

# Pressure Regulators

## Instructions for Use

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# 1. Symbols

**Warning!** Indicates a potentially hazardous situation which, if not avoided, could result in personal injury to the user or others

**Caution!** Indicates a potentially hazardous situation which, if not avoided, could result in damage to the equipment or property



Use no oil

Service due date

# 2. Warnings and Cautions

## 2.1. Warnings!

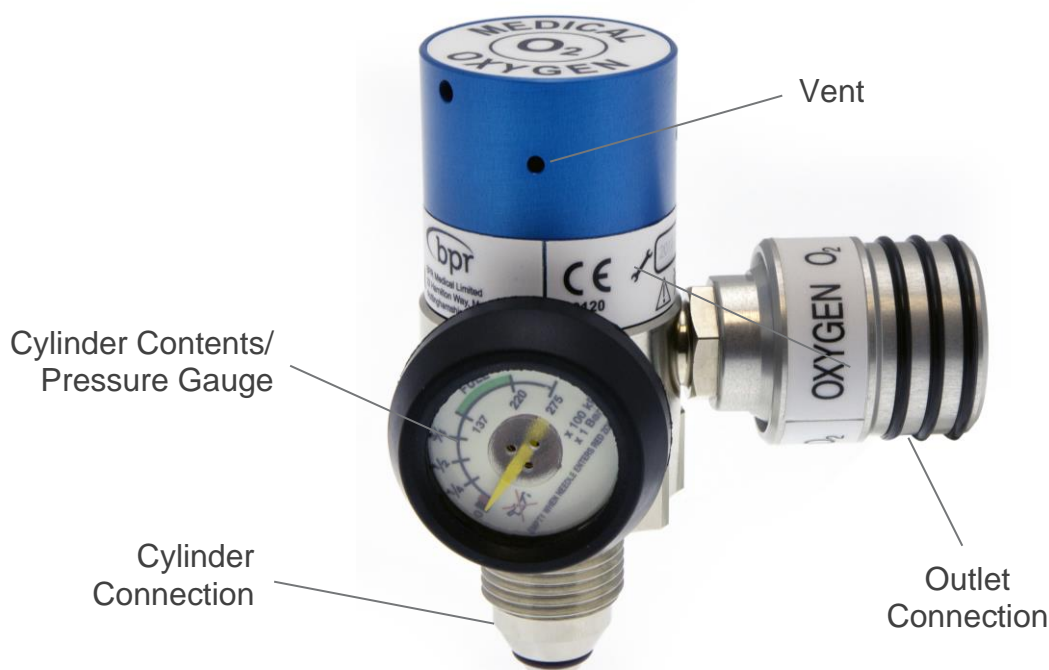
- ▶ Read through this entire instruction manual before using or showing others how to use a pressure regulator. As with all medical equipment, attempting to use this device without a thorough understanding of its operation may result in patient or user injury.
- ▶ Medical gas is or should be considered a drug and should only be used for medical purposes as prescribed by a physician or authorised clinician and in accordance with the medicinal product labelling.
- ▶ Never administer oxygen while smoking or when near an open flame.
- ▶ Oxygen is not flammable; however, the presence of oxygen will drastically increase the rate and severity of combustion. Oil and/or grease in the presence of oxygen become highly combustible. Oxygen must never be allowed to contact oil, grease or other petroleum-based substances. Therefore, do not use oil or grease on pressure regulators, flowmeters, cylinders, valves or other related equipment.
- ▶ Many hand creams and moisturisers contain paraffin and petroleum bases which are highly flammable and must never be allowed to contact the pressure regulator. Ensure hands are clean and dry before operating the equipment.
- ▶ Oxygen therapy may be a critical treatment. The effectiveness of supplemental oxygen therapy can only be determined by continuous monitoring of blood oxygen levels. It is essential that PaO<sub>2</sub> or SpO<sub>2</sub> monitoring is carried out when supplemental oxygen is prescribed for critical treatments.
- ▶ The use of a pressure regulator for gases other than that on the device labelling is expressly prohibited.
- ▶ Never permit compressed medical gases to enter a regulator suddenly, always open the cylinder valve slowly.
- ▶ Gas specific connectors are fitted to the pressure regulator. Do not attempt to modify the fittings to suit other gases or fitting systems.
- ▶ Always close the cylinder valve when the device is not in use.
- ▶ Never install a pin index pressure regulator with more than one yoke seal between the valve and the device. Before attaching the device, verify that the post valve is not already fitted with a yoke seal.

- ▶ Ensure that the pin-indexed connector on the pressure regulator inlet is compatible with the gas cylinder to which it is to be fitted. Never attempt to force an incompatible connection.
- ▶ Ensure that you have the correct pressure regulator for the type of cylinder you are intending to use. Never attempt to fit a regulator to an incompatible cylinder.
- ▶ Do not stand in front of a pressure regulator outlet when opening the cylinder valve.
- ▶ Before removing a pressure regulator from a cylinder, fully close the cylinder valve and release all gas first.
- ▶ Secure gas cylinders to a wall, stand or cart.
- ▶ Do not submerge the device in any fluid. Ensure that no fluid is allowed to enter the inlet valve or the vent holes.
- ▶ Only appropriately trained personnel working in controlled conditions must perform disassembly, assembly and testing of pressure regulators.
- ▶ The holes in the side of the body of the device are for venting gas in the event that the over pressure valve is activated. Do not obstruct these holes or interfere with the over pressure valve in any way.
- ▶ The threaded bull nose cylinder connection for medical oxygen and medical air may be the same. Ensure that you have the correct cylinder for the application (UK only).
- ▶ This pressure regulator is designed for use for cylinder pressures up to 20,000 kPa (3,000 psi/ 200 bar), do not attempt to connect to cylinders having fill pressures in excess of this value.

## 2.2. Cautions

- ▶ Device performance may be affected if it is stored or transported in temperature outside of the range -20°C to +60°C (-4°F to +140°F).
- ▶ The pressure regulator is not suitable for autoclaving.

## 3. Functional Description



### **3.1. Intended Use**

The pressure regulator is intended to provide a safe and convenient way of connecting high pressure gas cylinders to flowmeters, ventilators and other equipment requiring a low pressure medical gas supply.

Medical gases are or should be considered a drug and should only be used for medical purposes on the authority of a physician and then strictly in accordance with their instructions. Always refer to the product labelling.

### **3.2. Technical Description**

The pressure regulator reduces the high pressure of the cylinder to a safe, more manageable pressure for application to patients. There are many types of cylinder connection used and these may be different from one country to another, ensure that the pressure regulator has the correct connector for the cylinder to be used.

An over pressure valve (OPV) protects the user from any high gas pressures by venting excess pressure to ambient. The OPV is a spring loaded valve with a pre-set operating pressure.

Particulate filtering in the form of a 40 micron sintered brass inlet filter is incorporated to prevent the ingress of debris, which could alter the performance of the device and increase the risk of a fire.

Outlet pressure is available at the outlet connector to enable the end user to fit the intended delivery device (e.g. flowmeter).

## **4. Operating Instructions**

### **4.1. Preparation and Connection**

Check that the cylinder type and pressure regulator inlet connector are compatible. Check the presence and condition of the input connector seal, which for pin index pressure regulators is a washer type seal (Bodoc) and for bullnose pressure regulators an O-ring.

Fit the pressure regulator to the cylinder ensuring that it is properly mated and the connectors are done up hand tight.

Connect the required gas delivery device to the pressure regulator, ensuring the handwheel is tightened correctly.

Open the cylinder valve slowly with a suitable cylinder key. Check the cylinder contents gauge to verify that there is sufficient gas available.

### **4.2. Testing Prior to Use**

Check the gas delivery device connected to the outlet of the pressure regulator is delivering the correct output.

### **4.3. Operation**

During operation monitor the patient as advised by the clinician. Check the pressure regulator contents gauge regularly.

### **4.4. After Use**

Upon completion of the therapy, close the cylinder valve.

If you need to remove the pressure regulator from the cylinder, bleed off any residual gas pressure within the device by turning on the connected ancillary device. Remove the pressure regulator from the cylinder and store it carefully where it will be protected from contamination.

## 5. Maintenance

### 5.1. Interim Inspection

Pressure regulators should be inspected and tested on an annual basis to ensure correct performance.

**Warning!** If any defect is found during inspection, the device must be taken out of service.

#### 5.1.1. Inspection

Check the exterior condition of the device. Pay particular attention to the input connector seals, which should be replaced if damaged or missing. Check that the holes in the side of the device, which are designed to vent gas in the event of relief valve activation, are not obstructed or have otherwise been tampered with.

#### 5.1.1. External Leak Test

If required ensure the outlet connector is blanked off to prevent flow. This is not required for sealed connections (e.g. BS5682 schrader connectors).

Note the gas cylinder contents displayed on the pressure gauge and then close the gas cylinder valve. Monitor the gauge to see if the gauge falls over a 5-minute period. If the gauge remains constant, the device is leak free.

### 5.2. Cleaning

Wipe down the outside of the device with an alcohol or disinfectant wipe. Do not allow the ingress of water or other solution into the device.

### 5.3. Planned Preventative Servicing

Pressure regulators must be serviced every 4 years to ensure the device continues to perform in accordance to its specification. All pressure regulators have a Service Due date on their label, indicating when the next service is due.

When serviced by BPR Medical Ltd, and where the time to end of life is less than the normal service interval, the Service Due date will be replaced by the End of Life date and preceded by a symbol (⌘). In these cases, the date now indicates when the device reaches end of life.

**Warning!** Servicing must be carried out by a suitably qualified person working in a controlled environment.

BPR Medical provides routine servicing if required. Full details of the recommended servicing requirements can also be found in the Service Manual or on our SupportWeb service training system. Please contact us for details.

## 6. Specification

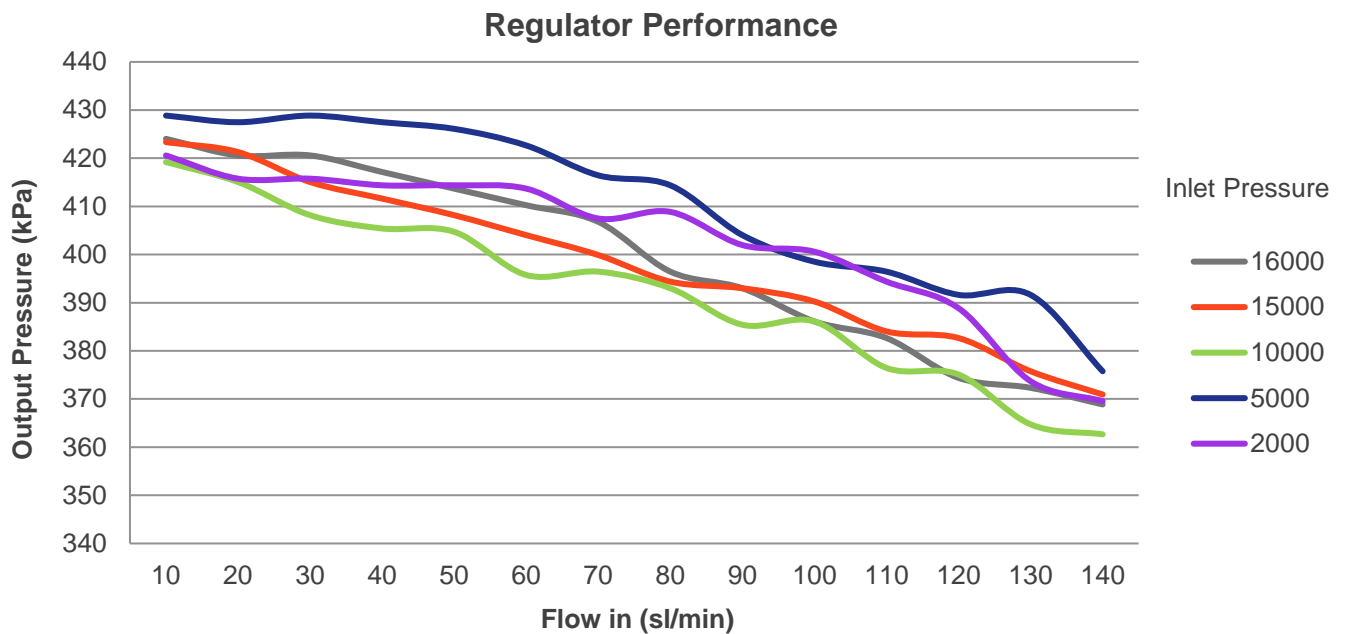
### Specification

Inlet pressure	Minimum: 1,500 kPa
	Maximum: 20,000 kPa
Nominal outlet pressure	400 kPa
Outlet Pressure Range*	360 kPa to 550 kPa
Rated Flow	40 sl/min
Inlet filtration	40 µm
Intended life	12 years
Service interval	4 years
Over pressure valve set point	~700 kPa
Gas compatibility	Medical oxygen, medical air of O <sub>2</sub> /N <sub>2</sub> O 50%/50% v/v gas mixture (model dependent)
Transport/storage temperature range	-25 to +70°C
Temperature range of operation	-20 to +60°C

### Applied Standards

EN 1041:2008+A1:2013 - Medical devices - Information to be supplied by the manufacturer
EN ISO 15223-1:2020 - Symbols to be used with medical device labels, labelling and information to be supplied
EN ISO 10524-1:2019 - Pressure regulators and pressure regulators with flow-metering devices
EN ISO 15001:2011 - Anaesthetic and respiratory equipment. Compatibility with oxygen
EN ISO 14971 :2012 - Medical devices. Application of risk management to medical devices
EN ISO 10993-1:2020 - Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
EN 62366-1 :2015 - Medical devices – Part 1: Application of usability engineering to medical devices
ISO 18562-1 :2017 - Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 1: Evaluation and testing within a risk management process
BS 5682:2015 - Dimensions of probes and terminal units for medical gas supply systems – Requirements
ISO 407:2004 - Small medical gas cylinders - Pin-index yoke-type valve connections
BS EN 837-1 - Pressure gauges - Part 1. Bourdon tube pressure gauges - Dimensions, metrology, requirements and testing

## 6.1. Typical Flow Performance



## 7. Parts and Spares List


Part Number	Inlet Connection	Outlet Connection	Gas Type
819-0009	Pin Index	3/8" BSP	Oxygen
819-0010	Pin Index	BS 5682	Oxygen
819-0011	Pin Index	1/4" Hose	Oxygen
819-0012	Pin Index	1/8" BSP	Oxygen
819-0015	Bullnose	3/8" BSP	Oxygen
819-0016	Bullnose	BS 5682	Oxygen
819-0017	Bullnose	1/4" Hose	Oxygen
819-0033	Pin Index	3/8" BSP	Air
819-0034	Pin Index	BS 5682	Air
819-0035	Pin Index	1/4" Hose	Air
819-0039	Bullnose	3/8" BSP	Air
819-0040	Bullnose	BS 5682	Air
819-0063	Pin Index	BS 5682	O2/N2O

### Spare Parts and Servicing

212-0012	Bull Nose Seal
212-0094	Pin Index Yoke Seal
303-0030	Boot for Cylinder Gauge
303-0060	Swivel Cylinder Contents Gauge
610-0039	Pressure Regulator Service Kit (Pack 10)
610-0057	Bodok Bonded Seal (Pack 50)
610-0058	Bull Nose O-ring Seal (Pack 50)



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