

USER MANUAL

OXYGEN MONITOR

Model: PM5900



SAVE THESE INSTRUCTIONS

CAUTION

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 Oxygen Monitor from the packaging and inspect for damage. If there is any damage, **DO NOT USE** and contact your Provider.

INTENDED USE

Precision Medical, Inc. Oxygen Monitor provides continuous, direct monitoring of oxygen mixtures in a wide variety of medical applications such as anesthesiology (e.g., anesthesia machines), respiratory devices (e.g., respirators, ventilators, pediatric incubators), and oxygen therapy (e.g., oxygen tents).

OPERATOR PROFILE

The oxygen monitor is to be used by trained healthcare professionals under the supervision, or on the order, of a physician in a hospital (or other clinical setting). The Precision Medical, Inc. Oxygen Monitor is not intended for transport use. This device is not an oxygen supply source.

READ ALL INSTRUCTIONS BEFORE USING

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

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.



Direct current.

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)**



PM5900 WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL60601-1, IEC60601-1, CAN/CSA C22.2 No. 601.1

DANGER

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

WARNING

- Only trained, qualified medical personnel under the direct supervision of a licensed physician should operate the Oxygen Monitor.
- Use this Oxygen Monitor only for its intended use as described in this manual.
- Medical Oxygen should meet the requirements of USP.
- Always follow ANSI and CGA standards for Medical Gas Products, Flowmeters, and Oxygen Handling.
- The Oxygen Monitor should be serviced by a qualified hospital/ dealer service technician, or by Precision Medical, Inc.
- **DO NOT** obstruct the alarm grill on the back of the Oxygen Monitor.
- **DO NOT** use near any type of flame or flammable/ explosive substances, vapors or atmosphere.
- **DO NOT** allow an excess length of cable near the patient's head or neck, this could result in strangulation. Secure excess cable to bed rail or suitable object.
- **DO NOT** use Oxygen Monitor with a cable that appears worn, cracked or has damaged insulation.

CAUTION

- The Oxygen Monitor contains magnetic, ferrous material that may affect the results of an MRI.
- Store the Oxygen Monitor in a clean, dry area when not in use.
- **DO NOT** use if dirt or contaminants are present on or around this Oxygen Monitor or connecting devices.
- **DO NOT** smoke in an area where oxygen is being administered.
- **DO NOT** clean with aromatic hydrocarbons.
- **DO NOT** steam autoclave.
- **DO NOT** gas sterilize with (EtO) Ethylene Oxide.
- **DO NOT** immerse Oxygen Monitor or Sensor in liquid.

SPECIFICATIONS

Base Unit Specifications

Dimensions: *(Monitor without Cable and Sensor attached)*

Length:	1.72 in	(4.36 cm)
Width:	3.56 in	(9.04 cm)
Height:	5.44 in	(13.82 cm)
Cable Length: <i>(Fully extended)</i>	10 ft	(3.05 m)

Weight:

Oxygen Monitor, Sensor, Batteries and Cable Weight:	1.11 lbs	(0.50 kg)
Shipping Weight:	1.64 lbs	(0.75 kg)

Operating Conditions:

Temperature:	50°F to 113°F	(10°C to 45°C)
Altitude:	Sea Level to 8,000 ft / 2438 m	

Storage Conditions:

Temperature:	5°F to 122°F	(-15°C to 50°C)
Humidity:	0 - 95% Noncondensing	

Power Requirements:

4 AA Alkaline Batteries (4 x 1.5=6 Volts)

Battery Life:

Approximately 2,000 hours continuous use non-alarm condition

Diverter Fitting:

15 mm "T" adapter

Measurement Range:

0.0 - 100% Oxygen

Resolution:

0.1 increments

Accuracy & Linearity:

± 1% of full scale at constant temperature, relative humidity and pressure when calibrated at full scale

Total Accuracy:

± 3% actual oxygen level over full operating temperature range

Response Time:

90% of final value in less than 12 seconds at 77°F (25°C)

Warm-up Time:

None required

Low Battery Indication:

"LO BATTERY" message displayed on graphics screen, and audible alarm

Alarm System:

High/Low alarms, flashing red LEDs and graphics, and nominal 68 db audible alarm @ 1 meter

Alarm Accuracy: displayed value ±0.1

Low Alarm Range: 18% - 99% Oxygen

High Alarm Range: 19% - 100% Oxygen

High Alarm De-Activation Setting: Above 100% ("---" will appear)

Sensor Specifications:

Sensor Type: Galvanic Oxygen Sensor (fuel cell)
Precision Medical Part Number (504877)

Expected Sensor Life: > 1,000,000 O₂% Hours

Drift: < 1% volume O₂ / month @ air

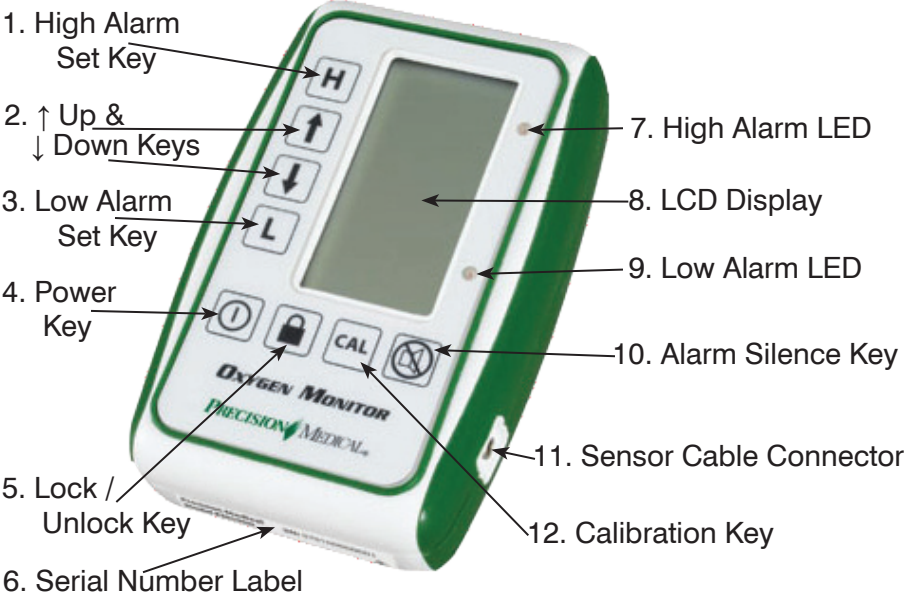
Specifications are subject to change without prior notice













COMPONENT DESCRIPTION













⚠ CAUTION

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

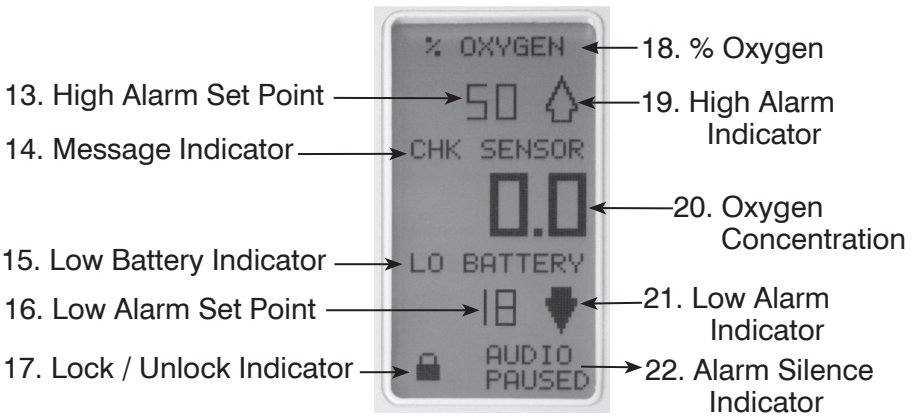
OXYGEN MONITOR IDENTIFICATION





NO.	ITEM NAME	DESCRIPTION
1	High Alarm Set Key 	<p>Pressing the  key when the keypad is unlocked, the high alarm set point will flash. The high alarm setting can be adjusted with the  UP/DOWN keys. When the high alarm value is changed, pressing the  key will save the setting. The Oxygen Monitor will also save the setting and revert to normal operation if no keys are pressed within 10 seconds. The High Alarm Set is adjustable up to 100% Oxygen. To disable the HIGH Alarm, raise the HIGH Alarm setting above 100%. Dashes (---) will be displayed next to the  UP key on the LCD display.</p> <p>NOTE: When the High alarm is disabled dashes (---) will appear next to the  UP key on the LCD display, the Low alarm will still function.</p> <p>NOTE: Factory Preset = 50% Oxygen.</p>
2	Up and Down Keys 	<p>The  keys are used in conjunction with the alarm set keys. Pressing either of these keys will change the alarms set points by 1% increments or 5% if held down continuously.</p>
3	Low Alarm Set Key 	<p>Pressing  key when the keypad is unlocked, the Low Alarm set point will flash. The Low Alarm setting can be adjusted with the  UP/DOWN keys. When the Low Alarm value is changed, pressing the  key will save the setting. The Oxygen Monitor will also save the setting and revert to normal operation if no keys are pressed within 10 seconds. The Low Alarm Set is adjustable down to 18% Oxygen.</p> <p>NOTE: Factory Preset = 18% Oxygen.</p>

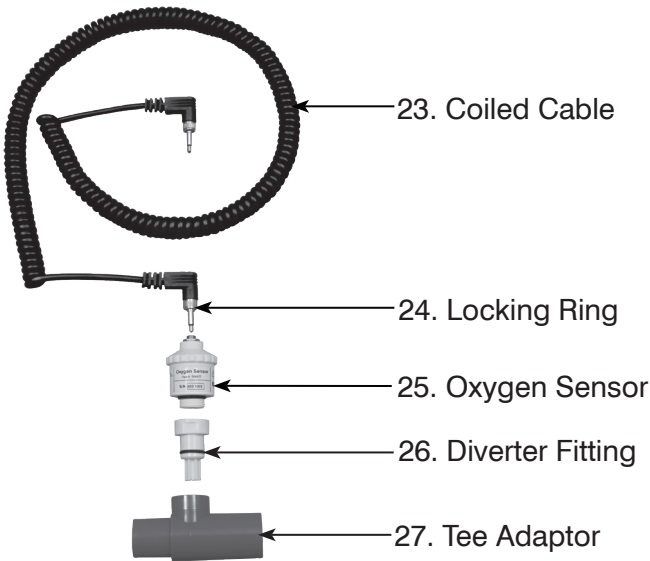
NO.	ITEM NAME	DESCRIPTION		
4	Power Key 	The  key turns the Oxygen Monitor ON and OFF. The  LOCK/UNLOCK key must be pressed to unlock the Oxygen Monitor, before being powered OFF.		
5	Lock / Unlock Key 	Pressing the  key will “Unlock  key to “Lock  6	Serial Number Label	
7	High Alarm LED	During a High Alarm condition, the red LED will flash accompanied by the triple pulse audible alarm.		
8	LCD Display	Graphic Display with backlight.		
9	Low Alarm LED	During a Low Alarm condition, the red LED will flash accompanied by the triple pulse audible alarm.		
10	Alarm Silence Key 	In alarm condition, pressing the  Key will deactivate the audible alarm for 120 seconds. The visual alarm will continue to display.		
11	Sensor Cable Connector	Cable Interface connection between Oxygen Monitor and Oxygen Sensor Cable.		
12	Calibration Key 	Pressing the  key calibrates the Oxygen Monitor with air or oxygen.		

OXYGEN MONITOR LCD DISPLAY IDENTIFICATION



13	High Alarm Set Point	The High Alarm set point value.
14	Message Indicator	CHK SENSOR CAL @ AIR CAL @ 100 CAL FAIL DONE SERVICE NEED
15	Low Battery Indicator	Indicates when the batteries shall be replaced.
16	Low Alarm Set Point	The Low Alarm set point value.
17	Lock / Unlock Indicator	Indicates if the keypad is “Locked  ”/ “Unlocked  ”.
18	% Oxygen	Unit of measure.
19	High Alarm Indicator	Indicates High Alarm.
20	Oxygen Concentration	Displays percentage of Oxygen Concentration.
21	Low Alarm Indicator	Indicates Low Alarm.
22	Alarm Silence Indicator	“AUDIO PAUSED” Indicates Alarm Silence Mode.

OXYGEN SENSOR COMPONENT IDENTIFICATION



NO.	ITEM NAME	DESCRIPTION
23	Coiled Cable with Male Plugs	The Coiled Cable allows the Sensor to be positioned up to 10 ft from the side of the Oxygen Monitor. There are Male Plugs at each end of the Coiled Cable.
24	Locking Ring	Male Plug has a Locking Ring and must be engaged when in use.
25	Oxygen Sensor	Galvanic Oxygen Sensor
26	Diverter Fitting	Fitting used to connect to the Oxygen Source.
27	Tee Adaptor	The Tee Adaptor is used to connect the Oxygen Sensor and Diverter Fitting to a oxygen pathway circuit.

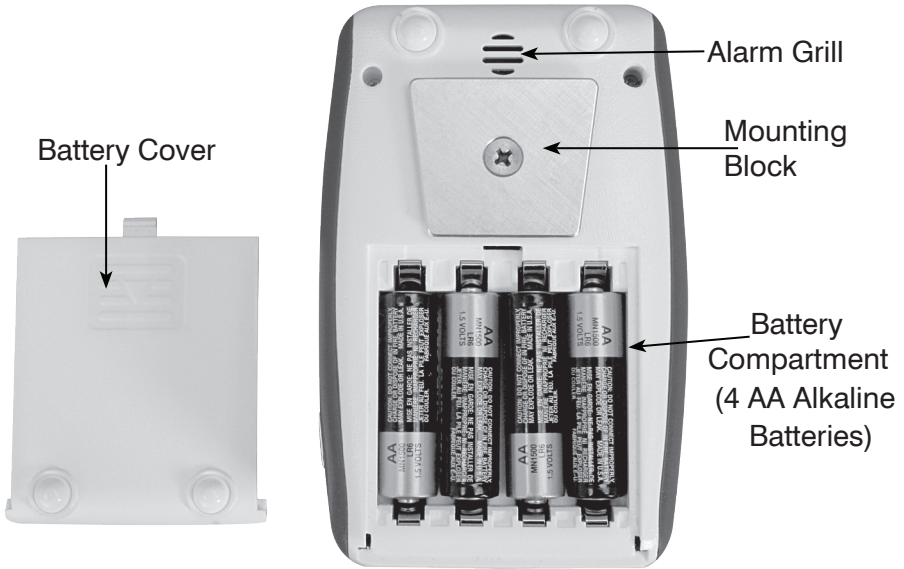
BATTERY INSTALLATION

⚠ CAUTION

Use ONLY AA Alkaline Batteries.

1. Press down the center, top edge of the battery cover and slide down.
2. Remove old batteries, if applicable.
3. Install 4 AA Alkaline Batteries, and follow the diagram stamped in the bottom of the battery compartment.
4. Slide the battery cover back into position until the cover snaps on to the Monitor.

BATTERY INSTALLATION DIAGRAM



OPERATING INSTRUCTIONS

CAUTION

Inspect the Oxygen Monitor, Sensor and Cable for visual damage before use, DO NOT USE if damaged.

⚠ WARNING

Read this User Manual before installing or operating the Oxygen Monitor.

QUICK SETUP GUIDE

1. Install 4 AA Alkaline Batteries.
2. Connect the Oxygen Sensor and Diverter Fitting.
3. Connect the Coiled Cable.
4. Calibrate the Oxygen Monitor.
5. Set the High/Low Alarms.

SENSOR INSTALLATION

⚠CAUTION

- Inspect the Oxygen Sensor and Diverter Fitting for visual damage or electrolyte leakage before use. **DO NOT USE** if damaged.
- Use **ONLY** an Oxygen Sensor specified by Precision Medical, Inc.
- The Oxygen Sensor should not be used in the presence of flammable anesthetics such as Diethyl Ether or Cyclopropane.

⚠WARNING

- **DO NOT** attempt to open or repair the Oxygen Sensor.
- The Sensor electrolyte is corrosive, and contains lead. **DO NOT** let it come in contact with the skin. If it does, flush affected area with water.
- Check the Sensor regularly for leaks. If the Sensor is leaking, replace with **NEW** Sensor. Leaking or used Sensors should be handled and disposed of in accordance with local regulations. An MSDS is available from Precision Medical, Inc.
- If the Oxygen Sensor is used in breathing circuits, the Diverter must be attached to the Sensor and must be used with the Tee Adapter.
- The Oxygen Sensor must be installed before the Oxygen Monitor can be operated.



1. Screw the Diverter to the bottom of the Oxygen Sensor, tighten until snug.
2. If using the Tee Adapter, attach to the Diverter.
3. Insert the one end of the Coiled Cable into the top of the Sensor, and secure by tightening the Locking Ring, until snug.



4. Insert the other end of the Coiled Cable into the Sensor Cable Connection located on the right side of the Oxygen Monitor. Secure it in place by tightening the Locking Ring, until snug.
5. Wait approximately 20 minutes for the NEW Sensor to stabilize to the environment.
6. Calibrate the Oxygen Monitor with the NEW Sensor.

⚠ CAUTION

- Calibrate the Oxygen Monitor before each use, and when replacing the Oxygen Sensor or the batteries.
- The Precision Medical Oxygen Monitor can only be calibrated accurately using 100% Oxygen or 20.9% Oxygen (Room Air). Using any other concentration will result in inaccurate readings.
- Air calibration is not recommended unless the Sensor can be exposed to a known source of clean air. Hospital room air is often enriched with excess oxygen.
- Calibrate the Oxygen Monitor at a pressure and flow similar to your clinical application.
- Before calibrating the Oxygen Monitor, the oxygen concentration readout should be stable and not drifting more than 0.2%.
- **DO NOT** calibrate the Oxygen Monitor in humidified gas, as water vapor makes the oxygen concentration appear lower than the actual value.

CALIBRATION

1. Place the Sensor with Diverter and Plastic Tee attached into the gas stream of 100% USP Oxygen or room air. The highest accuracy is achieved when using 100% USP Oxygen at a constant pressure and flow.
2. Wait at least 20 seconds or more for the oxygen to purge the line.
3. Turn the Oxygen Monitor “ON” by pressing the  POWER key.
4. Let the oxygen concentration display stabilize, the readout should not drift more than 0.2%.
5. Press the  key to UNLOCK the keys.

6. Press the  CAL key. The display will show “CAL @ Air” or “CAL @ 100” oxygen. When “DONE” appears, the calibration is complete. The Oxygen Concentration will be displayed in a gas percent value. Press  LOCK/UNLOCK to save the calibration data. If no keys are pressed within 3 seconds, the setting will be saved, and the keypad will be locked.
7. Remove the Oxygen Sensor from the oxygen supply and confirm that the display reads between 19-22% Oxygen in room air.

EFFECTS OF TEMPERATURE:

To minimize temperature effects:

1. In a breathing circuit, place the Oxygen Sensor upstream of the heater.
2. Allow time for the Oxygen Sensor to stabilize to its new room temperature.
3. Perform the calibration procedure at a temperature close to or similar to your clinical application.

EFFECTS OF HUMIDITY:

High Moisture levels will dilute the oxygen concentration, decreasing the concentration of oxygen being monitored by the Oxygen Sensor.

High humidity can cause condensation to collect on the Oxygen Sensor, obstructing the passages and reducing the effectiveness of the Oxygen Sensor.

CAUTION

To reduce the effects of humidity on the Sensor:

- DO NOT USE the Oxygen Sensor in environments with greater than 95% humidity.
- Place the Oxygen Sensor upstream from the humidifier in a breathing circuit.

EFFECT OF PRESSURE:

When the Oxygen Sensor is placed in a breathing circuit, the alternating “breathing” pressure cycles will be sensed as an increase in oxygen concentration. The concentration is not actually changing, but it appears to be due to the change in pressure.

The following recommendation is provided to reduce the chances of pressure causing false readings.

Calibrate the Precision Medical Oxygen Monitor using 100% Oxygen or room air at the same pressure and flow as the gas to be monitored.

EFFECTS OF ANESTHETIC GASES:

ANESTHETIC AGENT	TEST CONCENTRATION	Oxygen CONCENTRATION ERROR
Helium	50%, Balance Oxygen	0%
Nitrous Oxide	80%, Balance Oxygen	0%
Carbon Dioxide	10%, Balance Oxygen	0%
Halothane	4%	< 1.5% Oxygen*
Enflurane	5%	< 1.5% Oxygen*
Isoflurane	5%	< 1.5% Oxygen*
Sevoflurane	5%	< 1.5% Oxygen*
Desflurane	15%	< 1.5% Oxygen*

Test mixture = 30% O₂, balance 70% N₂O except where noted.

* Errors may vary based on concentrations and exposure times.

These results meet or exceed the requirements of ISO 7767 and DIN EN 12598.

⚠ CAUTION










The Oxygen Sensor should not be used in the presence of flammable anesthetics such as Diethyl Ether or Cyclopropane.

ALARMS

The Precision Medical Oxygen Monitor will store the HIGH/LOW alarm settings in memory after the Oxygen Monitor is turned “OFF”.

The Oxygen Monitor is designed to prevent crossing of the HIGH/LOW alarm settings. The LOW alarm cannot be set above the HIGH alarm and the High alarm cannot be set below than the LOW alarm.


TO SET ALARM:

1. With the  Power key ON.
2. Press the  LOCK/UNLOCK key.
3. To set the HIGH Alarm: Press the  HIGH ALARM SET key once. Press the  UP and DOWN arrow keys until the desired value is displayed next to the Up arrow in the upper right corner of the display. Continuously pressing the arrow keys will move the value in increments of 5. Press the  HIGH ALARM SET key to save the setting. Flashing Number indicates the Number can be changed. If no keys are pressed for 10 seconds, the setting will be saved and the Oxygen Monitor will revert to locked mode.
4. To set the LOW Alarm: Press the  LOW ALARM SET key once. Press the  UP and DOWN arrow keys until the desired value is displayed next to the Down arrow in the lower right corner of the display. Continuously pressing the arrow keys will move the value in increments of 5. Press the  LOW ALARM SET key to save the setting. Flashing Number indicates the Number can be changed. If no keys are pressed for 10 seconds, the setting will be saved and the Oxygen Monitor will revert to locked mode.
5. Lock the display by pressing the  LOCK/UNLOCK key.
6. To disable the HIGH Alarm, raise the HIGH Alarm setting above 100%. “---” will be displayed next to the Up arrow on the display. The LOW alarm will still function while the HIGH alarm is disabled.

ALARM SITUATION:

During a HIGH or LOW alarm.

1. Triple pulse alarm sounds.
2. LED will flash.
3. Alarm Low/High set point will flash.
4. UP ↑ or DOWN ↓ Arrow will turn dark.

Pressing the  Alarm Silent key will deactivate the audible alarm for 120 seconds. If the alarm exists after 120 seconds, the alarm will sound again.

CLEANING

CAUTION

- **DO NOT** steam autoclave.
- **DO NOT** immerse the Oxygen Monitor into any liquid.
- **DO NOT** use any strong solvent or abrasive cleaners.
- **DO NOT** allow any liquid to enter the Oxygen Monitor or the Oxygen Sensor; this will damage the Oxygen Monitor or Oxygen Sensor and will void the Warranty.

1. Disconnect all connections before cleaning.
2. Clean exterior surfaces of the Oxygen Monitor and Coiled Cable with a cloth dampened with mild detergent and water.
3. Wipe dry with a clean cloth.

MAINTENANCE

SENSOR REPLACEMENT

(Reference “SENSOR INSTALLATION” on page 11.)

CAUTION

Sensor Replacement must be performed by a Qualified Medical Personnel.

BATTERY REPLACEMENT

Replace batteries when “LO BATTERY” is displayed.
(Reference “BATTERY INSTALLATION” on page 10.)

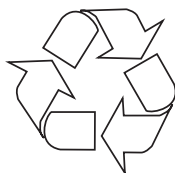
RETURNS

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

The Oxygen Sensor contains lead. Dispose of the Oxygen Monitor, batteries and its components in accordance with the local regulations.



Please Recycle



TROUBLESHOOTING

If the Oxygen Monitor fails to function, consult the Troubleshooting Guide. If the problem cannot be solved by using Troubleshooting Guide, consult your Provider.

Problem	Probable Cause	Remedy
A. Low Battery Indicator is displayed with a 30 second chirp alarm	1. Battery voltage too low	1. Replace with 4 NEW AA alkaline batteries
B. Check Sensor appears on display with a continuing pulsing alarm	1. Cable connections are not secure 2. Oxygen Sensor not functioning 3. Using Oxygen Sensor other than Precision Medical Oxygen Sensor	1. Make sure cable connections are secure and locking rings are tight 2. Replace with New Precision Medical Oxygen Sensor 3. Attach New Precision Medical Oxygen Sensor

Problem	Probable Cause	Remedy
C. New Oxygen Sensor responds slowly or seems to drift	1. Oxygen Sensor has NOT temperature stabilized	1. Wait approximately 20 minutes for Oxygen Sensor to stabilize with the environment, and then recalibrate the Oxygen Monitor
D. Oxygen Sensor does not react to changes in oxygen concentration	1. Condensation on the Oxygen Sensor 2. Non functioning Oxygen Sensor	1. Remove Condensation 2. Replace with New Precision Medical Oxygen Sensor
E. Triple Pulse Alarm and flashing LED	1. Oxygen readings are outside the High/Low Alarm limits 2. Loss of Air or Oxygen Supply	1. Adjust the High/Low Alarm setting to be above/below the oxygen value being displayed 2. Reconnect the Air or Oxygen Supply
F. Keys inoperable (Power ON)	1. The keypad is Locked 	1. Unlock  the keypad
G. No Display/ LCD screen will not power ON	1. Dead Batteries 2. Battery installed incorrectly	1. Check and replace with 4 New AA alkaline batteries 2. Check that batteries are installed in the proper position (+/-)
H. "SERVICE NEED" appears on the display	1. Electronic malfunction	1. Oxygen Monitor must be serviced
I. "CAL FAIL" appears on the display	1. Improper or wrong Oxygen Sensor 2. Improper Air / Oxygen source 3. Non functioning Oxygen Sensor	1. Recalibrate the Oxygen Monitor 2. Check the Air / Oxygen source 3. Replace with New Precision Medical Oxygen Sensor

REPLACEMENT PARTS

Description	Part #
User Manual	505127
Precision Medical Oxygen Sensor with Diverter	504877
Tee Adaptor	505126
Extendible Cable	504937
AA Alkaline Battery (4 Pack)	505124-4
Rubber Feet (4)	505122-4
Battery Cover	504909
V Block	505010
Diverter	505344
Circuit Board Assembly	505145
Key Pad	504926
Display	505125
Case Assembly, Front	504907
Case Assembly, Back	504908

ACCESSORIES

Description	Part #
Monitor Wall Mount Bracket	505189
Monitor Vertical Pole Mount Clamp	505013
Monitor Horizontal Pole Mount Clamp	505014
Dove tail Bracket	505012
Dove tail Bracket Screw	505712

NOTE: Orders for replacement parts should include the part number, if available and the model and serial number of the instrument for which the parts are intended.

LIMITED WARRANTY AND LIMITATION OF LIABILITY

Precision Medical, Inc. warrants that the Oxygen Monitor, (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 (received by Precision Medical, Inc. within 30 days of the customer's discovery of the alleged defect), along with return of the Product at the customer's expense 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 repair or replacement (at Precision Medical, Inc.'s option) at its own expense.

Precision Medical, Inc. warrants the 504877 Oxygen Sensor included with the PM5900 Oxygen Monitor to be free from defects in material and workmanship for a period of sixteen (16) months, from date of shipment. Should any failure to conform to this warranty appear within the applicable period, Precision Medical, Inc. shall, upon written notification thereof (received by Precision Medical, Inc. within 30 days of the customer's discovery of the alleged defect), along with return of the sensor at the customer's expense and substantiation that the sensor has 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 sensor, correct such defect by repair or replacement (at Precision Medical, Inc.'s option) at its own expense. Should a sensor require repair or replacement due to said defects, the sensor is warranted only for the remainder of the original sensor warranty period. **A sensor shall not be considered defective for failure to function beyond its normal estimated consumption capacity/rates, and this warranty does not cover normal wear due to consumption beyond the sensor's estimated O2% hours.**

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 warranty, 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 the warranty for the products covered by the applicable 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: Oxygen Monitor
Model(s): PM5900
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, Directive 2007/47/EC of The European Parliament and the following documents:

EN 60601-1, EN 60601-1-2, EN 60601-1-4, BS EN 60601-1-8, IEC TR 60878, BS EN 60068-2-27, BS EN 60068-2-6, BS EN 60068-2-64, EN 980, BS EN 1041, ISO 9899, EN ISO 14971, EN ISO 15001, EN ISO 21647

Notified Body: TÜV Rheinland Products Safety GmbH  0197

EC Certificate No.: HD 60019110 0001

PRECISION *MEDICAL*®

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www.precisionmedical.com

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