PRESSURE REGULATORS FOR USE WITH MEDICAL GASES

TECHNICAL DESCRIPTION

Part Number: **01R _____ - B**

Instruction for Use:

The O-Two Medical Technologies "Pressure Regulator for Use with Medical Gases" is intended for the administration of the medical gases to medical equipment and/ or patient. It is designed to regulate an input pressure up to 3000 PSI to a working pressure between 55 to 70 PSI. In addition, the regulator can simultaneously deliver the desired therapy flow by adjusting flow-selecting knob.The regulator has an internal pressure-relief valve to prevent over pressurization of the regulator.

Specifications:

Maximum Normal Inlet Pressure (p1):	3000 PSI (206.8 bar)
Operating Inlet Pressure:	500 to 3000 PSI (34.5 to 206.8 bar)
Nominal Outlet Pressure (p2):	60 PSI (4.14 bar)
Storage Temperature:	From -28°C to +60°C
Operating Temperature:	From -18°C to +50°C

OPERATING INSTRUCTIONS

A. Pre-use Check:

1) Remove any protective covers before attempting to connect the pressure regulator to a cylinder.

2) Visually inspect both the cylinder and regulator for any signs of grease or oil. Do not use this devices if grease or oil is suspected or found.

3) Visually inspect the intended gas symbol which is marked on the regulator label. It shall match the contents of the cylinder to be used.

4) Visually inspect the inlet and outlet connectors of the regulator for damage and to ensure compatibility with the cylinder and medical equipment to be connected

B. Installation of Pressure Regulator:

1) For Pin Index style inlet:

a. Check to ensure that the yoke seal washer is in place on the inlet of the regulator and in good condition. Replace with O-Two yoke seal washer if necessary. Do not use alternate seals. Never replace factory-installed seals with plastic yoke washer seals. Never install a regulator with more than one yoke seal washer

b. Slide the yoke over the top of the cylinder post valve and place the index pin into the holes in the cylinder valve. Ensure that the index pins properly fit into holes. Do not force the pins.

c. Line up the "screw point" at the end of the knob with the dimple on the cylinder valve and hand tighten the knob. Do not use a tool to tighten the knob. Doing so may damage the regulator.

2) For Nut and Stem style inlet:

a. In a clockwise direction, thread the regulator inlet nut by hand onto the thread of the cylinder post valve.

b.Tighten the inlet nut with the appropriate wrench.

C. Leak Test:

1) Attach the regulator onto an appropriate cylinder, leave all outlets plugged and turn the flow selector to "OFF"

2) Stand behind the cylinder so that the cylinder is between you and the regulator. Never stand in front of a cylinder outlet or regulator when opening the cylinder valve.

3). Slowly and gradually open the cylinder valve

4) Apply a compatible leak test solution to all outlets, fittings and threads in outlet fittings and gauge to check for leakage

5) Close cylinder valve. Tighten fittings as required to eliminate all external leaks. DO NOT over tighten threaded connections. Replace yoke washer if required.

D. Operation:

1) If the regulator is equipped with a flow outlet, ensure that the Flow Selector setting is at "0"position.

2) Stand behind the cylinder so that the cylinder is between you and the regulator. Never stand in front of a cylinder outlet or regulator when opening the cylinder valve.

3) Slowly and gradually open the cylinder valve.

4) Ensure pressure build up through the pressure gauge.

5) If leakage occurs between the regulator and cylinder, never tighten fittings when under pressure:

- **a.** Turn off cylinder valve immediately and vent any trapped pressure inside the regulator.
- **b.** Unscrew the pressure regulator,
- **c.** Inspect and replace the yoke washer if necessary,
- **d.** Attach the pressure regulator to the cylinder as per B1) or B2).

6) Connect regulator outlet to user medical equipment with suitable fittings.

7) Rotate the Flow Control knob to the required flow setting.

8) When medical gas is not needed any more, turn off the cylinder post valve first and vent any trapped pressure inside the regulator.

9) Turn the Flow Selector knob back to "0" position if applicable and then remove the pressure regulator from the cylinder.

10) Check yoke washer seal and replace it if necessary.

11) Store the pressure regulator in a clean and dry place.

E. Preventative Maintenance:

This pressure regulator can be cleaned with a clean, soft cloth after each use.

Replacement of yoke seal washer shall be carried out by the user every 6 months or in the event of a leak. The spare part used shall be obtained from O-Two Medical Technologies Inc. The part number for the yoke seal washer is 01OR1002. DO NOT use alternate seals. Never replace factory-installed seals with plastic yoke washer seals. Never install a regulator with more than one yoke seal washer.

The user shall also test the regulator (output pressure and therapy flow if applicable) periodically to ensure proper performance and safety. The frequency of such testing should be established according to usage, but it shall be performed at least every 1 year.

O-Two Medical recommends that the regulator be returned to the manufacturer or its authorized agents for evaluation for damage, contamination, wear and function every 5 years. The maximum service life for the pressure regulator is 15 years providing the above maintenance recommendations are followed.

⚠ SAFETY WARNINGS ⚠

1. The use of O-Two Medical Technologies pressure regulators for gases other than compressed medical gases of up to 3000 psi is expressly prohibited by O-Two Medical Technologies and the user must assume all liabilities.

2. Using oil, grease or other petroleum-based substances with oxygen and oxygen mixtures may cause fire or explosion. Therefore, do not use oil or grease on pressure regulators, cylinders, valves or other related equipment. Do not use or store oxygen equipment near excessive heat or open flame.

3. Never administer oxidizing gases when smoking or when near an open flame.

4. Never install a regulator to a post-type valve with more than one yoke washer between the valve and the regulator inlet.

5. Make sure that the threaded fittings on regulators or the indexing pins on yokes are properly mated for the gas intended. Never attempt to force an incompatible connection.

6. Always open the cylinder valve slowly. Never permit compressed oxygen to enter a regulator suddenly.

7. Fully open the cylinder valve when a regulator is attached and in use.

8. Never leave a cylinder valve open with regulator attached when regulator is not in use.

9. Before a regulator is removed from a cylinder, fully close the cylinder valve and release all gas from the regulator.

10. Never interchange regulators, hoses, or other equipment with similar equipment intended for use with other gases. Pressure regulators and related fittings should never be handled with oily or greasy hands or gloves. Never hold hand over the outlet(s) to test for the presence of pressure.

11. Do not stand in front of a regulator outlet when opening the cylinder valve in case foreign particles are present which could cause a hazardous malfunction of the regulator.

12. The flow outlet is intended for patient therapy use only. Do not use it for driving any medical equipment.

13. Do not set the flow-selecting knob between adjacent settings or it might cause no flow output.

14. The oxygen therapy may be critical treatment. The application of the regulator should be made in strict accordance with the prescription and instructions of a physician.

15. Secure cylinders to wall, stand, or cart in accordance with local fire codes.

16. The regulator is equipped with an internal safety, which is designed to protect the regulator. Downstream equipment used in conjunction with the regulator should be equipped with suitable safety valves to prevent over pressurization and damage.

17. Disassembly and assembly of regulators shall be performed only by O-Two authorized and trained personnel. The work area must be free of hydrocarbon contaminants and residues due to the danger of spontaneous combustion when residues are exposed to gaseous oxygen. Lubricant, if used in the maintenance of the pressure regulator, shall be compatible with the intended medical gases.

WARRANTY

The O-Two Pressure Regulators for Use with Medical Gases are manufactured from the finest quality materials. Each individual part is subject to strict quality control tests to ensure exceptionally high standards. The manufacturer warrants to the purchaser of the O-Two Pressure Regulator that its component parts are free from defects in material and workmanship for a period of five (5) years from the date of purchase. The manufacturer will replace and/or repair all parts of the Pressure Regulator at its option for five years from the date of purchase at no cost to the purchaser, upon the notification of the defects, in writing by the purchaser and confirmation of said defect by the manufacturer. All shipping costs shall be borne by the purchaser. The manufacturer shall be liable under this warranty only if the Pressure Regulator and its parts have been used and serviced in the normal manner described in the instruction manual. This warranty does not cover failure resulting from alterations, accidental damage, misuse or operation not in accordance with the instructions provided. Wear items are not covered hereunder. This warranty is null and void if unauthorized repairs are attempted or performed. There are no other expressed or implied warranties. This warranty gives no specific legal rights.

ACCESSORIES

01OR1002-CS	Brass/Viton Yoke seal (Case of 10)
01OR1007	Pressure Gauge 3000 PSI (200 bar)
02RT5400-CS	Nylon Cylinder Wrench w/ strap (Case of 10)
17MP4118	Post Valve plug with dust cap (Case of 25)

CE 1639

EC REP

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O-TWO MEDICAL TECHNOLOGIES INC.

PRESSURE REGULATOR CONFIGURATION

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Intended Medical Gases

O - Oxygen (O_2)
A - Medical Air
E - Nitrous Oxide/ Oxygen Mix (N_2O/O_2, 50/50% V/V)
H - Heliox- Helium/ Oxygen Mix (He/O_2, He not over 80%)
N - Nitrous Oxide (N_2O)
C - Carbon Dioxide (CO_2)
U - Oxygen/Carbon Dioxide Mix (O_2/CO_2, CO_2 not over 7%)
V - Nitric Oxide (NO)

Inlet Configuration

01 - CGA 870 Oxygen Pin Indexed Yoke
02 - CGA 540 Oxygen Nut and Nipple
03 - CGA 950 Medical Air Pin Indexed Yoke
04 - CGA 346 Medical Air Nut and Nipple
05 - CGA 965 Nitrous Oxide/Oxygen Pin Indexed Yoke
06 - CGA 280 Nitrous Oxide/ Oxygen Nut and Nipple
07 - CGA 890 Heliox (He ≤ 80%) Pin Indexed Yoke
08 - CGA 280 Heliox (He ≤ 80%) Nut and Nipple
09 - CGA 910 Nitrous Oxide Pin Indexed Yoke
10 - CGA 326 Nitrous Oxide Nut and Nipple
11 - CGA 940 Carbon Dioxide Pin Indexed Yoke
12 - CGA 320 Carbon Dioxide Nut and Nipple
13 - CGA 880 CO_2/O_2 (CO_2 ≤ 7%) Pin Indexed Yoke
14 - CGA 280 CO_2/O_2 (CO_2 ≤ 7%) Nut and Nipple
15 - CGA 660 Nitric Oxide Nut and Nipple
16 - BS 341 "No. 3" Oxygen
17 - Oxygen G3/4, DIN 477 nr.9 Fitting (Hand wheel)
18 - W21,8 DIN 477 nr.6 Fitting (Hand wheel)
19 - Oxygen M24x2 Fitting
20 - CGA 540 Oxygen Nut and Nipple (85mm)
21 - CGA 540 Oxygen Nut and Nipple (100mm)
22 - Oxygen G3/4, DIN 477 nr.9 Fitting (Hex)
23 - Oxygen Bene Bull (60mm)
24 - Oxygen Bene Bull (100)
25 - Oxygen 3/4-28 Steam
26 - Oxygen 3/4-28 Stem

Pressure Outlets

00 - None
O1 - 1x DISS (O_2)
O2 - 2x DISS (O_2)
O3 - 1 x Shrader Female quick disconnect
O4 - 2x Shrader Female quick disconnect
O5 - 1x Juno Female quick disconnect
O6 - 2x Juno Female quick disconnect
O7 - 1x Hansen Male quick disconnect
O8 - 1x British Female quick disconnect
O9 - 1x S.I.S. fitting
O10- 2x S.I.S. fitting
O11- 1x OHMEDA coupler & 1xDISS (O_2)
O12- 1x Hansen Female quick disconnect
O13- 2x AGA Female Couplers
O14- 1x AGA Female Coupler only
O15- 1x NIST (O_2) Socket
O16- 1x DISS (O_2) without check valve
O17- 1x SCHRADER coupler & 1xDISS (O_2)
O18- 1x Foster Socket
O1AU - 1x S.I.S. fitting w/ 2.5" extension
A1 - 1x DISS (medical air)
A2 - 2x DISS (medical air)
E1 - 1x DISS (N_2O/O_2 , 50/50% V/V)
E2 - 2x DISS (N_2O/O_2 , 50/50% V/V)
E3 - 1x SIS (N_2O/ O_2) Fitting
H1 - 1x DISS (He/O_2)
H2 - 2x DISS (He/O_2)
N1 - 1x DISS (N_2O)
N2 - 2x DISS (N_2O)
N3 - 1x NIST (N_2O) Socket
N4 - 1x SIS (N_2O) Fitting
C1 - 1x DISS (CO_2)
C2 - 2x DISS (CO_2)
C3 - 1x DISS (O_2/CO_2)
C4 - 2x DISS (O_2/CO_2)
S1 - 1x 5/8 Thread
S2 - 2x plugged pressure outlets
S3 - 1x unplugged pressure outle
S4 - 1x 5/8 Thread-F

Therapy

0 - None
1 - 0- 8 L/min
2 - 0-15 L/min
3 - 0-25 L/min
4 - 0- 6 L/min
7 - 0- 5 L/min
8 - 0- 10 L/min
* Add D for DISS Outlet

Body Material

B - Brass "Plated"

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