USER MANUAL

OXYGEN MONITOR
Model: PM5900

SAVE THESE INSTRUCTIONS
(For latest revision, go to www.precisionmedical.com)

RX **ONLY**   Federal (USA) law restricts this device to sale by or on the order of a physician.

CONTENTS

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.

⚊⚊⚊	Direct current.
CLASSIFIED c(UL)us UL-60601-1 62NA	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

OXYGEN MONITOR

	Follow instructions for use
	General Mandatory Action Sign
	Calibration
	Calibration Failed
	Audio Alarm Paused
	Low Battery
	Check
	Locked
O₂	Oxygen Sensor
	Pass
	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.
R$_X$ ONLY	Caution! U.S. Federal Law restricts this device to sale by or on the order of a physician.
CE 0473	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)

⚠ 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.

OXYGEN MONITOR

SPECIFICATIONS

Base Device Specifications

Dimensions (Monitor without cable and sensor attached):

Length:	1.72" (4.36 cm)
Width:	3.56" (9.04 cm)
Height:	5.44" (13.82 cm)
Cable Length:	10 ft. (3.05m) (fully extended)

Weight:

Device Weight:	1.11 lbs (0.50 kg) (includes: monitor, sensor, batteries and cable)
Shipping Weight:	1.64 lbs (0.75 kg)

Operating Conditions:

Temperature:	50ºF- 113ºF (10ºC - 45ºC)
Altitude:	Sea Level to 8000 feet

Storage Conditions:

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

Mode of Operation:	Continuous
Electrical Classification:	Internally powered Medical Electrical equipment
Power Requirements:	4, AA Alkaline Batteries (4 x 1.5 Volts) 6 VDC
Battery Life:	approximately 2000 hours (continuous use non-alarm condition)
Diverter Fitting:	fits industry standard, 15 mm "T" adapter
Measurement Range:	0.0 - 100%
Resolution:	0.1 Increments
Accuracy & Linearity:	± 1% of full scale at constant temperature, R.H. and pressure when calibrated at full scale
Total Accuracy:	± 3.0% Actual Oxygen Level over full operating temperature range
Response Time:	90% of final value in less than 12 seconds at 77°F (25ºC)
Warm-up Time:	none required

Low Battery Indication:	Low battery icon [⬛▭] displayed on graphics screen, and audible alarm
Alarm System:	high/low alarms, respective flashing red LEDs and graphics, 68db audible alarm @ 1 meter
Low Alarm Range:	*15% - 99% Oxygen (*Requires extra action to set below 18%)
High Alarm Range:	18% - 100% Oxygen
High Alarm De-Activation Setting:	Above 100% ("---" will appear)
Alarm Accuracy:	Displayed value +/- 0.1
Patient Contact:	Indirect contact via gas passing through sensor sampling site.

Sensor Specifications
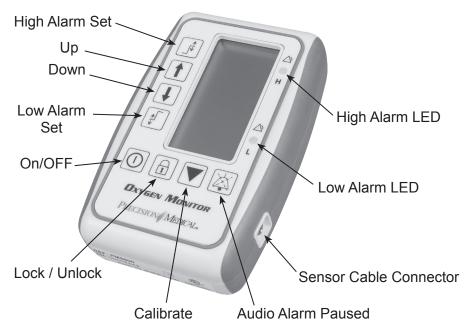
Sensor Type	Precision Medical 504877 galvanic oxygen sensor (fuel cell)
Expected Sensor Life	> 1,000,000 O2 % Hours

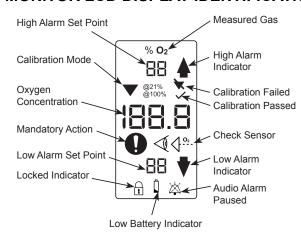Specifications are subject to change without notice.

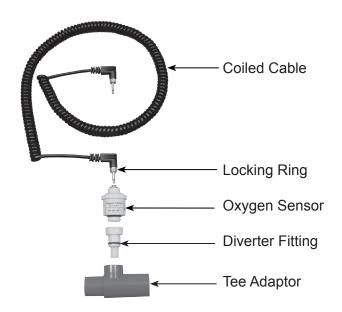# COMPONENT DESCRIPTION
OXYGEN MONITOR IDENTIFICATION

High Alarm Set
Up
Down
Low Alarm Set
On/OFF
High Alarm LED
Low Alarm LED
Lock / Unlock
Sensor Cable Connector
Calibrate
Audio Alarm Paused

ITEM NAME	DESCRIPTION
Power Key ⏻	The Power Key turns the Oxygen Monitor ON and OFF. The Lock/Unlock Key must be pressed to unlock the Oxygen Monitor, before being powered OFF.
Lock / Unlock Key 🔒	Pressing the Lock/Unlock Key will "Unlock" the keypad, so changes in the stored settings can be made. When pressing the key to "Lock" the Oxygen Monitor disables the key pad, and no changes can be made.
Alarm Silence Key 🔕	In alarm condition, pressing the Audio Alarm Paused Key will deactivate the audible alarm for 120 seconds. The visual alarm will continue to display.
⚠	General Alarm
Calibration Key ▼	Pressing the Calibration Key calibrates the Oxygen Monitor with air or oxygen.
Low Alarm Key ↥	Pressing � Low Alarm 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. NOTE: Factory Preset = 18% Oxygen.
Low Alarm LED	During a Low Alarm condition, the red LED will flash accompanied by the triple pulse audible alarm.

ITEM NAME	DESCRIPTION
High Alarm Key	Pressing the ⬚ High Alarm 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. 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. NOTE: Factory Preset = 50% Oxygen.
High Alarm LED	During a High Alarm condition, the red LED will flash accompanied by the triple pulse audible alarm.
Up / Down Keys ⬆ ⬇	The Up/Down 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.
Sensor Cable Connector	Cable Interface connection between Oxygen Monitor and Oxygen Sensor Cable.

OXYGEN MONITOR LCD DISPLAY IDENTIFICATION

High Alarm Set Point
Measured Gas
Calibration Mode
High Alarm Indicator
Oxygen Concentration
Calibration Failed
Calibration Passed
Mandatory Action
Check Sensor
Low Alarm Set Point
Low Alarm Indicator
Locked Indicator
Audio Alarm Paused
Low Battery Indicator

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OXYGEN SENSOR COMPONENT IDENTIFICATION

Coiled Cable

Locking Ring

Oxygen Sensor

Diverter Fitting

Tee Adaptor

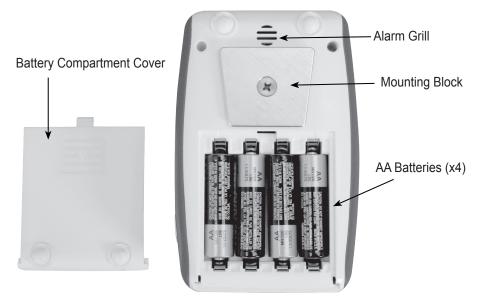| ITEM NAME	DESCRIPTION
Coiled Cable with Male Plugs	The Coiled Cable allows the Sensor to be positioned up to 10 ft from the side of the Oxygen Monitor. There are Male
Plugs at each end of the Coiled Cable.	Male Plug has a Locking Ring and must be engaged when in use.
Locking Ring	Male Plugs have a Locking Rings and must be engaged when in use.
Oxygen Sensor	Galvanic Oxygen Sensor
Diverter Fitting	Fitting used to connect to the Oxygen Source.
Tee Adaptor	The Tee Adaptor is used to connect the Oxygen Sensor and Diverter Fitting to an oxygen pathway circuit. Note: The Tee Adaptor is intended for single patient use only.

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

Battery Compartment Cover

Alarm Grill

Mounting Block

AA Batteries (x4)

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.

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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**
1. Calibrate the Oxygen Monitor before each use, and when replacing the Oxygen Sensor or the batteries.
2. 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.
3. 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.
4. Calibrate the Oxygen Monitor at a pressure and flow similar to your clinical application.
5. Before calibrating the Oxygen Monitor, the oxygen concentration readout should be stable and not drifting more than 0.2%.
6. 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 "@ 21%" or "@ 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

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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:

⚠ CAUTION
The Oxygen Monitor is no equipped with automatic barometric pressure compensation.

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% O_2, balance 70% N_2O 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.

Operator's Position - Visual alarms are best viewed at a distance of 3 feet (1m) or less from the Oxygen Monitor along with the following conditions;

– the Operator has a visual acuity of 0 on the logMAR scale or 6-6 (20/20) vision(corrected if necessary),

– the viewpoint is at the Operator's Position or at any point within an angle of 30° to the axis horizontal to the center of the plane of the monitoring display, and

– the ambient luminance in the range of 100 lx to 1 500 lx.

TO SET ALARMS

⚠ **WARNING**
Do Not set alarm limits to extreme values that can render the alarm system useless.

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.

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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.

To set the LOW Alarm below 18%: Press the 🔲 LOW ALARM SET key once. Press the ⬇ DOWN arrow key until 18% is displayed. Press and hold the   LOCK/UNLOCK key down and press the ⬇ DOWN arrow key to set the lower limit and then release 🔒 LOCK/UNLOCK key.

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"

⚠ CAUTION
Sensor Replacement must be performed by a Qualified Medical Personnel.

BATTERY REPLACEMENT
Replace batteries when ▭ (Low Battery) is displayed.
Reference "BATTERY INSTALLATION".

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 Monitor may contain electrical components that are hazardous to the environment. DO NOT dispose device into standard trash.

The Oxygen Monitor contains internal batteries. Batteries contain materials which can contaminate the environment when improperly disposed of.

The Oxygen Sensor contains lead. DO NOT dispose sensor into standard trash. Dispose in accordance with the local regulations.

Contact your local waste management for disposal of Electronic Equipment.

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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
Low Battery Indicator is displayed with a 30 second chirp alarm	1. Battery voltage too low	1. Replace with 4 NEW AA alkaline batteries
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
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
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
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
Keys inoperable (Power ON)	1. The keypad is Locked	1. Unlock the keypad
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 (+/-)
"SERVICE NEED" appears on the display	1. Electronic malfunction	1. Oxygen Monitor must be serviced
"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

ALARM CONDITIONS

Alarm Condition	Alarm Meaning	Corrective Action
High alarm LED flashing and audible beep	Measured O2 concentration is higher than the high alarm set point.	• Adjust O2 concentration source to prescribed dose. • Set high alarm to prescribed limit.
Low alarm LED flashing and audible beep	Measured O2 concentration is lower than the low alarm set point.	• Adjust O2 concentration source to prescribed dose. • Set low alarm to prescribed limit.
Low Battery symbol on and O2 displays "- - -" instead of a value.	The voltage output of the installed batteries is low and will require replacement soon.	• Replace all batteries with new batteries.
Oxygen Sensor symbol on.	Oxygen Sensor failure	• Replace O2 sensor • Recalibrate O2 Monitor

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

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

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.

OXYGEN MONITOR

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.

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

The customer is responsible for the shipping costs of repairs back to Precision Medical, Inc.

Precision Medical, Inc. will have in its sole and absolute discretion, the final determination if your product is covered under this limited warranty.

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

Precision Medical, Inc
300 Held Drive
Northampton PA 18067

$C \epsilon$
0473

EC	REP

Emergo Europe (European Office)
Motenstraat 15
2513 BH, The Hague
The Netherlands
Phone: +31 (0) 70.345.8570
Fax: +31 (0) 70.346.7299

REF

Oxygen Monitor
PM5900 Series

Classification: IIb

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.

Directives: General Application Directives: (MDD) Medical Device Directive, Council Directive 93/42/EEC
Of 14 June 1993 Concerning Medical Devices, Directive 2007/47/EC Of The European Parliament.

Applied Standards:

EN 1041: 2008	IEC 60601-1: Ed. 3.0: 2005
ISO 80601-2-55: 2011	IEC 60601-1-2 Ed. 4.0: 2014
ISO 15001: 2010	IEC 60601-1-6 Ed. 3.1b: 2013
ISO 15223-1: 2012	IEC 60601-1-8 Ed. 2.0b: 2007
EN ISO 14971: 2012	IEC 60068-2-6 Ed. 7.0b: 2007
IEC/TR 60878 Ed. 3.0b: 2015	IEC 60068-2-27 Ed. 4.0b: 2008
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Notified Body: Intertek AMTAC Certification Services Limited $C \epsilon$ 0473

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Certification Registration No's: 1126 CE   Date of Expiry: 03/August/2017

Devices already manufactured: S/N traceability Device History Records

Validity of DOC: 04 August 2012 to Date of Expiry

Manufacture Representative: Quality Manager

Position: Quality Systems/ISO Representative

Date of Issue: 04 August 2012

505127 Rev13 11/16 (?M) Printed in USA