

Pressure Regulators

Instructions for Use



CE
0120

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THE QUEEN'S AWARDS
FOR ENTERPRISE:
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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



Attention, consult accompanying documents



Use no oil



CE Marked to Medical Device Directive 93/42/EEC as amended by directive 2007/47/CE



No smoking



Service due date

SN 1304X12345
YYMM

Date of manufacture identification

2. Warnings and Cautions

2.1. Warnings!

- ▶ Before using the regulator read through the entire instruction manual. As with all medical equipment, attempting to use this device without a thorough understanding of its operation may result in patient or user injury.
- ▶ 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 oxygen regulators, flowmeters, cylinders, valves or other related equipment.
- ▶ Never administer oxygen while smoking or when near an open flame.
- ▶ Oxygen therapy may be a critical treatment. A regulated flowmeter should be used in strict accordance with the prescription and instructions of a physician. The effectiveness of supplemental oxygen therapy can only be determined by continuous monitoring of blood oxygen levels.
- ▶ Never permit compressed medical gases to enter a regulator suddenly, always open the cylinder valve slowly.
- ▶ Never use medical gases from a cylinder without reducing the pressure through a suitable regulator intended for that gas.
- ▶ Always close the cylinder valve when the regulator is not in use.

- ▶ Never install a pin index regulator with more than one yoke seal between the valve and the regulator. Before attaching the regulator verify that the post valve is not already fitted with a yoke seal.
- ▶ Ensure that the pin-indexed connector on the 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 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 regulator outlet when opening the cylinder valve.
- ▶ Before removing a regulator from a cylinder, fully close the cylinder valve and release all gas from the regulator.
- ▶ Do not use or store oxygen equipment near excessive heat (>50°C or 125°F) or open flame.
- ▶ Only appropriately trained personnel working in controlled conditions must perform disassembly, assembly and testing of regulators and flowmeters.
- ▶ Only BPR Medical approved spare parts should be used to maintain the regulator.
- ▶ Do not submerge the device in any fluid. Ensure that no fluid is allowed to enter the inlet valve or the vent holes.
- ▶ 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).
- ▶ 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.
- ▶ These regulators are designed for use for cylinder pressures up to 20,000 kPa (3,000 psi/ 200 bar), do not attempt to connect BPR Medical regulators to cylinders having fill pressures in excess of this value.

2.2. Cautions

- ▶ The performance of the device may be affected if it is stored or transported in temperature outside of the range -20°C to +60°C.

3. Functional Description

The BPR Medical range of regulators provide a safe and convenient way of connecting high pressure gas cylinders to flowmeters, ventilators and other equipment required to run from a low pressure gas source.

A regulator is connected to the gas cylinder via one of a number of different designs of inlet connector that are the result of differing gas bottle connection standards across the world.

The lower outlet pressure of the regulator is achieved by balancing the force applied by the gas on a piston head with a spring of known characteristics. A valve seat limits the flow of gas, restricting the force that can be applied on the piston head until such time as a state of equilibrium can be reached in the system (i.e. the outlet pressure). The specific characteristics of the valve seat, piston and spring combine to determine the outlet pressure. As gas is drawn from the regulator, the outlet pressure drops and the valve opens in an attempt to maintain the equilibrium under the new gas flow conditions.

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 inlet filter is incorporated to prevent the ingress of debris, which may 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

Check that the cylinder type and regulator inlet connector are compatible. Check the presence and condition of the input connector seal.

Note: For pin index regulators this is a washer type seal (yoke seal) and an O-ring for bull nose regulators.

Check that a suitable device (e.g. flowmeter) is correctly connected to the output of the regulator. Fit the regulator to the cylinder ensuring that it is properly mated and the connectors are done up hand tight. Open the cylinder valve with a suitable cylinder key. Check the regulator cylinder contents gauge to verify that there is sufficient gas available.

Continue to check the regulator contents gauge. Upon completion of the therapy, close the cylinder valve and disconnect any outlet hoses that might be connected to the patient.

To remove the regulator from the cylinder, first ensure the cylinder valve is closed. Bleed off any residual gas pressure in the regulator by turning on the connected ancillary device. Remove the regulator from the cylinder and store it carefully where it will be protected from contamination.

5. Maintenance

5.1. User Maintenance and Inspection

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

Wipe down the outside of the device with an alcohol wipe.

Do not allow the ingress of water or other solution into the device. Check the exterior condition of the device.

Notes:

- Pay particular attention to the input connector seal and cylinder contents gauge.
- Check that the holes in the side of the body of the device for venting gas in the event of relief valve activation are not obstructed or have otherwise been tampered with.

5.2. Service/Repair

Regulators must be serviced on or before the Service Due date stated on the regulator rating label.

The lack of servicing or incorrect servicing are the main causes of incidents with medical gas regulators and it is strongly advised that devices are serviced according to the instructions given in the Service Manual.

Servicing may be undertaken by suitably qualified engineers working in appropriate conditions who have undergone formal training with BPR Medical.

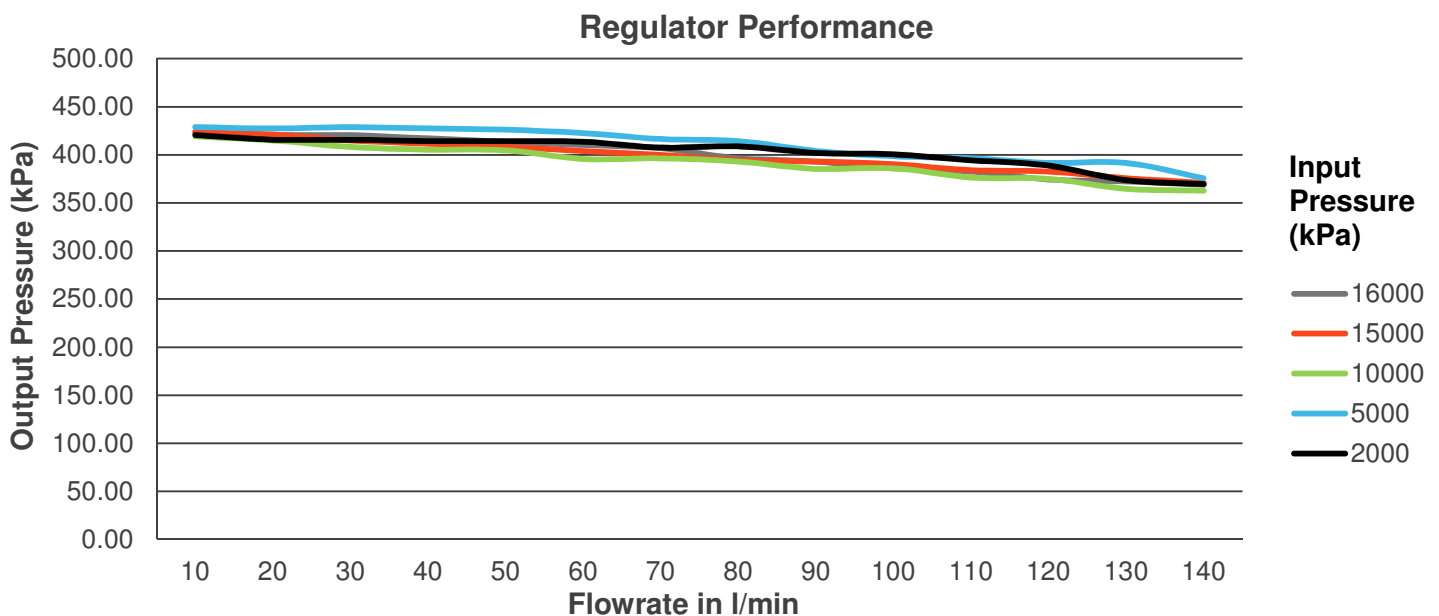
6. Specification

Specification	Oxygen/Air Pressure Regulator	O ₂ /N ₂ O Pressure Regulator
Rated Pressure (P ₁)	900 kPa – 20,000 kPa	2,000 kPa – 20,000 kPa
Rated Outlet Pressure (P ₂)	400 kPa	
Standard Discharge (Q ₁)	40 l/min	
Operating, Storage and Transport Temperature Range	-20 °C to +60 °C	
Standard Warranty	1 year	
Service Interval	4 years	

Applied Standards

BS EN ISO 10524-1	Pressure regulators for use with medical gases. Pressure regulators and pressure regulators with flow-metering devices
BS EN ISO 14971	Medical devices. Application of risk management to medical devices
BS EN ISO 15223-1	Medical Devices. Symbols to be used with medical device labelling and information to be supplied. General requirements.
BS EN 1041	Information supplied by the manufacturer of medical devices

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 Female	Oxygen
819-0015	Bullnose	3/8" BSP	Oxygen
819-0016	Bullnose	BS 5682	Oxygen
819-0017	Bullnose	1/4" Hose	Oxygen
819-0034	Pin Index	Schrader	Air
819-0035	Pin Index	1/4" Hose	Air
819-0039	Pin Index	3/8" BSP	Air
819-0040	Bullnose	Schrader	Air
819-0063	Pin Index	Schrader	Oxygen
819-0076	Bullnose	BS 5682 (left)	Oxygen
819-0079	Bullnose	Schrader (left fixed block)	Oxygen
819-0083	Pin Index	BS 5682	Air (high flow)

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 0.3mm Restriction
610-0039	Regulator Service Kit (Pack 10)
610-0057	Bodok Bonded Seal (Pack 50)
610-0058	Bull Nose O-ring Seal (Pack 50)

8. Distributor Details

BOC Healthcare
Customer Service Centre
Priestly Road
Worsley
Manchester
M28 2UT
T: +44 (0)8456 447 764
F: +44 (0)8450 870 062
www.bochealthcare.co.uk



BPR Medical Limited
22 Hamilton Way, Mansfield
Nottinghamshire
NG18 5BU, United Kingdom

T: +44 (0)1623 628 281
F: +44 (0)1623 628 289
cs@bprmedical.com
www.bprmedical.com

