MEDICAL GAS CONTROL

Pressure Regulator

Instructions for Use

CE
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THE QUEEN'S AWARDS
FOR ENTERPRISE:
INNOVATION
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1. Symbols

Warning!	Indicates a potentially hazardous situation which, if not avoided, could result in injury to the patient, 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!

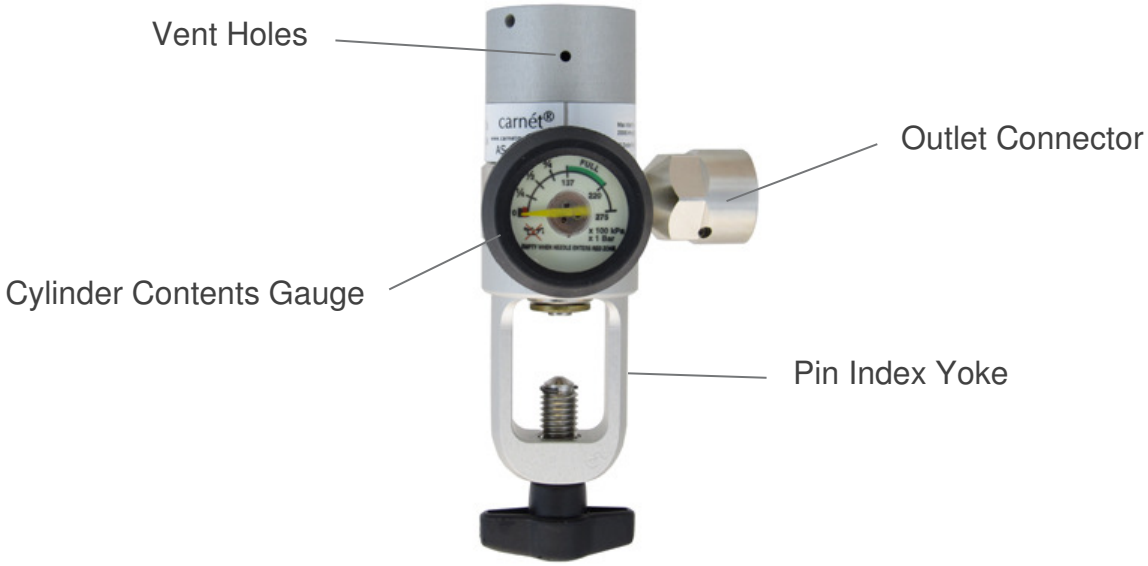
- Before using the Pressure Regulator read through the entire instruction manual. As with all medical equipment, attempting to use this device without a thorough understanding of its operation may result in patient or user injury.
- Oxygen and O_2/N_2O 50%/50% v/v, hereinafter referred to as analgesic gas, are or should be considered, drugs 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 or analgesic gas while smoking or when near an open flame.
- Oxygen and analgesic gas mixture is not flammable; however the presence of it will drastically increase the rate and severity of combustion. Oil and/or grease in the presence of an oxygen enriched atmosphere will become highly combustible. Never allow to come into contact with oil, grease or other hydrocarbon based substances. Do not use oil or grease on this Pressure Regulator.
- 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 PaO2 or SpO2 monitoring is carried out when supplemental oxygen is prescribed for critical treatments.
- 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.
- The use of a BPR Medical Pressure Regulator for gases other than that on the device labelling is expressly prohibited.
- Never permit compressed medical gases to enter a Pressure Regulator suddenly. Always open cylinder valves 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 and disconnect the device when 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 Pressure Regulator, verify that the post valve is not already fitted with a yoke seal.
- Ensure that you have the correct Pressure Regulator for the type of cylinder you are intending to use. Never attempt to fit a Pressure Regulator to an incompatible cylinder.
- 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.
- 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 from the device.
- Secure 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 may disassemble or assemble this Pressure Regulator.
- Pressure Regulators are not MRI compatible.
- The holes in the side of the body of the device are for venting gas in the event that the relief valve is activated. Do not obstruct these holes or interfere with the relief valve in any way.
- This Pressure Regulator is designed for use with cylinder pressures up to 20,000 kPa (3,000 psi/ 200 bar) at 15 °C. Do not attempt to connect BPR Medical Pressure Regulators to cylinders having fill pressures in excess of this value.

2.2. Cautions!

- The performance of the flowmeter may be affected if it is stored or transported in temperatures outside of the range -20 °C to +60 °C (-4 °F to +140 °F).
- Pressure regulators are not suitable for autoclaving.

3. Functional Description



3.1. Intended Use

The BPR Medical range of Pressure 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.

3.2. Technical Description

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

The lower outlet pressure of the Pressure 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 is reached in the system (i.e. the outlet pressure). The characteristics of the valve seat, piston and spring combine to determine the outlet pressure. As gas is drawn from the Pressure Regulator, the outlet pressure drops and the valve opens in order to maintain the equilibrium under the new gas flow condition.

An over pressure valve (OPV) protects the user from any high gas pressures by venting excess pressure to ambient if the valve is unable to close at the set pressure for any reason. 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 fire.

Outlet pressure is delivered to an outlet connector where an intended delivery device (e.g. flowmeter) is connected.

4. Operating Instructions

4.1. Pre-Use Checks

Warning! If any defect is found during a pre-use checks, the device must be taken out of service.

Check the Pressure Regulator is not past its intended life (12 years after date of manufacture, see section 1 of this manual and the first 4 digits of the serial number on the device label.

Check that the Pressure Regulator is not overdue the planned service interval. See the device label adjacent to the spanner / wrench symbol.

Check that the cylinder type and Pressure Regulator inlet connector are compatible.

Check the inlet connector Bodok / yoke seal is present, clean and in good condition

Check that the device is in good condition and there are no signs of damage.

Connect the Pressure Regulator to the gas cylinder ensuring the connection is hand tight.

Caution: Do not use tools to provide additional leverage to tighten the connection, it is not necessary and may damage the device.

SLOWLY open the gas cylinder valve cylinder and check for audible leaks.

4.2. Operation

Check the Pressure Regulator cylinder contents gauge to verify that there is sufficient gas available.

Connect the required gas delivery device to the Pressure Regulator, ensuring the handwheel is tightened correctly. If there is no gas flow refer to Section 7 Troubleshooting of this manual.

Continue to check the Pressure Regulator contents gauge regularly. 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

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 over the external surfaces of the Pressure Regulator with an alcohol or disinfecting wipe. Never immerse the Pressure Regulator in any fluid.

5.3. Planned Preventative Servicing

The Pressure Regulator must be serviced every 4 years to ensure that it continues to perform in accordance with its specification. The devices have a Service Due date on their labelling, adjacent to the spanner / wrench symbol, which indicates 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 competent person working in a controlled environment.

Full details of the recommended servicing requirements can be found in the Service Manual. The Service Manual can be obtained from your local BPR Medical distributor, details of which can be found at **www.bprmedical.com**. Complete the service in accordance with the instructions given in the Service Manual or return the device to a recognised BPR Medical Service Centre on or before the date shown.

6. Specification

Specification	Oxygen / Air	O_2/ N_2O
Inlet Pressure (P_1)	1000 kPa to 20,000 kPa	2,000 kPa to 20,000 kPa
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	
Intended Life	12 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 15001	Anaesthetic and respiratory equipment. Compatibility with oxygen	
BS 5682	Specification for probes (quick connectors) for use with medical gas pipeline systems	
AS 2473.3	Valves for compressed gas cylinders Part 3: Outlet connections for medical gases (including pin-indexed yoke connections)	
AS 2902	Installation and testing of non-flammable medical gas pipeline systems	
AS 3840.1	Pressure regulators for use with medical gases. Part 1: Pressure regulators and pressure regulators with flow-metering devices	

7. Troubleshooting

Fault	Possible Cause	Solution
No gas flow	Gas cylinder turned off	Check gas supply
	Output not connected properly	Check gas specific probe is correctly connected
	Gas cylinder empty	Replace gas cylinder
	Filter blocked	Service or repair required

Internal/external leak	Seal failure	Service or repair is required
Insufficient gas flow	Filter partially occluded	Service is required
	Supply pressure too low and/or gas cylinder nearly empty	Check gas supply and/or replace gas cylinder

8. Parts and Spares List

Part Number	Description
819-0071	Pressure Regulator - O_2 Pin Index (AS 2902)
819-0073	Pressure Regulator - O_2/N_2O Pin Index (AS 2902)
819-0077	Pressure Regulator - Air Pin Index (AS 2902)
819-0080	Pressure Regulator - O_2 Pin Index (BS 5682)
819-0081	Pressure Regulator - O_2/N_2O Pin Index (BS 5682)
819-0082	Pressure Regulator - Air Pin Index (BS 5682)

Spare Parts and Servicing	
212-0012	Pin Index Yoke Seal
610-0069	Regulator Service Kit Australia (Pack 10)
999-0053	Pressure Regulator – Pin Index

9. Distributor Details

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BOC Healthcare
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