



Holdings Ltd

F1600 Series Pipeline Flowmeter

Instructions for use

9. Technical Data - Specifications

- a) Single Flowmeter: working pressure: 400 kPa (58psi/4 bar)
- b) Twin Flowmeter: working pressure: 400 kPa (58psi/4 bar)
- c) 18LPM Flowmeter: Working pressure: 400 kPa (58psi/4bar) Max Flow 18 LPM
- d) Flowrates: 0-15 LPM (Oxygen & Air) 0-4 LPM (Oxygen & Air)
 0-12 LPM (Co2 & N20) 0-3 LPM (Co2)
 0- 8 LPM (Helium & Heliox)

Inlet Fittings

All Single and Twin Flowmeters are available with either a BS Standard Probes or Nut type fitting (AFNOR & DIN fitting are also available). No Connections are to be changed on the flowmeters.

Calibration Range

All Flowmeters are factory calibrated to ±10% of the full-scale reading.

Test Specification

- a) Required testing pressure: 400 kPa (58psi/4 bar)
- b) Calibration tolerance: ± 10%
- c) Leak test: permissible leak: None

10. Accessories and Replacement Parts

	Product Code
a) Adult Oxygen Face Mask:	IS1106
b) Pediatric Oxygen Face Mask:	IS1140
c) Delivery Tube:	IS1174
d) Humidifier Adapter:	SP554
e) Humidifier Bottle Assembly:	H110
f) Tubing Nipple:	SP46 (White)/SP46B (Black)
g) Air Safety Shield:	FM0001 (Female); FM0002 (Male)
h) Service Kit	SKF6-O2; SKF6-AIR

Note: All devices carry a 7-year warranty.

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End of Life – Return to Oxylitre or dispose of via local protocol

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Consult instructions for use



Product should be kept dry.
 Fragile – handle with care.
 Temperature limitation 0° – 40°C
 Refer to user instructions



Single Flowmeter with Probe

Twin Flowmeter

Made in the UK



1. Introduction

The Oxylitre F1600 series (Pressure Compensated) Flowmeter has been designed specifically for medical use and conforms to the requirements of BS EN ISO 15002, BS EN ISO 14971, BS EN ISO 15001 and the 93/42/EEC European Medical Device Directive (Class IIa device). Products are available in either Single or Twin Flowmeter configurations and for use with Oxygen, Nitrous Oxide, Heliox, Medical Air and Carbon Dioxide gases. The 18 LPM format is specific for Medical oxygen & Air only. The devices are constructed with a brass/chrome plated alloy body and with an easy-to-read ball type flow indicator tube calibrated in litres per minute.

2. Specifications

Inlet Connection

Flowmeter gas probe connectors comply with the BS & European Standards for the safety prevention of connecting an incorrect gas. Flowmeters that are fitted with 3/8 BSP nut connectors are specifically for the attachment to Oxylitre R1610 series Regulators. **ATTENTION:** Under no circumstance are the connectors to be changed.

Outlet Connection

The units are fitted with a universal sized tubing connector that will accept most types of delivery tube. Flowmeters are also available with a 9/16unf male Humidifier adapter for the attachment of a (female threaded) Humidifier Bottle Assembly. **ATTENTION:** Under no circumstances are connectors to be changed.

Filters

The Flowmeter is fitted with an integral filter, which protects the device and the patient from receiving any foreign matter.

Please Note: The filters are replaceable by qualified technicians only.

Gas Supply

The F1600 Series Flowmeter has been designed to operate from a gas supply of 400 kPa (4 bar/58 psi) of pressure.

Accuracy

The Flowmeters are factory calibrated to an accuracy of $\pm 10\%$ of the full-scale reading at a temperature of 20°C. The readings on the inner tubes have been calibrated with a pressure source 400 kPa (58 psi). The accuracy of the flow rate may be affected if there are any restrictions either at the inlet or outlet.

3. Flowmeter Set-up

Safety Warning: Before use, the Flowmeter must be inspected for any obvious damage such as cracks and broken parts.

Ensure that the Flowmeter has been tested for any detectable leaks. Qualified servicing personnel only should perform this.

NO leaks are permissible on the device.

Before connecting the Flowmeter to a pressurised gas supply, ensure that the Flowmeter has been fully shut off. This is achieved by turning the control knob clockwise until it is shut off.

4. Flowmeter Inspection & Test Procedure

- (Before Patient Use)
- The following Flowmeter Inspection and test procedure must be carried out prior connection to a patient therapy device. Please complete the "Flowmeter Set Up" procedure in section "3".



Always read from the centre of the ball

- Connect the pressure Flowmeter into the appropriate gas outlet (identified on the product label) and ensure that the unit is securely locked into the outlet.
- With the Flowmeter fully shut off ensure that the Flowmeter Ball rests on the bottom of the inner tube without any movement.
- Turn the control knob anti-clockwise to increase the gas flow and until the Flowmeter Ball reaches the "Flush" indicator. Keep it at this point for approximately 2 seconds, this test ensures that the gas flow can be obtained. Turn the control knob clockwise and shut off the gas supply.

Select the flow that will be required for patient therapy. Turn the control knob anti-clockwise until the Flowmeter Ball reaches the selected gas flow rate. The calibrated markings are to be read at the centre of the ball. Ensure that the Flowmeter Ball does not fluctuate.

Turn the control knob clockwise fully to shut off the gas flow.

DO NOT disassemble the Flowmeter while it is under pressure

The user should review the instructions for use of all devices, being used in conjunction with these product/s

5. Patient Therapy

- Ensure that the Flowmeter test and inspection procedure has been carried out in section 4 prior to use.
- Attach the therapy device (i.e., tubing or humidifier bottle with mask etc) to the outlet fitting.
- Turn the control knob anti-clockwise until the selected gas flow rate is reading at the centre of the ball.
- During the patient administration periodically check the flow rate is reading the selected flow. Due to possible in line restrictions the gas the flow rate may require re-adjustment.

6. Fire and Explosion Safety Precautions

DO NOT use any grease or oil within Oxygen filled environment, as these substances are combustible in the presence of Oxygen.

DO NOT use an Oxygen/Nitrous Oxide Flowmeter within an environment where the gas may be exposed to any naked flames, sparks, cigarettes/cigars, or any open electrical appliances. This precaution applies during and after a reasonable period of patient administration.

7. Maintenance

A Medical Flowmeter forms part of an essential support system. Flowmeters must be treated with care and be serviced on a regular basis, (i.e. preventative maintenance) to ensure the unit's reliability and quality for the intended purpose. Clean outer surfaces with a propriety diluted mild non-alkaline disinfectant/detergent or wipe (always read and follow manufacturer's instructions, especially noting material compatibility). **It is important to note that the Polycarbonate used in the Flowmeter Tube Cover, Tubing Nipple and Control Knob is degraded by alkaline solutions, ammonia gas and its solutions, and amines.**

Inspection

Recommended at least annually by a Service Engineer and consist of:

- Leak Test
- Calibration Check

Service/Repair

Fully qualified technicians should only carry out servicing. **A Major Service is recommended every 5 years.** For service/repair enquiries and information, please contact our sales office.

NEVER USE FAULTY EQUIPMENT.

Preventative maintenance ensures safety for the patient and user¹.

1. MHRA Device Bulletin DB2006(05); Managing Medical Devices; November 2006.

8. Warning: (General)

- **DO NOT** use a Flowmeter if any damage has been detected (i.e. any cracks and/or damage to any plastic components, loose fittings etc). It may cause possible injury when the unit becomes pressurised.
- Always carry out the test and inspection procedure before use. If a Flowmeter fails the test and inspection the unit will require servicing or repair.
- The Flowmeter should only be used with the flow tube in an upright position.
- **DO NOT** apply any labels to the outer plastic case
- Only trained healthcare professionals to use.
- The user should review the instructions for use of all devices, being used in conjunction with these product/s