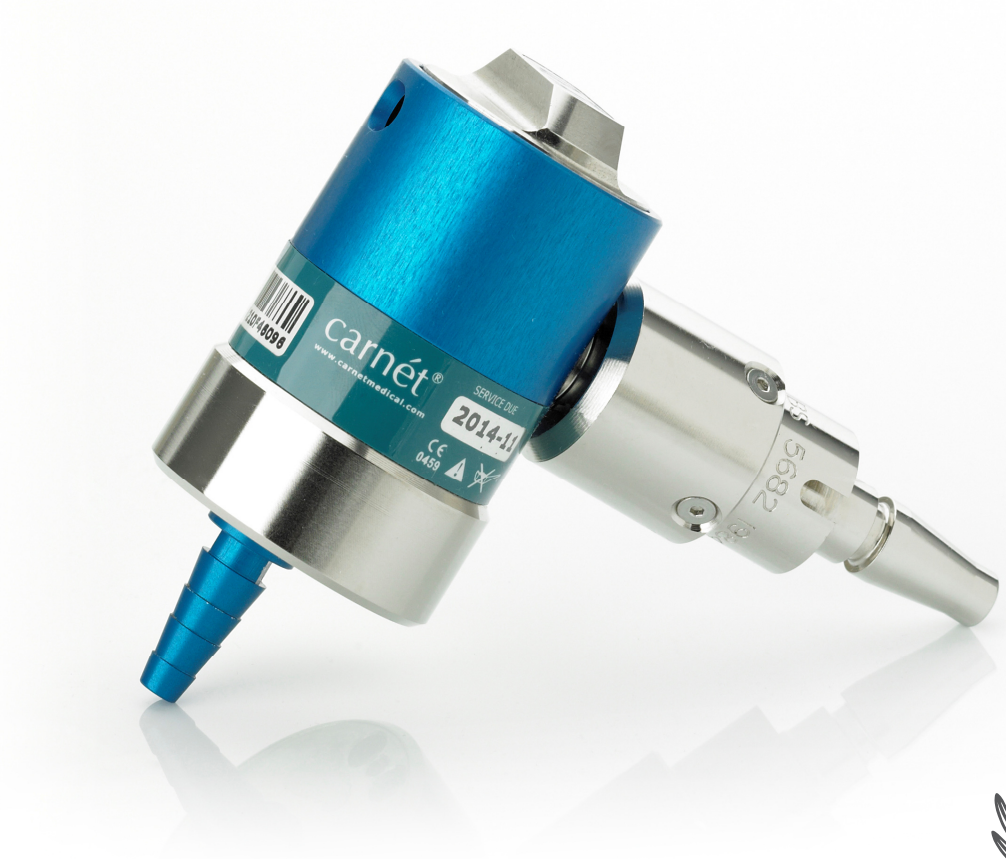
microflow

Microdial Flowmeter

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
	Attention, consult accompanying documents
	Use no oil
CE 0120	CE Marked to Medical Device Directive 93/42/EEC as amended by directive 2007/47/CE
	No smoking
	Service due date
SN 1304X12345 YYMM	Date of manufacture identification

2. Warnings and Cautions

2.1. Warnings!

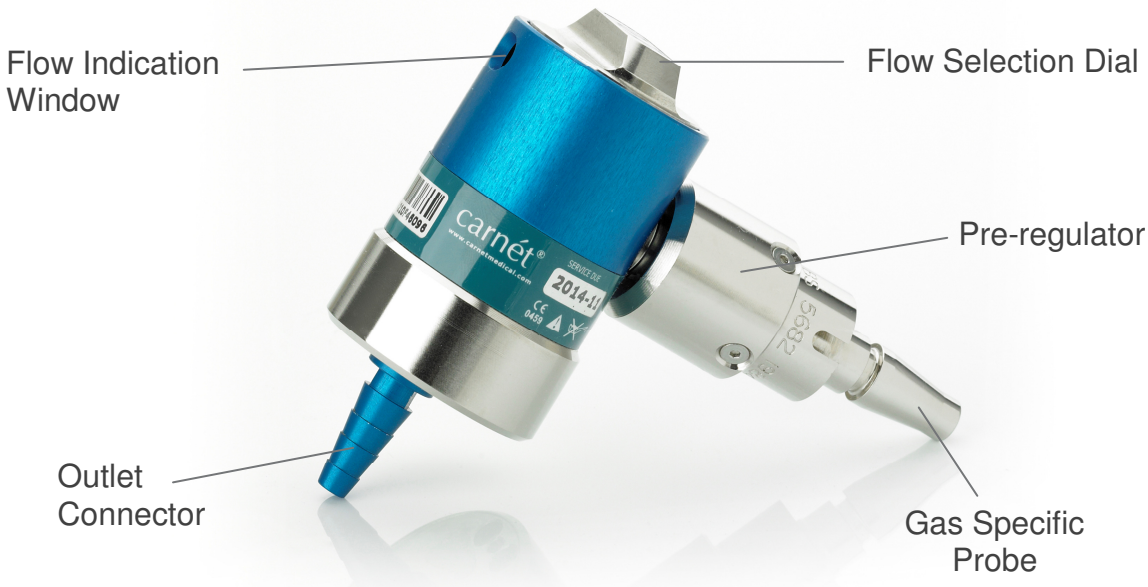
- Read through this entire instruction manual before using or showing others how to use a Microdial Flowmeter. As with all medical equipment, attempting to use this device without a thorough understanding of its operation may result in patient or user injury.
- Medical oxygen is or should be considered a 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.
- If using a cylinder and regulator, ensure that the device is connected to the regulator and the cylinder valve is properly opened before beginning therapy.
- Ensure that the medical oxygen supply is sufficient for the proposed therapy and is supplied within the pressure range given in the Device Specification. If the supply is a gas cylinder, check the cylinder contents gauge regularly.
- 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. It is essential that PaO2 or SpO2 monitoring is carried out when supplemental oxygen is prescribed.

- The Microdial Flowmeter 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 cover the vent hole in the pre-regulator as this will change the device calibration.
- Do not submerge a Microdial Flowmeter in any fluid. Ensure that no water is allowed to enter ports or vent holes.
- The accuracy of the flowmeter will be affected if the input pressure is other than stated in the specifications.
- Always disconnect the flowmeter from the gas supply when it is not in use.
- 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 come into contact with oil, grease or other hydrocarbon based substances. Do not use oil or grease on this Microdial Flowmeter.
- Never administer oxygen while smoking or when near an open flame.
- A gas specific connector is fitted to the Microdial Flowmeter. Do not attempt to modify the fittings to suit other gases or fitting systems.
- Only appropriately trained personnel working in controlled conditions may disassemble or assemble this Microdial Flowmeter.

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 Microdial Flowmeter is intended to control the flow of medical oxygen during oxygen therapy in both homecare and clinical environments. The flow selection dial has 12

positions, including 11 discrete flow rates and an off position. Flow is indicated in litres per minute (l/min) and is visible through a window adjacent to the flow selection dial.

Medical oxygen 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 medical oxygen product labelling.

3.2. Technical Description

The Microdial Flowmeter has a flow selection dial that is rotated to select the desired oxygen flow. Rotating the dial changes the size of the orifice through which the gas passes and consequently adjusts the gas flow rate.

The Microdial Flowmeter includes a pre-regulator (pressure regulator) upstream of the metering orifice plate. The pre-regulator provides a consistent pressure upstream of the metering orifice plate over a wide range of inlet pressures.

The Microdial Flowmeter has inlet and outlet connectors. The inlet connector is the larger of the two and is a gas specific oxygen probe for connection to the oxygen supply. The smaller outlet connector may be either a barbed outlet for direct connection to oxygen delivery tubing or a threaded DISS (9/16" UNF) connector for connection to a bubble humidifier.

4. Operating Instructions

4.1. Preparation and Connection

Turn the flow selection dial fully clockwise and check that the indication in the flowmeter window is zero.

Connect the medical oxygen probe securely to the oxygen wall outlet or the equivalent outlet of a pressure regulator connected to an oxygen cylinder.

Warning! Where the gas specific connector is dependent on a threaded fastener (e.g. DISS CGA – V5 1240, AS 2902/SIS handwheel) offer device to outlet and connect a few turns. Align device to the final vertical position and fully hand tighten the connection before turning on the supply pressure. Do not use the device to tighten or lock the connection.

For quick connector probes (e.g. BS5682, DIN, AFNOR), ensure that the connection is correctly made by gently pulling the flowmeter before turning on the supply pressure.

If the medical oxygen supply is provided from a gas cylinder, turn on the oxygen supply at the cylinder.

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

4.2. Testing Prior to Use

Turn the flow seclection dial to its highest setting and check that gas flow can be felt at the patient end of the supply tubing. If no medical oxygen flow is sensed refer to Section 7 Troubleshooting of this manual.

Turn off the oxygen flow by turning the flow selection dial fully clockwise.

4.3. Operation

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

Determine the approximate oxygen flow rate in l/min required for the patient. Turn the flow selection dial until the closest rate to this is clearly visible in the flowmeter window. Ensure the flow selection dial is in the latched position and the flow rate is visible in the window. It will be obvious to the touch when the selection dial clicks into place.

Warning! The Microdial Flowmeter will deliver zero flow between flow settings.

If the patient requires more or less oxygen flow, this is simply achieved in distinct stages by rotating the flow selection dial.

Check the gas cylinder contents regularly (if applicable) during use of the Microdial Flowmeter and be aware that the supply tubing may be a trip hazard.

4.4. After Use

When therapy is complete, disconnect the Microdial Flowmeter from the gas supply. Where the medical oxygen is being supplied from a cylinder, turn the cylinder off.

Store the Microdial Flowmeter in a clean and dry environment between uses.

5. Maintenance

5.1. Interim Inspection

Microdial Flowmeters should be cleaned, inspected for damage and performance checked regularly. The frequency of such checks depends on usage, but as a guideline if the flowmeter 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 Microdial Flowmeter with an alcohol or disinfecting wipe.

5.1.2. Internal Leak Test

Attach the flowmeter to the medical oxygen supply and turn the flow selection dial to '0'. Connect a length of tubing to the outlet barb and immerse the other end of the tube in water. Any gas bubbling through indicates an internal leak. If any leakage is found the flowmeter should be removed from use and serviced as described in section 5.2.

5.1.3. External Leak Test

Attach the flowmeter to the medical oxygen supply and turn the flow selection dial to its highest flow rate (1 or 3 l/min depending on model). Apply an oxygen compatible leak test solution to all joints and check for signs of leakage. If any leakage is found the flowmeter should be removed from use and serviced as described in section 5.2.

5.1.4. Flow Test

Verify flow rates at all flow settings against specification.

5.2. Service

The Microdial Flowmeter must be serviced every 2 years to ensure that it continues to perform in accordance with its specification. Microdial Flowmeters 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**. 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	
Supply Pressure	Nominal Inlet Pressure 345 kPa to 500 kPa (50 psi to 73 psi)	
	Maximum 1000 kPa (145 psi)	
	Minimum 280 kPa (40 psi)	
Flow Setting (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 E: 0, 0.01, 0.02, 0.03, 0.04, 0.05, 0.06, 0.07, 0.08, 0.09, 0.1, 1.0	
Filtration	Sintered bronze: 40 µm nominal first stage, 5 µm nominal second stage	
Flow Accuracy	±10 % of setting at 1 l/min and above, +20 % to -10 % of setting below 1 l/min	
Effects on Accuracy	Varying Inlet Pressure:	Less than 6 % of reading for a ±100 kPa change in nominal inlet pressure. Less than 15 % change in reading in the range 280 kPa to 580 kPa.
	Varying Temperature:	±7 % in the range 20 ℃ ±20 ℃
	Varying Outlet Resistance:	Less than 1 % of reading up to 5 kPa back pressure
Environmental	Transport/Storage/Operation: -20 ℃ to +60 ℃ (-4 ℉ to +140 ℉) Humidity: 0-100% RH non-condensing	
Regulatory	CE: Medical Device Directive 93/42/EEC – Class lla FDA: Class 1	

Applied Standards	
BS EN ISO 10524-4	Pressure regulators for use with medical gases. Low-pressure regulators
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 EN 13544-2+A1	Respiratory therapy equipment. Tubing and connectors
BS 5682	Specification for probes (quick connectors) for use with medical gas pipeline systems
SS 875 24 30	Medical gas pipeline systems. Connectors for medical gases

7. Troubleshooting

Fault	Possible Cause	Solution
No gas flow	Gas cylinder turned off	Check gas supply
	Flowmeter not connected properly	Check gas specific probe is correctly connected
	Gas cylinder empty	Replace gas cylinder
	Medical gas terminal unit on a pipeline system is isolated	Seek advice from someone authorised to operate the medical gas pipeline system isolation valves
	Filter blocked	Service or repair required
	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
816-0026	Microdial Flowmeter - Range A - Hose Barb Outlet (AS 2902)
816-0027	Microdial Flowmeter - Range E - Hose Barb Outlet (AS 2902)
816-0039	Microdial Flowmeter - Range A - Hose Barb Outlet (BS 5682)
816-0040	Microdial Flowmeter - Range E - Hose Barb Outlet (BS 5682)

Spare Parts and Servicing	
604-0034	Microdial Flowmeter Output Barb Assembly
604-0035	Microdial Flowmeter DISS Assembly
610-0040	Microdial Flowmeter Service Kit (5 pack)
999-0003	Microdial Flowmeter Service

9. Distributor Details

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Customer Service Centre
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Worsley
Manchester
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www.bochealthcare.co.uk