

Dialflow Regulator

Instructions for Use



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!

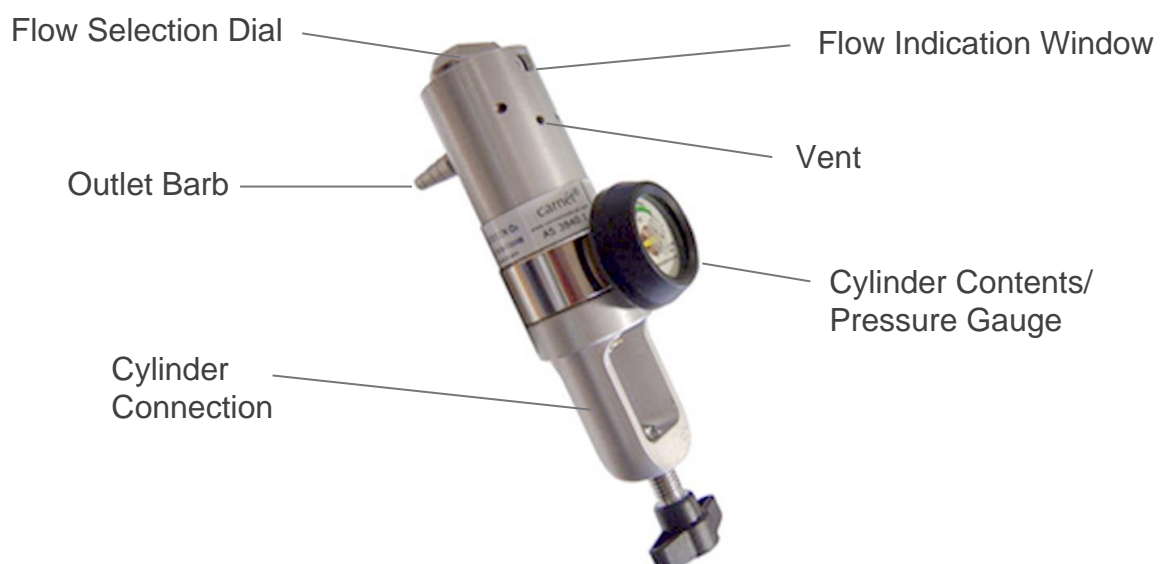
- ▶ Read through this entire instruction manual before using or showing others how to use a Dialflow Regulator. As with all medical equipment, attempting to use this device without a thorough understanding of its operation may result in patient or user injury.
- ▶ Medical gases are, or should be considered, 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.
- ▶ The Dialflow Regulator will deliver zero flow between flow settings. When selecting a new flow setting, ensure that the flow selection dial clicks into place and that a flow is correctly selected. Do not attempt to set it between settings.
- ▶ Never administer oxygen while smoking or when near an open flame.
- ▶ Oxygen is not flammable however an oxygen enriched atmosphere 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. Oxygen must never be allowed to contact oil, grease or other hydrocarbon based substances. Do not use oil or grease on this Dialflow 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 Dialflow Regulator. Ensure hands are clean and dry before operating the equipment.
- ▶ The use of a BPR Medical Dialflow Regulator for gases other than that on the device labelling is expressly prohibited.
- ▶ Never permit compressed medical gases to enter a Dialflow Regulator suddenly. Always open the cylinder valve slowly.
- ▶ Gas specific connectors are fitted to the Dialflow 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 Dialflow 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 Dialflow 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 Dialflow Regulator outlet when opening the cylinder valve.
- ▶ Before removing a Dialflow Regulator from a cylinder, fully close the cylinder valve and release all gas from the regulator.
- ▶ Secure gas cylinders to a wall, stand or cart.
- ▶ Do not submerge the device in any fluid. Ensure that no fluid enters the inlet valve or the vent holes.
- ▶ Only appropriately trained personnel working in controlled conditions must perform disassembly, assembly and testing of regulators and flowmeters.
- ▶ Dialflow 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 device is designed for use for cylinder pressures up to 20,000 kPa (3000 psi/200 bar). Do not attempt to connect this device 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 Dialflow Regulator is not suitable for autoclaving.

3. Functional Description



3.1. Intended Use

The Dialflow Regulator is intended to deliver medical gas at one of eleven pre-set rates directly from a high pressure gas cylinder. Flow is indicated in litres per minute (l/min) and is visible through a window adjacent to the flow selection dial.

3.2. Technical Description

The Dialflow Regulator reduces the high pressure within a gas cylinder to a safe, more manageable pressure for application to patients. There are many types of medical gas cylinder connection used and these may be different from one country to another. Ensure that this regulator is the correct connector for the cylinder to be used.

Once connected to a gas cylinder, and with the cylinder valve opened, the user may select the flow rate prescribed by rotating the gas flow selection dial until the correct flow rate is seen in the viewing window.

The rate at which gas flows from the regulator is controlled by a hole of known size and accuracy. Each flow rate has a different size hole. The output connector allows the user to connect an oxygen facemask, cannula or other application device as appropriate.

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 Dialflow 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 Dialflow Regulator is not beyond the planned service due date. 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 Dialflow 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.

Check that the flow control dial is set to zero and then SLOWLY open the gas cylinder valve cylinder and check for audible leaks.

Turn the flow selection dial to the prescribed setting for the patient and check that gas flow can be felt. If no gas flow is detected, refer to section 7 of this manual.

4.2. Operation

Connect the free end of the oxygen delivery tubing to the outlet barb fitting.

Determine the appropriate gas flow rate in litres per minute (l/min) required for the patient. Turn the flow selection dial until the required rate is visible in the flow indication window; the dial clicks into place and is obvious to the touch.

Warning! There is no flow between the indicated settings provided on the oxygen flowmeter. Do not attempt to set it between settings.

Continue to monitor the patient and check the cylinder contents gauge regularly.

4.3. After Use

Upon completion of the therapy, turn the flow selection dial to zero, close the cylinder valve and disconnect the outlet hose from the Dialflow Regulator.

If you need to remove the Dialflow Regulator from the cylinder, bleed off any residual gas pressure within the regulator by turning on the flow control dial until flow ceases. Remove the Dialflow Regulator from the cylinder and store it carefully where it will be protected from contamination.

5. Maintenance

5.1. Interim Inspection

Dialflow 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. Internal Leak Test

Connect the Dialflow Regulator to a gas cylinder in accordance with this Instruction for Use. Set the flow selection dial to zero and open the cylinder valve. Connect tubing to the outlet barb and immerse the other end of the tube in water. Observe whether any bubbles are formed, which will indicate an internal leak.

5.1.2. Flow Rate Verification

Verify flow rates at all flow settings against those given in the Device Specification in section 6. Mass flow meters with appropriate full-scale ranges for the flow rates are particularly suitable for this.

Alternatively, where flow measuring equipment is not available, a qualitative check can be performed by confirming that gas flow can be sensed to be increasing with each step increase in flow across the full flow range. For higher flow rates, this can be sensed audibly or by holding a hand close to the flow outlet; moistening the skin can increase the cooling sensation and therefore sensitivity to the flow.

For very low flow rates, this may better be achieved by placing the end of a connected tube in a glass of water to observe the bubbles.

5.1.3. External Leak Test

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

Flow ranges A and E must be serviced every 2 years and ranges C and D every 4 years, to ensure the device continues to perform in accordance to its specification. All Dialflow 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 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	Value
Flow Accuracy	±15 % of setting for flow rates above 1 L/min +20 % - 10 % of settings of 1 L/min and below
Input Pressure Range	1000 to 20,000 kPa (10 bar to 200 bar)
Flow Settings (l/min)	Range A: 0, 0.02, 0.03, 0.05, 0.08, 0.12, 0.2, 0.3, 0.5, 0.75, 1.0, 3.0
	Range C: 0, 0.1, 0.2, 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, 1.0, 1.5
	Range D: 0, 0.5, 1.0, 1.5, 2.0, 3.0, 4.0, 5.0, 6.0, 8.0, 10.0, 15.0
	Range E: 0, 0.01, 0.02, 0.03, 0.04, 0.05, 0.06, 0.07, 0.08, 0.09, 0.1, 1.0
Effects on Accuracy	Varying Outlet Pressure: ±3.4 % change in flow per ±20 °C deviation in temperature from 20 °C
	Varying Temperature: Range C and D: No effect up to 136 kPa back pressure. With higher back pressure, flow is reduced and the accuracy specifications herein will not be met. Range A and E: No effect up to 5 kPa back pressure. With higher back pressure, flow is reduced and the accuracy specifications herein will not be met.
Environmental	Transport/Storage/Operation: -20 °C to +60 °C (-4 °F to +140 °F) Humidity: 0-100 % RH non-condensing
Regulatory	UKCA: UK Medical Devices Regulations 2002 – class IIa

Intended Life	12 years
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Applied Standards

AS 2473.3	Valves for compressed gas cylinders Part 3: Outlet connections for medical gases (including pin-indexed yoke connections)
AS 3840.1*	Pressure regulators for use with medical gases Part 1: Pressure regulators and pressure regulators with flow-metering devices
BS EN ISO 10524-1	Pressure regulators for use with medical gases. Pressure regulators and pressure regulators with flow-metering devices
BS EN ISO 15002	Flow-metering devices for connection to terminal units of medical gas pipeline systems

*Conformity to AS 3840.1 has been certified by the manufacturer.

7. Troubleshooting

Fault	Possible Cause	Solution
No gas flow	Gas cylinder turned off	Check gas supply
	Dial-Flow Regulator not connected properly	Check gas specific probe is correctly connected
	Gas cylinder empty	Replace gas cylinder
	Filter blocked	Service or repair is required
	Flow selection dial set to '0'	Select a positive flow rate
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
818-0040	Dial-Flow Regulator - O ₂ Range A - Pin Index/Barb
818-0041	Dial-Flow Regulator - O ₂ Range C - Pin Index/Barb
818-0043	Dial-Flow Regulator - O ₂ Range E - Pin Index/Barb
818-0051	Dial-Flow Regulator - O ₂ Range D - Pin Index/Barb
818-0056	Dial-Flow Regulator – Medical Air Range D - Pin Index/Barb

Spare Parts and Servicing

212-0012	Pin Index Yoke Seal
303-0030	Cylinder Gauge Boot
303-0060	Swivel Cylinder Gauge, 0.3mm Restriction

9. Distributor Details

Australia

BOC Healthcare
Customer Service Centre
10 Julius Avenue
North Ryde, Sydney
NSW, 2113
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