

# Dialflow Regulator

## Instructions for Use

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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



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.
- ▶ 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.
- ▶ 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 PaO<sub>2</sub> or SpO<sub>2</sub> monitoring is carried out when supplemental oxygen is prescribed for critical treatments.
- ▶ 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 when 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.
- ▶ 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).
- ▶ 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 cylinder. Flow is indicated in litres per minute (l/min) and is visible through a flow indication window adjacent to the flow selection dial.

Medical gas is or should be considered a drug and should only be used for medical purposes on the authority of a physician and then strictly in accordance with their instructions. Always refer to the product labelling.

### **3.2. Technical Description**

The Dialflow Regulator reduces the high pressure of the cylinder to a safe, more manageable pressure for application to patients. There are many types of 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 cylinder, and with the cylinder valve opened, the user may select the flow rate prescribed by rotating the flow selection dial until the correct flow rate is seen in the flow indication 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.

Dialflow Regulators have an intended life of 12 years.

## **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, which for pin index regulators is a washer type seal (Bodoc) and for bullnose regulators an O-ring.

Fit the regulator to the cylinder ensuring that it is properly mated and the connectors are done up hand tight.

Turn the flow selection dial (1) fully clockwise and check that the indication in the flow indication window (4) is zero.

Open the cylinder valve slowly with a suitable cylinder key. Check the regulator cylinder contents gauge (6) to verify that there is sufficient gas available.

Connect a sufficient length of tubing (not supplied) to the outlet barb (2).

### **4.2. Testing Prior to Use**

Turn the flow selection dial (1) to its highest setting and check that gas flow can be felt at the patient end of the supply tubing. If no gas flow is sensed, refer to the troubleshooting guide in section 7 of this manual.

Turn off the gas flow by turning the flow selection dial (1) fully clockwise.

### **4.3. Operation**

Connect the free end of the tubing to the patient or patient enclosure using the appropriate connector (not supplied).

Determine the appropriate 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.

Continue to monitor the patient as advised by the clinician. Check the regulator contents gauge (6) regularly.

#### **4.4. After Use**

Upon completion of the therapy, turn the flow selection dial (1) to zero, close the cylinder valve and disconnect the outlet hose from the regulator and the patient.

If you need 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 the flow selection dial (1) to any flow setting until flow ceases. Remove the regulator from the cylinder.

## **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 (1) to zero and open the cylinder valve. Connect tubing to the outlet barb (2) 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 (6) 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. Service

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 suitably qualified person working in a controlled environment.

BPR Medical provides routine servicing if required. Full details of the recommended servicing requirements can also be found in the Service Manual or on our SupportWeb service training system. Please contact us for details.

## 6. Specification

Specification	Value
Flow Accuracy (across inlet pressure range)	±20 % of setting above 1.5 l/min ±30 % of setting for 1.5 l/min and below
Input Pressure Range	1,500 to 20,000 kPa (15 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
Operating, Storage and Transport Temperature Range	-20 °C to 60 °C (-4 °F to +140 °F)
Effects on Accuracy	Varying Inlet Pressure: Typically less than 20 % change across the input pressure range: Minimum: 1,500 kPa Maximum: 20,000 kPa
	Varying Outlet Pressure (Range A and E): No effect up to ~10 kPa back pressure. With higher back pressure, flow is reduced and the accuracy specifications herein will not be met

	Varying Outlet Pressure (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
	Varying Temperature:	±3.4 % change in flow per ±20 °C deviation in temperature from 20 °C
Environmental	Transport/Storage/Operation:	-20 °C to +60 °C (-4 °F to +140 °F)
	Humidity:	0-100 % RH non-condensing
Regulatory	UKCA:	UK Medical Device Regulations 2002 - Class IIb
	Health Canada:	Class 2 - Licence No: 83602

## Applied Standards

BS EN ISO 10524-1:2019	Pressure regulators for use with medical gases. Pressure regulators and pressure regulators with flow-metering devices
BS EN ISO 15001:2011	Anaesthetic and respiratory equipment. Compatibility with oxygen
BS EN ISO 15002:2011	Flow-metering devices for connection to terminal units of medical gas pipeline systems
BS 5682:2015	Specification for probes (quick connectors) for use with medical gas pipeline systems

## 7. Troubleshooting

Fault	Possible Cause	Solution
No gas flow	Gas cylinder turned off	Check gas supply
	Dialflow Regulator not connected properly	Check gas specific probe is correctly connected
	Gas cylinder empty	Replace gas cylinder
	Filter blocked	Service or repair 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
818-0001	Dialflow Regulator - O <sub>2</sub> Range A - UK Bullnose/Barb
818-0002	Dialflow Regulator - O <sub>2</sub> Range A - Pin Index/Barb
818-0005	Dialflow Regulator - O <sub>2</sub> Range C - Pin Index/Barb
818-0006	Dialflow Regulator - O <sub>2</sub> Range C - UK Bullnose/Barb
818-0009	Dialflow Regulator - O <sub>2</sub> Range D - Pin Index/Barb



818-0010	Dialflow Regulator - O <sub>2</sub> Range D - UK Bullnose/Barb
818-0017	Dialflow Regulator - O <sub>2</sub> Range D - Pin Index/Barb/Aux Schrader
818-0018	Dialflow Regulator - O <sub>2</sub> Range D - UK Bullnose/Barb/Aux Schrader
818-0024	Dialflow Regulator - Air Range D - UK Bullnose/Barb
818-0025	Dialflow Regulator - Air Range D - UK Bullnose/Barb
818-0028	Dialflow Regulator - Air Range D - Pin Index/Barb/Aux Schrader
818-0030	Dialflow Regulator - O <sub>2</sub> Range E - UK Bullnose/Barb
818-0031	Dialflow Regulator - O <sub>2</sub> Range E - Pin Index/Barb
818-0037	Dialflow Regulator - Air Range D - UK Bullnose/Barb/Aux Schrader

## Spare Parts and Servicing

303-0030	Cylinder Contents Gauge
303-0060	Cylinder Contents Gauge Boot
212-0012	Pin Index Yoke Seal
212-0048	Benelux Bullnose O-ring
212-0094	UK Bullnose O-ring
610-0056	Dialflow Regulator Service Kits (Pack of 10)
610-0057	Bodok Bonded Seal (Pack of 50)
610-0058	Bullnose O-ring (Pack of 50)

## 9. Distributor Details

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