USER MANUAL

OXYGEN SELECT FLOWMETER

MODEL: 3MFA1001

ISO 13485 C ERTIFIED

Your local distributor:

Medical Dynamics

TECHNOLOGY OF THE FUTURE, TODAY

866-624-3952

www.thinkMDI.net

CE 0197

SAVE THESE INSTRUCTIONS

⚠CAUTION Federal (U SA) law restricts this device to sale by or on the order of a physician.

PRECISION MEDICAL

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RECEIVING / INSPECTION

Remove the Precision Medical, Inc. Flowmeter from the packaging and inspect for damage. If there is any damage, DO NOT USE and contact your Provider.

INTENDED USE

The flowmeter is intended for use by physicians, respiratory therapists and other authorized hospital personnel to administer selected doses of medical oxygen to a patient.

READ ALL INSTRUCTIONS BEFORE USING

This manual instructs a Professional to install and operate the Flowmeter. This is provided for your safety and to prevent damage to the Flowmeter. If you do not understand this manual, DO NOT USE the Flowmeter and contact your Provider.

SAFETY INFORMATION - WARNINGS AND CAUTIONS

⚠WARNING Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

⚠CAUTION Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.

CAUTION Used without the safety alert symbol indicates a potentially hazardous situation which, if not avoided, may result in property damage.

CONSULT ACCOMPANYING DOCUMENTS

Symbol for “USE NO OIL”

Symbol for “NO SMOKING”

CE
0197

Symbol indicates the device complies with the requirements of Directive 93/42/EEC concerning medical devices and all applicable International Standards. **(On CE marked Devices ONLY)**

⚠WARNING

- **ALWAYS** confirm prescribed flow before administering to patient and monitor flow on a frequent basis.
- This Flowmeter contains magnetic, ferrous material that may affect the results of an MRI.
- **ALWAYS** rotate and lock connector body into place before using the Flowmeter. After activating flowmeter, be sure patient is receiving flow from proper outlet port.
- FLOW IS ONLY DELIVERED to the selected port indicated by the "ON" arrow ON.
- NO FLOW is delivered to the ports indicated by the "OFF" arrows OFF.

To Reduce the Risk of Fire or Explosion:

- ALWAYS follow ANSI and CGA standards for Medical Gas Products and Flowmeters (E-7) and Oxygen Handling (G-4).
- **DO NOT** use oils, greases, organic lubricants or any combustible materials on or near this Flowmeter.
- **DO NOT** use near any type of flame or flammable/explosive substances, vapors or atmosphere.
- **DO NOT** smoke in an area where oxygen is being administered.

⚠CAUTION

- This Flowmeter must be operated with the Flow Tube in a vertical, upright position.
- Only personnel instructed and trained in its use should operate this Flowmeter.
- Be sure all connections are tight and leak free.
- Only use oxygen-safe leak detector to test for leaks.
- **DO NOT** autoclave.
- **DO NOT** gas sterilize with EtO (Ethylene Oxide)
- **DO NOT** clean with aromatic hydrocarbons.
- **DO NOT** immerse Flowmeter in any kind of liquid. This will void the warranty.
- Store Flowmeter in a clean area when not in use.
- Only qualified personnel should repair this Flowmeter.

(Continued on inside)

SPECIFICATIONS

Model	3MFA1001
Flow Range	0-15 lpm
Gas	Oxygen
Increments	.5 lpm from .5 to 5 lpm 1 lpm from 5 to 15 lpm
Accuracy	±.25 lpm from .5 to 5 lpm ±.5 lpm from 6 to 15 lpm
Max Flush Flow Range	60 - 80 lpm @ 50 psi (3.4 bar) FOR INTERNATIONAL UNITS SEE PRODUCT LABEL
Transport / Storage Requirements	-40°F (-40°C) to 140°F (60°C)

NOTE: Storage / Transport outside the specified range may cause damage to the flowmeter.

The effect on accuracy of flow due to variations in ambient temperature is standard accuracy +7.3% @ 0°C and -3.0% @ + 40°C.

Flowmeters calibrated at 50 psi (3.4 bar), 70°F (21°C), standard atmospheric pressure.

International flowmeters are calibrated per specifications marked on Flow Tube.

Specifications are subject to change without prior notice.

OPERATING INSTRUCTIONS

⚠WARNING

Read this User Manual before installing or operating the Flowmeter.

CAUTION

Inspect the Flowmeter for visual damage before use, DO NOT USE if damaged.

NOTE: Precision Medical, Inc. strongly recommends the use a of kink proof Cannula.

1. Turn Knob to the "OFF" position.
2. Connect the Flowmeter to a 50 psi (3.4 bar) oxygen gas source. For international Flowmeters, connect to appropriate oxygen source pressure.
3. Verify that the Float Ball is at the very bottom of the Flow Tube.
   NOTE: If the Float is not resting at the bottom of the Flow Tube, the Flowmeter is leaking; consult the Troubleshooting Guide.
4. Adjust Flow:
   To **increase** - Turn Knob **counterclockwise**
   To **decrease** - Turn Knob **clockwise**
5. Set flow by aligning center of Float Ball with indicator lines on the Flow Tube.
6. Adjusting flow beyond the last calibrated indicator line will result in an undetermined flow.
7. To obtain maximum flush flow, turn Knob fully Counterclockwise.
   NOTE: Flush flow is any flow above the last calibrated line on the Flow Tube with an unrestricted flow, as per Specifications.
8. Connect up to three (3) medical devices to the outlet ports.
9. Push the Locking Button UP and rotate Connector Body to align the "ON" indicating ON arrow with the desired outlet port. "OFF" indicating arrows OFF should align with the other two (2) ports not in use.

⚠WARNING

- **ALWAYS** rotate and lock connector body into place before using the Flowmeter. After activating flowmeter, be sure patient is receiving flow from proper outlet port.
- FLOW IS ONLY DELIVERED to the selected port indicated by the "ON" arrow ON.
- NO FLOW is delivered to the ports indicated by the "OFF" arrows OFF.

To avoid injury to patient:

- ALWAYS confirm prescribed flow before administering to patient and monitor flow on a frequent basis.

CAUTION

- **DO NOT** over tighten Knob when turning off. This will cause damage to the Flowmeter.
- Pressures other than those indicated on the Flow Tube may affect the accuracy of the indicated flow.
- Gas Temperatures other than 70°F (21°C) may affect the accuracy of the indicated flow.
- Attaching accessories to the outlet (which may increase resistance to outlet flow) may change indicated flow but will not affect the accuracy of the flow.
- ONLY use oxygen indexed fittings to connect Flowmeter to oxygen source.

CLEANING INSTRUCTIONS

1. Disconnect all connections before cleaning.
2. Clean exterior surfaces of the Flowmeter with a cloth dampened with a mild detergent and water.
3. Wipe dry with a clean cloth.

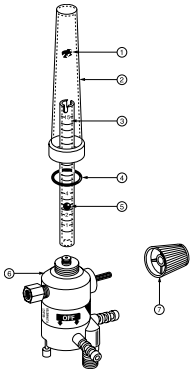
TROUBLESHOOTING

If the Flowmeter fails to function, consult your Provider or Precision Medical, Inc.

Problem	Probable Cause	Remedy
Will not shut off	• Leak • Defective Valve	• Replace Tetraseal and/or Housing • Replace Body Assembly
Sticking Float Ball	• Debris in Flow Tube	• Clean Flow Tube
Unable to set desired flow	• Blocked Inlet	• Replace Body Assembly
Knob will not turn	• Valve seized	• Replace Body Assembly
No flow at outlet	• Outlet port in “OFF” position	• Align Outlet port with “ON” arrow • Turn Knob counterclockwise

ANY product returned to Precision Medical, Inc. for repair must be packaged so as to prevent shipping damage. Repairs for damage due to improper packaging will be charged to the customer.

REPLACEMENT PARTS



Description		Model# 3MFA1001 0-15 lpm Oxygen 50 psi (3.4 bar)
1	Disc	1114
2	Housing	1143
3	Flow Tube	1010
4	Tetraseal™	1123
5	Float Body	1005
6	Body Assy	503506
7	Knob	1007

International parts specifications and specific ratings are available upon request.

DECLARATION OF CONFORMITY

Manufacturer: Precision Medical, Inc.
300 Held Drive, Northampton, PA 18067, USA
CONTACT: Quality Manager
Phone: 610-262-6090

Authorized European Representative: Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands

Product: Flowmeters
Model(s): 3MFA
MDD Class: IIb
Classification criteria: Clause 3.2 Rule 11 of Annex IX of MDD

As delivered, the object of the declaration described above is in conformity with the requirements of MDD 93/42/EEC Annex II.3 and the following documents:

Document	Title	Edition
93/42/EEC	Council Directive Concerning Medical Devices	1993
BS EN 13220	Flow Metering Devices for Connection to Terminal Units of Medical Gas Pipeline Systems	1999
ISO 14971	Medical Devices - Application of risk management to Medical Devices, 2nd Edition	2007
EN 980	Graphical Symbols for Use in the Labeling of Medical Devices	2003
EN 1041	Information supplied by the Manufacturer with Medical Devices	1998
EN ISO 15001	Anaesthetic and Respiratory Equipment - Compatibility with Oxygen	2003

Notified Body: TÜV Rheinland Products Safety GmbH CE 0197
EC Certificate No.: HD 60019110 0001

LIMITED WARRANTY AND LIMITATION OF LIABILITY

Precision Medical, Inc. warrants that the Medical Gas Flowmeter (the Product) will be free of defects in workmanship and/or material for the following period:

(a)	Flow Tube and Housing	Lifetime of the product
(b)	Needle Valve	Five (5) years from shipment
(c)	All other parts of the Medical Gas Flowmeter not identified in (a) or (b) above	One (1) year from shipment

Should any failure to conform to this warranty appear within the applicable period, Precision Medical, Inc. shall, upon written notification thereof and substantiation that the goods have been stored, installed, maintained and operated in accordance with Precision Medical, Inc.'s instructions and standard industry practice, and that no modifications, substitutions, or alterations have been made to the goods, correct such defect by suitable repair or replacement at its own expense.

ORAL STATEMENTS DO NOT CONSTITUTE WARRANTIES.

The representative of Precision Medical, Inc. or any retailers are not authorized to make oral warranties about the merchandise described in this contract, and any such statements shall not be relied upon and are not part of the contract for sale. Thus, this writing is a final, complete and exclusive statement of the terms of that contract.

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OTHER WARRANTY OF QUALITY, WHETHER EXPRESS OR IMPLIED.

Precision Medical, Inc. shall not under any circumstances be liable for special, incidental or consequential damages including but not limited to lost profits, lost sales, or injury to person or property. Correction of non-conformities as provided above shall constitute fulfillment of all liabilities of Precision Medical, Inc. whether based on contract, negligence, strict tort or otherwise. Precision Medical, Inc. reserves the right to discontinue manufacture of any product or change product materials, designs, or specifications without notice.

Precision Medical, Inc. reserves the right to correct clerical or typographical errors without penalty.

503283 Rev5 09/5/08 (5M) Printed in USA