the oxygen concentrator or any oxygen carrying accessories are located. If you intend to smoke, you must always turn the oxygen concentrator off, remove the cannula and leave the room where the oxygen concentrator is located. If unable to leave the room, you must wait 10 minutes after you have turned the oxygen concentrator off before smoking.
- Open flames during oxygen therapy are dangerous and is likely to result in fire or death. Do not allow open flames within 2 m of the oxygen concentrator or any oxygen carrying accessories.
- To ensure receiving the therapeutic amount of oxygen delivery according to your medical condition, the PM4130 Oxygen Concentrator must be used with the specific combination of parts and accessories that are in line with the specification of the concentrator manufacturer and that were used while your settings were determined.
- To ensure receiving the therapeutic amount of oxygen delivery according to your medical condition, the PM4130 Oxygen Concentrator must be used only after one or more settings have been individually determined or prescribed for you at your specific activity levels by your healthcare provider.
- If you feel discomfort or are experiencing a medical emergency while undergoing oxygen therapy, seek medical assistance immediately to avoid harm.
- There is a risk of fire associated with oxygen enrichment during oxygen therapy. Do not use the oxygen concentrator or accessories near sparks or open flames.

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.
- The proper placement and positioning of the prongs of the nasal cannula in the nose is critical to the amount of oxygen delivered to the respiratory system of the patient.
- **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.
- **DO NOT** use while sleeping.

GENERAL SPECIFICATIONS

- When measuring any published tolerance, be sure to consider the tolerance of accuracy of the measuring equipment.
- Gas volume and flowrate specifications for gas delivered to the patient are expressed at ATPD (ambient temperature and pressure, dry).
- Precision Medical Inc, and your equipment provider are accountable for ensuring the compatibility of the oxygen concentrator and all of the parts or accessories used to connect to the patient before use.
- The PM4130 Oxygen Concentrator, its parts or accessories do not contain known phthalates which are classified as carcinogenic, mutagenic or toxic.
- The PM4130 Oxygen Concentrator, its parts and accessories are intended for use by a single patient and should be cleaned\disinfected before use on a new patient. Note: The nasal cannula cannot be cleaned and should be disposed of.

SPECIFICATIONS

Dimensions:	Height:	8.5 in (21.6 cm)
	Width:	6.5 in (16.5 cm)
	Depth:	4.5 in (11.4 cm)
Weight:		4.9 lbs (2.22 kg)
Shipping Weight:		10.8 lbs (4.91 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)
<i>Operating / Storage / Transport</i>		
Relative Humidity:		Up to 95% Non-Condensing
Start Up Time:		87% O ₂ Concentration ≤ 10 min

SPECIFICATIONS (continued)

Oxygen Minute Volume*:	Setting 1:	240 +/-15% mL/min
	Setting 2:	380 +/-15% mL/min
	Setting 3:	520 +/-15% mL/min
Oxygen Concentration:	87% to 95% on all settings	
Mode of Delivery:	Pulsed Dose only	
Trigger Sensitivity:	0.50 cmH ₂ O maximum	
Trigger Delay:	0.11 seconds typical	
Power:	<i>AC Power Adapter:</i>	100-240 VAC (1.0 A @ 120 VAC)
	<i>DC Power Adapter:</i>	11-16 VDC (5.0 A @ 12 VDC)
Battery Duration: (Approximate)	Setting 1:	5.5 hrs
	Setting 2:	4.0 hrs
	Setting 3:	3.0 hrs

Times may vary based on atmospheric conditions and battery age.

Sound (@ Setting 2): 39 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
IP21	- Protected from touch by fingers and objects greater than 12 millimeters. \ Protected from condensation.

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)	

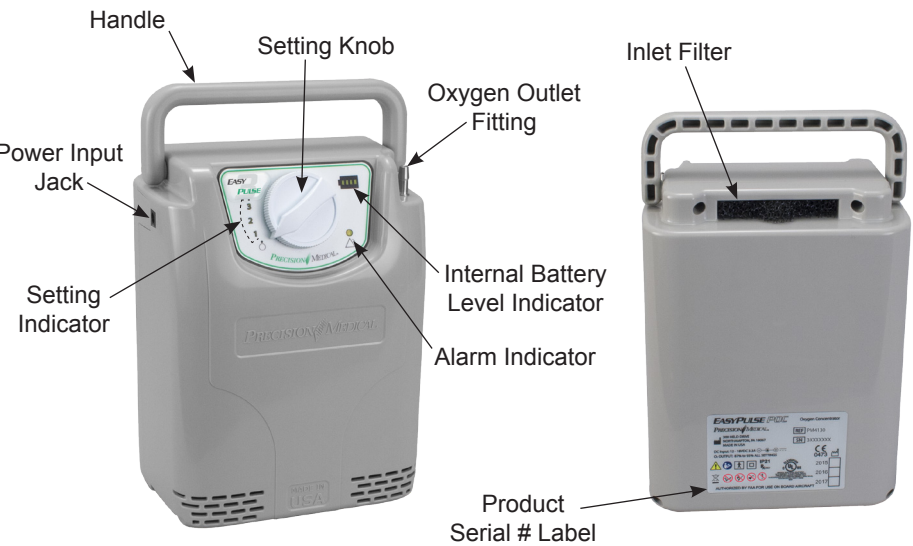
* At Sea level

Specifications are subject to change without prior notice.


COMPONENT DESCRIPTION

 **CAUTION**


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



OPERATING INSTRUCTIONS

 **WARNING**

- 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 (⊖) position” or over “setting 3” will damage the Concentrator.**


 **CAUTION**

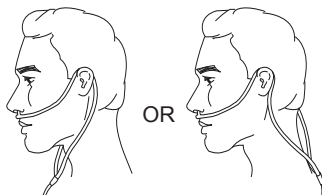
- **ALWAYS** confirm prescribed dose before administering to patient and monitor on a frequent basis.
- For Proper Oxygen Flow, be sure that cannula is not kinked or obstructed before or during use.
- **DO NOT** use humidifier bottles with the POC.
- **DO NOT** use pediatric, low flow nasal cannulas 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. Verify battery status (level) prior to each use, charge as necessary.
2. 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.
3.  *To ensure proper device operation, use only an adult single lumen cannula maximum 7 ft (2.1 m).*
4. Place the cannula over your ears and position the prongs in your nose as instructed by your Equipment Provider or cannula manufacturer.
5. Prior to operation, ensure the inlet and exhaust vents on the POC are clear. Any blockage of the vents can inhibit performance.
6. 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).
7. 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.
8. 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.
9. To turn "OFF" the POC, rotate the setting knob **counterclockwise** to the "OFF" (O) position.



WARNING

ISO 80601-2-69 (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



2" Tubing Connector - Precision Medical Part # 507707

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



Exhaust vents and mesh area properly aligned



Proper carrying position

WARNING



- 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.

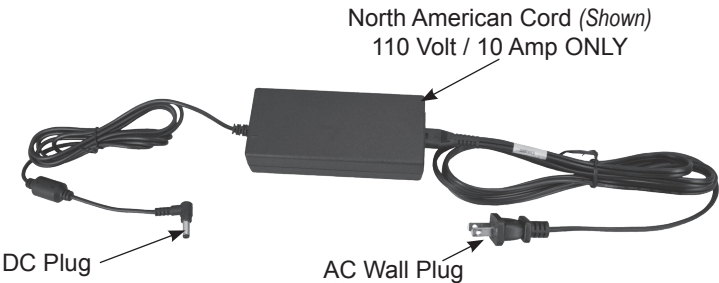


POWER SUPPLY

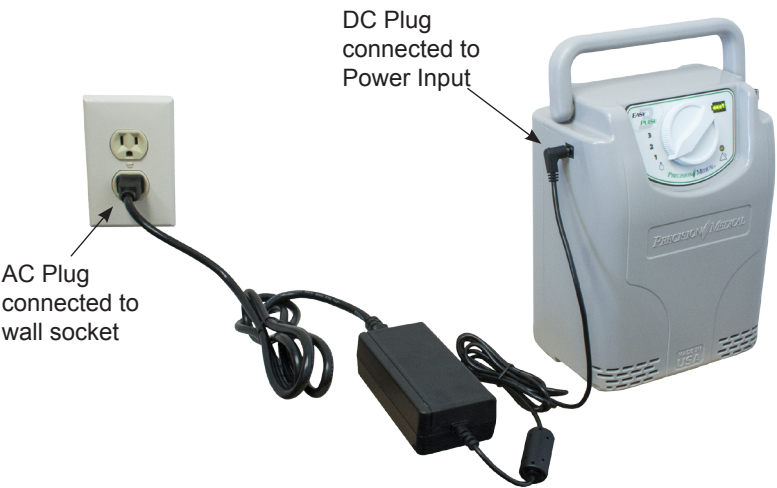
! *To prevent damage to the device, use only Precision Medical approved external power sources.*

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.

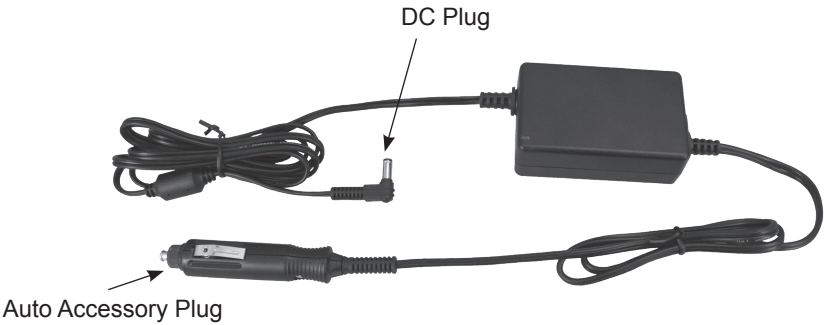


Connection: To connect the AC Power Adapter to the POC, insert the DC Plug Connector into the Power Input jack on the POC and insert the AC Wall Plug into a wall socket.

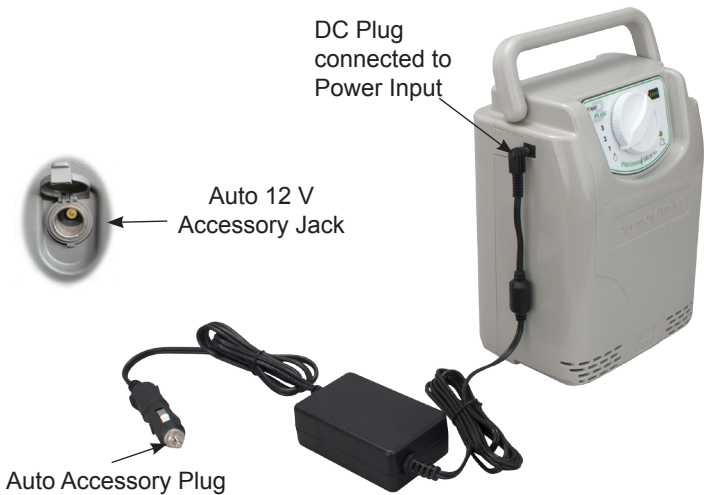


DC Power Adapter:

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 DC 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 5.5 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.

ENSURE BATTERY IS FULLY CHARGED PRIOR TO FIRST USE.

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.

Lithium Ion Battery Guidelines

Proper Use: <i>In order to prolong life of the battery, it is best to charge the battery frequently rather than waiting until the battery is fully discharged.</i>	Storage: <i>When storing for long periods of time without use (> 1 month) be sure to charge the battery to around 50% charge level to prolong life of battery.</i>
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ACCESSORIES / REPLACEMENT PARTS

Only the items listed below are to be used with the POC.

Description	Part #
Inlet Filter	505847
AC Power Cord	506961
AC Power Supply	506629
DC Power Supply	506750
Carry Bag	507947
Cannula	504833

Use of accessories or replacement parts not listed in this instruction may cause adverse effects to basic safety or essential performance of the Oxygen Concentrator.


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

ALARM / INDICATORS / TROUBLESHOOTING



<i>Green</i>	Ready for use
<i>Amber</i>	Caution - Prompt response by the OPERATOR is required
<i>Red</i>	Warning - Immediate response by the OPERATOR is required

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	<ol style="list-style-type: none"> 1. Connect the POC to the AC Power Adapter, DC Power Adapter, or external battery pack 2. 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	<ol style="list-style-type: none"> 1. Verify the cannula is not kinked 2. Verify the cannula is properly connected to oxygen outlet 3. 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	<ol style="list-style-type: none"> 1. Verify the cannula is not kinked 2. Verify the cannula is properly connected to oxygen outlet 3. Verify the cannula is properly positioned in the nose 4. 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	<ol style="list-style-type: none"> 1. Reduce level of activity to allow breath rate to slow 2. 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	<ol style="list-style-type: none"> 1. Turn the POC to the "OFF" position 2. Turn the POC back "ON" to prescribed setting 3. If alarm persists, change to alternate oxygen source and contact your Equipment Provider
Red Alarm and 2 & 3 Setting Numbers Illuminated and device Shuts Down	Single Beep	Cannula Occluded/ Kinked	<ol style="list-style-type: none"> 1. Ensure the Cannula and/or Outlet are Not Blocked 2. Turn the POC to the "OFF" position for at least 15 seconds. 3. Turn the POC back "ON" to prescribed Setting 4. If Alarm persists, change to alternate Oxygen source and Contact your Equipment Provider.
All other Alarm Conditions	Unknown 1. Switch to another source of Oxygen.	Unknown 1. Switch to another source of Oxygen.	<ol style="list-style-type: none"> 1. Switch to another source of Oxygen. 2. Contact Equipment Provider.

MAINTENANCE / CLEANING

WARNING

- 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.
- **DO NOT** use harsh and/or flammable chemicals to clean the device.

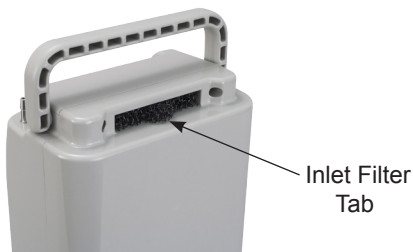
Perform cleaning as required.

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: Sporidicin® 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 *180 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



Precision Medical, Inc.
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CE
0473



PM4130

Classification: IIa

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

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, EN ISO 14971, EN 60601-1, EN 60601-1-2, EN 60601-1-8, EN 62366, EN ISO 3744, ISO 80601-2-67, ISO 80601-2-69, EN ISO 15001, ISO 13485, ISO 15223-1, 2006/66/EC, 2011/65/EC (RoHS 2)*

Notified Body:



AMTAC Certification Services Limited CE 0473

Address:

Davy Avenue Knowlhill Milton Keynes MK5 8NL, UK

Certification Registration No's: 1126 A CE

Date of Expiry: 26 July 2017

Devices already manufactured: S/N traceability Device History Records

Validity of DOC: 31 August 2012 to Date of Expiry

Manufacture Representative: Quality Manager

Position: Quality Systems/ISO Representative

Date of Issue: 31 August 2012

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

Tell us how we are doing!
Visit us at www.precisionmedical.com



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