

USER MANUAL

EASYPULSE5

Oxygen Conserving Regulator

1900 SERIES (CGA 870 Connection)



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, Inc. *EasyPulse5* Oxygen Conserving Regulator (Conserver) from the packaging and inspect for damage. If there is any damage, DO NOT USE and contact your Provider.

INTENDED USE

To regulate high pressure cylinders that provide supplemental oxygen to patients who may have difficulty extracting oxygen from the air they breathe. It is for patients who would normally receive the oxygen via a nasal cannula. The device delivers 100% oxygen at flow settings. It is intended to be used as an oxygen saving device that reduces the drying of the airways.

READ ALL INSTRUCTIONS BEFORE USING

This manual instructs a user to install and operate the Oxygen Conserving Regulator (Conserver). This is provided for your safety and to prevent damage to the Conserver. If you do not understand this manual, DO NOT USE the Conserver and contact your Provider.

DANGER

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

EXPLANATION OF ABBREVIATIONS

| | |
|-----|------------------------|
| kPa | Kilopascal |
| psi | Pounds Per Square Inch |
| lpm | Liters Per Minute |
| bpm | Breathes Per Minute |

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

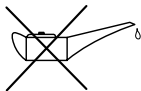
Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.

CAUTION

Used without the safety alert symbol indicates a potentially hazardous situation which, if not avoided, may result in property damage.



CONSULT ACCOMPANYING DOCUMENTS



Symbol for "USE NO OIL"



Symbol for "NO SMOKING"



Symbol for "COVERING DEVICE WITH GARMENTS WILL PRODUCE OXYGEN ENRICHED ATMOSPHERE"



Symbol for "SINGLE USE"

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)**

WARNING

- **ALWAYS** confirm prescribed dose before administering to patient and monitor on a frequent basis.
- Always follow ANSI and CGA standards for Medical Gas Products and Oxygen Handling (G-4).
- Keep cylinder valve closed at all times when cylinder is not in use.
- NO OXYGEN is delivered when the pointer ∇ is aligned with “OFF”, or between settings.
- This Conserver is not to be used by patients who breathe through their mouths.
- **DO NOT** use if dirt or contaminants are present on or around cylinder, valve, product or connecting devices.
- **DO NOT** use oils, greases, organic lubricants or any combustible materials on or near this product. Wash and dry hands properly prior to usage.
- **DO NOT** use a humidifier with the Conserver.
- **DO NOT** allow cylinders to tip or fall. Secure gas cylinders so they cannot fall. For optimum safety keep cylinder upright whenever possible.
- **DO NOT** store cylinders near sources of heat or flame.
- **DO NOT** use while sleeping without consulting your Provider.
- **DO NOT** smoke in an area where oxygen is being administered.
- **DO NOT** use near any type of flame or flammable/explosive substances.
- Use only USP grade medical oxygen.
- The Conserver is equipped with a relief valve. If you hear a loud hissing or popping sound coming from the product, discontinue use of product, close cylinder valve, and contact your Provider.
- The Conserver is designed to operate with a single lumen, adult cannula with a maximum length of 7 feet (2.1 m).
- The cannula is for single patient use only.

CAUTION

- Only personnel instructed and trained in its use should operate the Conserver.
- The Conserver contains magnetic, ferrous material that may affect the results of an MRI.
- **DO NOT** autoclave.
- **DO NOT** gas sterilize with Ethylene Oxide.
- **DO NOT** clean with aromatic hydrocarbons.
- Store the Conserver in a clean area when not in use.
- Avoid dropping the Conserver or placing it in a position where it could fall and become damaged.
- Consistent with the recommendations of the medical community on the use of conserving devices, it is recommended that the Oxygen Conserving Regulator be qualified on patients in the situations it will be used.
- The Conserver may not be able to detect all respiratory efforts of the patient. (Shallow breathers may not be able to trigger the Conserver.)
- Operating the Conserver outside its range of operating conditions may affect its accuracy and performance.

PRINCIPLES OF OPERATION

The Oxygen Conserver is designed to be used with high-pressure oxygen systems. It consists of a cylinder connection, cylinder contents gauge (if equipped), high-to-low pressure regulator, orifice plate and a conserving demand module. The regulator reduces the high pressure of the cylinder to the working pressure of the orifice plate. The orifice plate uses calibrated orifices to deliver a selected flow to the conserving demand module. The conserving demand module controls the pulse size and timing to the patient. It supplies a pulse of oxygen at the beginning of each breath. This reduces the oxygen demand on the system and limits the drying of the airways. The flow is determined by setting the flow control knob to the prescribed flow. The oxygen is supplied to the patient through the cannula.

SPECIFICATIONS

Inlet Pressure Range: 300 - 3000 psi (2068 - 20684 kPa)

Internal Regulated Pressure: 50 psi (345 kPa)

Pressure Gauge Accuracy: 3 - 2 - 3% of full scale

Dimensions: (Are approximate and may vary by model)

Model: 198705

Weight: 9.9 oz (279 g)

Overall Length: 4.75 in (12.07 cm)

Width: 2.63 in (6.67 cm)

Height: 2.50 in (6.35 cm)

Pulse Settings: 1, 2, 3, 4, & 5 lpm Equivalents

Flow Settings: 2 lpm Continuous

Accuracy: Within +/- 15% of the nominal bolus value (at each breath rate)

Continuous Setting: 2 lpm \pm 10%

Savings Ratio: Up to 5.7:1

Trigger Method: Inspiratory effort (Negative pressure from patient inhalation)

Breathing Frequency: Up to 35 bpm

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

Operating Conditions:

Temperature: 35°F to 105°F (1.7°C to 40.6°C)

Altitude: Sea level to 10,000 ft (0 to 3,048 m)

Storage Conditions:

Temperature: -40°F to 140°F (-40°C to 60°C)

Maximum Humidity: 95% Noncondensing

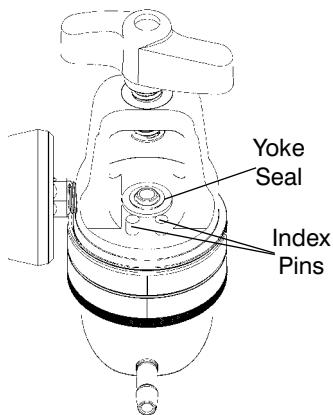
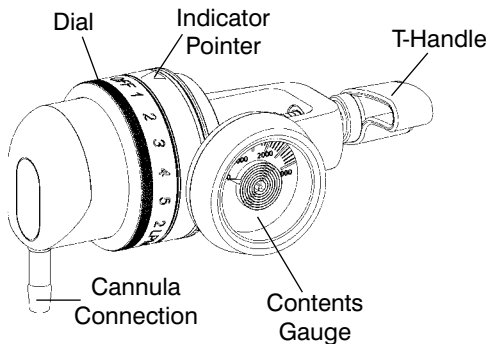
Oxygen Cylinder Connection: CGA 870 Valve

Ignition and Fault Tolerance: Meets ASTM G175-03

COMPONENT DESCRIPTION

⚠ CAUTION

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



INSTALLATION

WARNING

- Read this User Manual before installing or operating the Oxygen Conserving Regulator.
- Inspect the Conserver and cylinder valve to ensure they are free of oils, greases or other contaminants.
- **DO NOT** direct flow of oxygen at any person, or flammable material when cracking open the cylinder.
- **DO NOT** use without yoke seal.
- **DO NOT** use plastic yoke seals.
- Use Precision Medical, Inc. yoke seal made of viton and brass.
- The yoke seal supplied with the Conserver is reusable.

CAUTION

- Inspect the Oxygen Conserving Regulator for visual damage before use, **DO NOT USE** if damaged.
- **DO NOT** use tools to tighten T-handle, this can lead to over tightening and will cause damage to the Conserver.
- Be sure all connections are tight and leak free.
- **DO NOT** use liquid leak detector to test for leaks.

NOTE: For operational instructions on how to operate the cylinder consult your Provider.

1. Position the cylinder so the oxygen cylinder valve outlet is pointing away from the user and any other person(s).
2. Before installing the Conserver, “crack” cylinder valve by opening the valve slightly to remove any foreign particles and then close valve.
3. Be sure the Conserver is in the “OFF” position. Align “OFF” with the indicating pointer ▽.
4. Be sure the CGA 870 connection high pressure inlet has a yoke seal.
5. Align Index Pins with Index Pin Alignment Holes in Post Valve.
6. Hand tighten T-handle until snug.

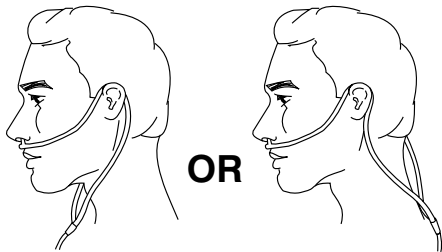
OPERATING INSTRUCTIONS

1. Attach a **standard adult single lumen oxygen nasal cannula**, no longer than 7 feet (2.1 m) to the Conserver's outlet according to the cannula manufacturer's instructions.

⚠CAUTION

- **DO NOT** use pediatric, low flow nasal cannulas or oxygen masks with the Conserver.
- **DO NOT** block the cannula connection or kink cannula tubing when the Conserver is in use, this may damage the Conserver.

2. Place the cannula over your ears and position the prongs in your nose as instructed by your Provider or cannula manufacturer.



3. Slowly open cylinder valve counterclockwise, until completely open.
4. Turn dial on the Conserver until indicating pointer ▽ is aligned with the prescribed setting.
5. Breathe through your nose and feel a pulse of oxygen as you inhale.

- NOTE:**
- When on a pulse setting, there is flow or a pulse only at the beginning of each breath. If you do not feel the pulse at the beginning of each breath, check the setting. If there is still no pulse, turn dial to “2 LPM Continuous” setting.
 - Because each patient's breathing pattern is different and the environment varies, it may be difficult to feel some low setting pulses.

6. To remove the Conserver from cylinder:
- **Completely close oxygen cylinder valve.**
 - Turn the Conserver dial to “2 LPM Continuous” position.
 - Wait for oxygen to stop flowing from Conserver.
 - Remove the Conserver from cylinder valve.
 - **DO NOT** try to loosen T-handle beyond stop. Damage to the Conserver will occur.

DANGER

NEVER attempt to remove the Conserver from a cylinder unless the cylinder valve is closed.

WARNING

- When pointer on contents gauge enters red zone, (500 psi (3447 kPa) and below), it is recommended to change to a full oxygen cylinder.
- NO OXYGEN is delivered in between settings.

To avoid injury to patient:

- **ALWAYS** confirm prescribed setting before administering to patient and monitor flow on a frequent basis.



WARNING



- Use only Precision Medical, Inc. carry bag designed for the *EasyPulse5* to prevent an oxygen enriched environment.
- **DO NOT** place the unit under clothing while in use. When the Conserver is in use, a small amount of oxygen is vented. Wearing the unit under clothing may saturate fabrics with oxygen and cause them to burn rapidly, if exposed to sparks or flame. It may take several hours for oxygen levels in fabrics to return to normal.
- **ALWAYS** insert cylinder and Conserver into bag, cylinder first with gauge facing mesh. Reference accessory photo, (pg. 13).

MAINTENANCE / CLEANING

1. Disconnect all connections before cleaning.
2. Clean exterior surfaces of the Conserver with a cloth dampened with mild detergent and water .
3. Wipe dry with a clean cloth.
4. Store the Conserver in a clean area free of grease, oil, and other sources of contamination.

CAUTION

- **DO NOT** use cleaning solutions.
- **DO NOT** immerse the Conserver in any kind of liquid.
- **DO NOT** attempt to repair the *EasyPulse5* Oxygen Conserving Regulator.
- All repairs must be performed by Precision Medical, Inc. or Authorized Representative.

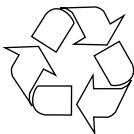
RETURNS

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

This device and its packaging contain no hazardous materials. No special precautions need to be taken when disposing the device and/or its packaging.

Please Recycle



TROUBLESHOOTING

If the Converter fails to function, consult the Troubleshooting Guide below. If problem cannot be solved, consult your Provider.

TROUBLESHOOTING GUIDE

| Problem | Probable Cause | Remedy |
|---------------------------------------|--|--|
| No flow | <ol style="list-style-type: none">1. Cylinder valve closed2. Regulator in "OFF" position3. Cylinder empty4. Dial not set at proper position5. Converter not sensing breath | <ol style="list-style-type: none">1. Open the valve on cylinder2. Set to prescribed setting3. Replace cylinder4. Set dial so indicator points to a setting5. Check position of cannula in nose, DO NOT breathe through mouth |
| Leaking at cylinder connection | <ol style="list-style-type: none">1. Missing or defective yoke seal2. Defective cylinder valve | <ol style="list-style-type: none">1. Replace with Precision Medical yoke seal2. Contact your Provider |

REPLACEMENT PARTS

| Description | Part # |
|-------------|--------|
| Cannula | 504833 |
| Yoke Seal | 1221 |

ACCESSORIES

| Description | Part # |
|-------------------|--------|
| Carry Bag M6 | 503920 |
| Carry Bag M4/M6 | 504184 |
| Carry Bag ML6/ML9 | 504185 |



Carry Bag with
shoulder strap



Conservator properly
installed in Carry Bag

LIMITED WARRANTY AND LIMITATION OF LIABILITY

Precision Medical, Inc. warrants that the Easy Pulse Oxygen Conserving Regulator (the Product) will be free of defects in workmanship and/or material for the following periods:

Two (2) years 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 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 representative 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
Molenstraat 15
2513 BH, The Hague
The Netherlands

Product: *EasyPulse5* Oxygen Conserving Regulator

Model(s): 1900 Series

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 and the following documents:

| Document | Title | Edition |
|--------------|--|--------------|
| BS 341-3 | Transportable Gas Container Valves, Part 3: Valve Outlet Connections | 2003 |
| DIN 477-1 | Gas Cylinder Valves rated for test pressures up to 300 Bar; Types, Sizes, Connections, Screw Threads | 1990 |
| EN 738-3 | Pressure Regulators for Use with Medical Gases Part 3: Pressure Regulators Integrated with Cylinder | 1999 |
| EN 837-1 | Bourbon Tube Pressure Gauges – Dimensions, Metrology, Requirements and Testing | 1998 |
| EN 980 | Graphical Symbols for Use in the Labeling of Medical Devices | 2003 |
| EN 1041 | Information supplied by the Manufacturer with Medical Devices | 1998 |
| EN ISO 15001 | Anesthetic and Respiratory Equipment - Compatibility with Oxygen | 2003 |
| ISO 10993-1 | Biological Evaluation of Medical Devices, Part 1 | 2003 |
| ISO 10993-5 | Biological Evaluation of Medical Devices, Part 5 | 1999 |
| ISO 10993-10 | Biological Evaluation of Medical Devices, Part 10 | 2002+A1:2006 |
| ISO 10524-1 | Pressure Regulators for Use with Medical Gases Part 1 - Pressure Regulators and Pressure Regulators with Flow Metering Devices | 2006 |
| ISO 14971 | Medical Devices - Application of Risk Management to Medical Devices | 2000+A1:2003 |
| ISO 18779 | Medical Devices for Conserving Oxygen and Oxygen Mixtures - Particular Requirements | 2005 |
| ISO 228-1 | Pipe threads where tight joints are not made on the threads. Dimensions, Tolerances & Designation | 2000 |
| SS 367615 | Gas Cylinders - Valve Outlets & Couplers | 2001 |

Notified Body: TÜV Rheinland Products Safety GmbH C E 0197

EC Certificate No.: HD60019110 0001

ISO 13485 Certified

