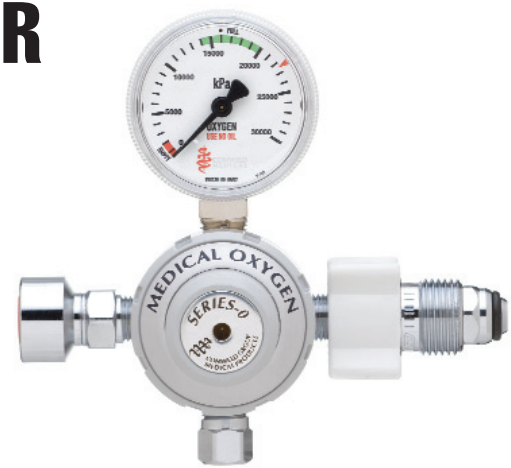
COMWELD MEDICAL

SERIES-0 REGULATOR

Instructions for use



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Contents

1. INTRODUCTION

These instructions are intended to provide users with information on the features, use and care of the SERIES-O medical gas regulator.

The instructions should be read carefully by every intended user of a SERIES-O regulator in any of its applications before attempting to use it to ensure that they are fully conversant with all the information on the features, use and care of the regulator.

Warning

Read and understand the entire Instructions for Use before operating this medical device. Keep them always with the device. Failure to do so may cause clinical damage to a patient or damage to the device.

COMWELD MEDICAL

2. INTENDED USES

The SERIES-O regulator is intended to be connected to high pressure medical gas cylinders in order to supply medical gases at reduced and regulated pressures similar to those from medical gas pipeline systems. It should be used only in accordance with these Instructions, and by persons instructed and familiar with basic handling of medical gases in gas cylinders.

The gas supply from the regulator is delivered by an SIS compatible pressure outlet at reduced and regulated pressure similar to those from medical gas pipeline systems. The regulated pressure gas is supplied to medical devices intended for typical applications like Respiratory Therapy, Resuscitation and Suction.

The regulator can only perform its pressure regulating and gas supply functions when properly connected to a downstream application. The downstream application is expected to control the supply of gas to the patient or ultimate application. The regulator alone cannot perform these functions.

Use of the SERIES-O regulators should always be undertaken in accordance with the instructions for use of the medical device which will be connected to its outlet connection to deliver care to a patient. This may require clinical or medical advice.

The SERIES-O regulator may be used as a source of pressure regulated medical gas for a demand valve. However, assembly of a complete Resuscitator or Analgesic Administration System requires consideration of all other components to be used, which together with their use for the intended application should be undertaken only by persons who have received adequate training. These Instructions for Use cover only the regulator.

Details of the performance of each SERIES-O model is given in Section 10 Specifications.

3. GENERAL DESCRIPTION

The SERIES-O regulator is a reliable, compact, preset single stage regulator. Pressure reduction is effected by means of an encapsulated pressure regulating valve, protected by a unique triple filtration system in the high pressure side to protect the regulator and downstream equipment from entry of foreign particles.

The SERIES-O regulator does not require user pressure adjustment. It has been factory preset to deliver the outlet pressure specified in AS 2896 or applicable Standard. Since it is always adjusted and ready to deliver outlet pressure and does not include a shut-off valve, it is essential that it should be connected to the high pressure gas cylinder with careful attention to the operation of the valve in the gas cylinder and only when attached downstream devices are fitted with an outlet valve.

A pressure gauge is fitted in the high pressure side of the regulator in order to allow indication of the gas cylinder contents. The gauge is of the safety back design to allow gas to escape away from the operator ensuring maximum safety in the unlikely event of a failure occurring. A solid metal case also provides protection to the internal mechanism.

A pressure relief valve is fitted to the outlet pressure side of the regulator to give protection against most seat failures.

Gas specific inlet and outlet connections allow the regulator to be connected only to the gas for which it is intended. Colour coded pressure gauges and identification labels help for quick identification of the gas for which the regulator is intended.

4. PARTS IDENTIFICATION

4.1 Contents of Package:

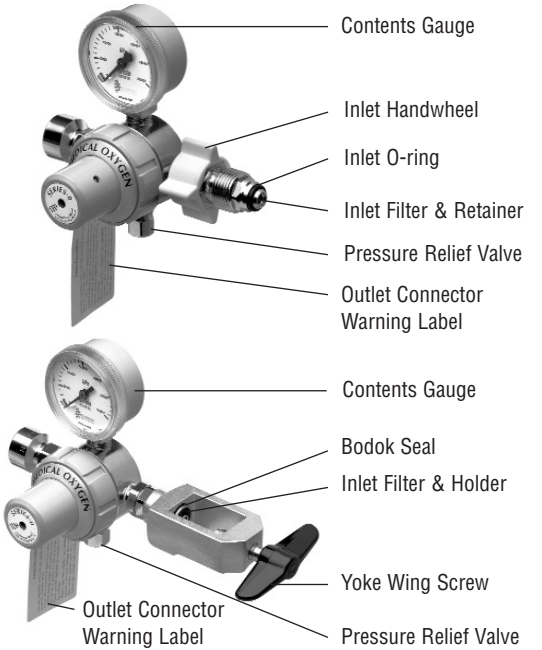
Item	Description	Quantity
1	SERIES-O regulator assembly	1
2	Instructions for Use	1
3	Outlet connector Warning label (attached to the regulator)	1

Note: Instructions for Use and Warning label should always be kept with the regulator.

4.2 Pictorial Description:

Notes:
Apart from the Inlet Handwheel or Yoke Wing Screw, there are no user controls or shut-off valves on the SERIES-O Regulator. Flow control and shut-off may be done only through the gas cylinder valve or connected downstream equipment.

The cylinder contents pressure gauge only provides indication of the gas cylinder pressure.



5. SAFETY PRECAUTIONS

WARNING

The SERIES-O regulator should be used only if all its components are in correct operating condition as described in these instructions.

Use the regulator only for the purpose for which it is intended (Section 2) and in accordance with clinical or medical advice. Failure to do so may result in clinical damage to a patient.

Most models of the SERIES-O regulator range are intended to be connected to high pressure gas cylinders containing oxygen or oxidising gases. Materials that react normally in contact with air may react violently and ignite in an oxygen-enriched atmosphere.

Regulators connected to high pressure gas cylinders must be handled with care and in accordance with the recommendations from the gas supplier.

When using the SERIES-O regulator the following precautions should be observed:

- Never allow any source of ignition or naked flame near the equipment or patient during oxygen administration and for a reasonable period afterwards.
- Use no oil or greases as a fire or an explosion may result.
- When connected to a pressure regulator fitted to a gas cylinder, always open the cylinder valve **SLOWLY**. Rapid opening of the cylinder valve may damage downstream equipment.
- Ensure that the cylinder valve is not opened when there is no equipment connected downstream of the regulator. This may cause damage to the regulator.
- When removing downstream equipment, ensure first the cylinder valve is fully closed. Failure to do so may damage the regulator.
- Turn off the cylinder valve when the regulator is not in use.
- Keep gas cylinders cool.
- Do not dump or drop cylinders.

Use of the regulator with medical gas cylinders
Only use the SERIES-O regulator with the medical gas for which it is intended and labelled. Ensure it is connected to the correct gas cylinder by reading the cylinder label which is the primary identification of its gas. Consult safe gas cylinder handling procedures and guidelines from the medical gas suppliers to plan location and access to the gas cylinder and the connected regulator.

The SERIES-O regulator has been primarily designed for use connected to a static and properly secured medical gas cylinder. Ensure the regulator is well protected at all times against accidental contact with other objects. Impact on the regulator could cause malfunction and unintended gas release. Never use the regulator as a means of lifting, carrying and steadying the cylinder.

When the regulator is moved around whilst connected to a gas cylinder, the cylinder valve should always be closed first.

For applications where a mobile supply of medical oxygen is required, e.g. during patient transportation, a safe and suitable arrangement for securing the gas cylinder and pressure regulator is required. Ensure the regulator is adequately guarded and protected against impact and knocks during transport.

When the regulator is not in use, the cylinder valve should be turned off and the regulator depressurised.

Care of the regulator
Since SERIES-O Regulators are always preset to deliver outlet pressure and have no means to control or shut-off gas flow, they should be pressurised only when downstream equipment fitted with a control valve are attached to them.

Operation of the pressure relief valve indicates malfunction in the pressure regulating mechanism. The cylinder valve should be closed immediately and the regulator should be removed from use and subjected to servicing. Do not tamper with the setting of the pressure relief valve.

All repairs should be undertaken only by personnel trained in the servicing procedures for medical equipment.

Use only manufacturer approved spare parts when servicing.

6. EQUIPMENT USE

6.1 Installation

Connecting the Regulator to a Gas Cylinder

For a new regulator, remove the regulator from its packing, checking there has been no damage in transport. Remove the plastic protection caps from the inlet and outlet connections (where fitted).

In all cases, perform the recommended Checks and Inspections before use of the regulator (see Section 7).

To connect a regulator to a gas cylinder, first verify that the gas cylinder label indicates the correct medical gas for the regulator and the intended application.

WARNING

Supply of incorrect gas to a patient may result in clinical damage including death.

Remove any protective capping from the cylinder valve and check that the cylinder valve outlet is in good condition and matches the regulator inlet connection.

Briefly open and close the cylinder valve to remove any foreign matter. Check that the Bodok seal (Yoke inlet models) or inlet O-ring (screw connection models) are in a good condition and replace them as required. (see Section 7).

CAUTION

Refer to safe gas cylinder handling procedures and guidelines from the medical gas suppliers as required and appropriate. Connecting equipment to gas cylinders is different to connecting equipment to Terminal Units from pipeline systems.

Connect the regulator to the cylinder valve. If the regulator has a pin index yoke connection align the yoke pins with the matching holes in the cylinder valve. Secure by tightening the yoke wing screw until a leak tight seal is achieved.

If the regulator has an inlet handwheel simply tighten the inlet connection to the cylinder valve until a leak tight seal is achieved.

WARNING

- **Any difficulty in connecting the regulator indicates a possible fault or mismatch in the connections which should be investigated and repaired before use of the regulator.**

- **Do not open the cylinder valve for any purpose until downstream equipment is connected to the regulator outlet. The regulator alone cannot control flow and a large discharge of gas will result, possibly damaging the regulator.**

6.2 Connecting Downstream Equipment

WARNING

Use only downstream equipment that is compatible with the intended gas and suitable to operate at the rated outlet pressure of the regulator. The downstream equipment should be fitted with the correct SIS inlet connection matching the regulator outlet connection.

To connect downstream equipment (e.g. Demand valves, Flowmeters, Suction units) to a SERIES-O regulator, first ensure that the downstream equipment is turned off. The regulator is adjusted always to deliver flow at its reated pressure of 400 kPa through the SIS outlet (or other value given in Section 10 - Specifications) and has no means of adjusting or closing it off. Connect the inlet of any downstream equipment to the regulator outlet connection and tighten. **Only then slowly and fully open the cylinder valve.**

Check the regulator contents pressure gauge to confirm there is sufficient gas in the cylinder for the intended use. Check all connections for leaks. If necessary, re-tighten connections until a leak tight seal is achieved.

Use the downstream equipment as required and in accordance with its own Instructions for Use, and if necessary, under clinical or medical supervision.

When the downstream equipment is no longer in use, close the cylinder valve and depressurise the regulator.

6.3 Removing downstream equipment

CAUTION

When removing downstream equipment, ensure first the cylinder valve is fully closed. An open cylinder valve will result in release of gas and possible damage to the regulator.

To remove downstream equipment from the regulator, first close the cylinder valve. Depressurise the downstream equipment and the regulator by operating the downstream equipment until the regulator contents gauge reads zero pressure. Remove the downstream equipment.

6.4 Removing the Regulator from a Cylinder

To remove the regulator from the cylinder, first close the cylinder valve. Disconnect all the downstream equipment as indicated above in 6.3.

With the downstream equipment now disconnected and the regulator depressurised, remove the regulator from the cylinder valve by unscrewing the yoke wing screw or inlet handwheel.

6.5 Cleaning after use

A SERIES-O regulator should not require regular cleaning after use. If the exterior of the regulator needs cleaning, a mild soap solution should be used. Care should be taken to ensure that none of the cleaning solution enters the gas passages of the regulator. Do not attempt to clean the inside of the regulator.

CAUTION

If internal contamination is apparent, the regulator should be removed from use and inspected by trained personnel.

6.6 Storage after use

If the regulator is not going to be used immediately following removal from a cylinder, it should be stored in a clean, dry, secure place to prevent accidental knocks and impacts and to prevent the ingress of dust or contamination to its gas passages.

7. CHECKS AND INSPECTION BY THE USER

7.1 Operational Check and Inspection

A medical pressure regulator is a critical link in the gas supply to a patient. The following checks should be performed each time the SERIES-O regulator is connected to a gas cylinder prior to using the equipment to supply gas to a downstream application and/or patient.

- Check the condition of the inlet and outlet gas specific connectors. The connection fittings should be tight and secure.
- Check that the Bodok seal (Yoke inlet models) or inlet O-ring (screw connection models) is in a good condition.
- Check the pressure gauge to ensure that the pointer reads zero when there is no inlet pressure present.
- Check for any damage that may have occurred to the regulator.
- Check that units subject to Preventative Maintenance programs are within test date. (Refer to Section 8 Service Recommendations).

If the regulator satisfies the above requirements, it may be used.

CAUTION

If the unit fails any part of this checkout procedure, or any unusual conditions are evident or suspected, the regulator must be removed from service and repaired before use to supply gas to a patient.

7.2 Checking and replacing the Bodok seal

The Bodok seal in the yoke inlet should have a clean, undamaged appearance, especially the black elastomer sealing element. If any amount of excessive deformation, cuts or nicks are evident, the seal should be replaced.

To replace the Bodok seal, gently lever it out of position. A new seal should be inserted simply by pushing it into position.

7.3 Checking and replacing the inlet connection O-ring

The O-ring on the inlet connection should be in place and in good condition (i.e. no cuts, deformation or dirt).

A damaged O-ring may be replaced, when a correct replacement is available, by removing it with a pointed object, taking care not to damage the inlet nipple, and inserting the replacement O-ring in place.

7.4 Replacing the inlet filter

To replace the inlet filter, first remove the filter retaining screw using a correct size Allen key (3.2 mm - 1/8" for yoke inlet models, 4.8 mm - 3/16" for screw connection models). The filter should drop out of the inlet connector when the regulator is inverted. After fitting a new inlet filter its retaining screw should only be lightly tightened ("nipped up"). Do not over tighten.

7.5 Regulator testing

The regulator should be periodically tested for leaks, outlet set pressure and pressure relief valve setting. The recommended frequency of these tests is detailed in section 8 of this manual.

Leak Test

To test for leaks fit the regulator to a full gas cylinder and block off the regulator outlet. Open the cylinder valve and apply an approved leak detection solution to all regulator body connections (inlet, outlet, pressure gauge, pressure relief valve and bonnet). No bubbles should be generated within 30 seconds.

Approved leak detection solutions are BUBBLES™ or SNOOPY™.

Outlet Set Pressure and regulator seat performance

The outlet set pressure of the regulator should be periodically checked, and adjusted if required. This requires special test equipment and should only be carried out by trained service personnel. See Section 8.

Pressure Relief Valve Setting

The operation of the pressure relief valve should be periodically checked. This requires special test equipment and should only be carried out by trained service personnel. Contact your nearest authorised service agent for further information.

8. SERVICE RECOMMENDATIONS

A SERIES-O regulator is a critical link in the supply of medical gas to a patient. To ensure that the regulator is always in a safe, reliable, useable condition it is recommended that the unit be placed on a preventative maintenance program.

The program should include as a minimum fixed yearly and every three years servicing. Depending on usage, an additional more frequent service (e.g. six monthly, quarterly or monthly) is recommended.

Frequent Inspection program:

- Operational Check (Section 7.1)
- Leak test (Section 7.5)
- Outlet Set Pressure and regulator seat performance (Section 7.5)

Fixed Yearly servicing:

- Frequent Inspection
- Inlet filter, Bodok seal and inlet O-ring replacement (Section 7.2, 7.3 and 7.4)

Fixed Every Three Years Servicing

- Fixed Yearly servicing
- Pressure relief valve check
- Regulator seat capsule replacement.

All repairs or service to your SERIES-O regulator should be performed by trained service personnel only. Contact your nearest Comweld Medical Products distributor for further information.

9. SPARES AND ACCESSORIES

9.1 SERIES-O Accessories

Listed below are some of the accessories suitable for use with a SERIES-O regulator. It is recommended that if any other accessories are intended to be used with a SERIES-O regulator, your nearest authorised distributor should be contacted to check the compatibility of the accessory.

Description	Part No
EZI-FLOW 0-15 L/min oxygen flowmeter	515800
EZI-FLOW 0-2.5 L/min oxygen flowmeter	515824
EZI-FLOW 0-15 L/min air flowmeter	515820
Flowmeter Gauge type 0-14 L/min oxygen	TM17
Humidifier	TM11
Twin-O-Vac	TM117G
Oxygen Demand Valve Resuscitator	552095
Equinox Demand Valve with 2m hose	550011

CAUTION

Use the downstream equipment as required and in accordance with its own Instructions for Use, and if necessary, under clinical or medical supervision.

9.2 User Replacement Parts

Listed below are the items considered to be user replaceable parts. It is recommended that the owner keep stock of items such as Bodok seals to ensure that the SERIES-O regulator is always ready for use.

Description	Part No
Bodok seal, 10 pack	551022
Inlet filter RB38, 10 pack	551024
Inlet filter/retainer RB38/RB39, 10 pack (Screw connections)	551026
Inlet filter RB38 yoke retainer, 10 pack (Yoke inlets)	551028
Inlet O-ring 110 Neoprene, 5 pack (Screw connections)	301073
Instructions for Use	522460

10. SPECIFICATIONS

10.1 Model description

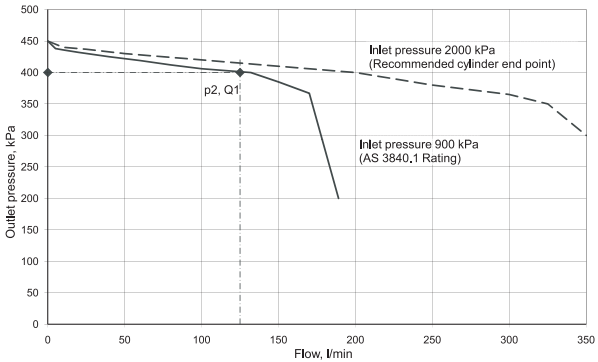
Part No.	Gas	Inlet Connection	Rated Inlet Pressure, P_1	Outlet Pressure, P_2	Standard Discharge, Q_1
518800	Oxygen	AS 2473.2 Type 10 (G5/8 RH INT - Side)	20 000 kPa @ 15˚C	400 kPa	125 l/min
518804	Oxygen	AS 2473.3 (Pin Indexed Yoke)	20 000 kPa @ 15˚C	400 kPa	125 l/min
518808	Nitrous Oxide	AS 2473.3 (Pin Indexed Yoke)	21 000 kPa	400 kPa	125 l/min
518809	Air	AS 2473.3 (Pin Indexed Yoke)	20 000 kPa @ 15˚C	400 kPa	125 l/min
518810	Nitrous oxide/Oxygen 50/50 nom.	AS 2473.3 (Pin Indexed Yoke)	20 000 kPa @ 15˚C	400 kPa	125 l/min
518803	Oxygen - (Oxy-Viva)	N/A	20 000 kPa @ 15˚C	400 kPa	125 l/min
518895	Oxygen	AS 2473.2 Type 10 (G5/8 RH INT - Vert)	20 000 kPa @ 15˚C	400 kPa	125 l/min

Notes:

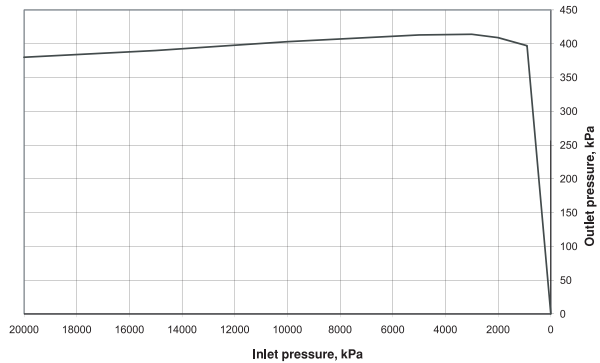
- AS 2473.3 (Pin Indexed Yoke) inlet connections for the nominated gas
- AS 2473.2 Type 10 inlet connection for Oxygen (Medical Oxygen cylinders currently fitted with valves with this connection will be converted to pin-indexed yoke connection over a period of time - see AS 2473.3).
- SIS - outlet connection compatible with Sleeve Indexed System from AS 2896 for the nominated gas

10.2 Technical specifications

Flow Capacity:



Pressure Rise:



Pressure Relief Valve:
All models are fitted with a pressure relief valve designed to vent a flow equivalent to the Standard discharge Q1 at a pressure twice the nominal outlet pressure P2 of the regulator (see AS 3840.1).

Filters:
All SERIES-O regulators are fitted with three inlet filters:

- a sintered filter in the inlet connection, nominal particle retention 50 micron

- a fibre strand filter upstream of the seat capsule,

- a sintered filter fitted to the seat capsule, nominal particle retention 34 micron.

11. WARRANTY

CIGWELD Pty. Ltd. warrants to the purchaser that this equipment is free from defects in material and workmanship for a period of three years from the date of purchase (conditions apply).

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