Pressure Regulators for Medical Gases
Instructions for Use
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

Europe CE

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

🚫
No smoking

🔧
Service due date

📅
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 and \( \text{O}_2/\text{N}_2\text{O} \) 50%/50% v/v, hereinafter referred to as analgesic gas, are or should be considered, 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 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. 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.
Gas specific connectors are fitted to the Pressure Regulator. Do not attempt to modify the fittings to suit other gases or fitting systems. Never permit compressed medical gases to enter a pressure regulator suddenly. Always open the cylinder valve slowly.

Never permit compressed medical gases to enter a Pressure 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 and disconnect the regulator when 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 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.

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.

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 medical gas near excessive heat (>50 °C/125 °F) or below 10 °C (50 °F). Always refer to the medical gas suppliers recommendations.

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.

Do not obstruct the vent holes or interfere with the over pressure valve in any way. These are for venting gas in the event that the over pressure valve is activated.

This regulator is designed for use with cylinder pressures up to 20,000 kPa (3,000 psi/200 bar). Do not attempt to connect BPR Medical Ltd 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).
3. Functional Description

3.1. Intended Use
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.

3.2. Technical Description
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 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 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).

4.2. **Testing Prior to Use**

Connect required output device to regulator, ensuring the handwheel is tightened correctly. If no medical gas flow is sensed refer to Section 7 Troubleshooting of this manual.

4.3. **Operation**

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. **Interim Inspection**

Pressure Regulators should be cleaned, inspected for damage and leaks and performance checked regularly. The frequency of such checks depends on usage, but as a guideline if the regulator is used daily this should be performed every six months, if used infrequently then an annual check will suffice.

5.1.1. **Cleaning**

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

*Note:* Pay particular attention to the input connector seal and the cylinder contents gauge.

*Note:* Check that the venting holes in the side of the main body are not obstructed or have otherwise been tampered with.

5.2. **Service**

The Pressure Regulator must be serviced every 2 years to ensure that it continues to perform in accordance with its specification. The devices have a Service Due date on their labelling, which indicates when the next service is due.

*Warning!* Servicing must be carried out by a suitably qualified 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](http://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

<table>
<thead>
<tr>
<th>Specification</th>
<th>Oxygen/ Air</th>
<th>O₂/ N₂O</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rated Inlet Pressure (P₁)</td>
<td>900 kPa to 20,000 kPa</td>
<td>2,000 kPa to 20,000 kPa</td>
</tr>
<tr>
<td>Rated Outlet Pressure (P₂)</td>
<td>400 kPa</td>
<td></td>
</tr>
<tr>
<td>Standard Discharge (Q₁)</td>
<td>40 l/min</td>
<td></td>
</tr>
<tr>
<td>Operating, Storage and Transport Temperature Range</td>
<td>-20 °C to +60 °C</td>
<td></td>
</tr>
<tr>
<td>Standard Warranty</td>
<td>1 year</td>
<td></td>
</tr>
<tr>
<td>Service Interval</td>
<td>4 years</td>
<td></td>
</tr>
</tbody>
</table>

**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 15001**: Anaesthetic and respiratory equipment. Compatibility with oxygen
- **BS EN ISO 15002**: Flow-metering devices for connection to terminal units of medical gas pipeline systems
- **BS EN ISO 15223-1**: Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
- **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

<table>
<thead>
<tr>
<th>Fault</th>
<th>Possible Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>No gas flow</td>
<td>Gas cylinder turned off</td>
<td>Check gas supply</td>
</tr>
<tr>
<td></td>
<td>Output not connected properly</td>
<td>Check gas specific probe is correctly connected</td>
</tr>
<tr>
<td></td>
<td>Gas cylinder empty</td>
<td>Replace gas cylinder</td>
</tr>
<tr>
<td></td>
<td>Filter blocked</td>
<td>Service or repair required</td>
</tr>
<tr>
<td>Internal/external leak</td>
<td>Seal failure</td>
<td>Service or repair is required</td>
</tr>
<tr>
<td>Insufficient gas flow</td>
<td>Filter partially occluded</td>
<td>Service is required</td>
</tr>
<tr>
<td></td>
<td>Supply pressure too low and/or gas cylinder nearly empty</td>
<td>Check gas supply and/or replace gas cylinder</td>
</tr>
</tbody>
</table>

## 8. Parts and Spares List

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>819-0071</td>
<td>Pressure Regulator - O₂ Pin Index (AS 2902)</td>
</tr>
<tr>
<td>819-0073</td>
<td>Pressure Regulator - O₂/N₂O Pin Index (AS 2902)</td>
</tr>
<tr>
<td>819-0077</td>
<td>Pressure Regulator - Air Pin Index (AS 2902)</td>
</tr>
<tr>
<td>819-0080</td>
<td>Pressure Regulator - O₂ Pin Index (BS 5682)</td>
</tr>
<tr>
<td>819-0081</td>
<td>Pressure Regulator - O₂/N₂O Pin Index (BS 5682)</td>
</tr>
<tr>
<td>819-0082</td>
<td>Pressure Regulator - Air Pin Index (BS 5682)</td>
</tr>
</tbody>
</table>

### Spare Parts and Servicing

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>212-0012</td>
<td>Pin Index Yoke Seal</td>
</tr>
<tr>
<td>610-0069</td>
<td>Regulator Service Kit Australia (Pack 10)</td>
</tr>
<tr>
<td>999-0053</td>
<td>Pressure Regulator – Pin Index</td>
</tr>
</tbody>
</table>
9. Distributor Details

Australia
BOC Healthcare
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