

USER MANUAL

FLOWMETER

MODELS: 8MFA1001 (shown)

8MFA2001

8MFA4001

ISO 13485 Certified

Your local distributor:

 **Medical Dynamics**

TECHNOLOGY OF THE FUTURE, TODAY

866-624-3952

www.thinkMDI.net



CE
0197

SAVE THESE INSTRUCTIONS

CAUTION

Federal (USA) 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 or air 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"

WARNING

- Use this Flowmeter only for its “Intended Use” as described in this manual.
- ALWAYS confirm prescribed flow before administering to patient and monitor flow on a frequent basis.
- This Flowmeter does not contain magnetic, ferrous material and should not affect the results of an MRI; however, any inlet fitting(s) used need(s) to be checked for MRI compatibility.

To Reduce the Risk of Fire or Explosion:

- Always follow ANSI and CGA standards for Medical Gas Products and Flowmeters and Oxygen Handling.
- **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.
- **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.
- Store the Flowmeter in a clean area free of grease, oil, and other sources of contamination.
- **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.

SPECIFICATIONS

Model	8MFA4001	8MFA1001	8MFA2001
Gas	OXYGEN	OXYGEN	AIR
Scale	0-8 lpm	0-15 lpm	0-15 lpm
Increments	0.5 lpm (starts at 0.5 lpm)	0.5 lpm from 0.5 to 5 lpm 1 lpm from 5 to 15 lpm	0.5 lpm from 0.5 to 5 lpm 1 lpm from 5 to 15 lpm
Accuracy	± 0.25 lpm	± 0.25 lpm from 0.5 to 5 lpm ± 0.5 lpm from 6 to 15 lpm	± 0.25 lpm from 0.5 to 5 lpm ± 0.5 lpm from 6 to 15 lpm
Maximum Flush Flow Range	44 - 67 lpm		
Transport / Storage Requirements	-40°F to 140°F (-40°C to 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.

The above flowmeter models are calibrated at 50 psi (3.4 bar), 70°F (21°C), standard atmospheric pressure. International models are calibrated at various pressures specified on the flow tube.

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 of kink proof Cannula.

1. Turn Knob to the “OFF” position.
2. Connect the Flowmeter to an appropriate gas source. The appropriate gas and pressure are specified on the Flow Tube.
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 product is leaking; consult your Provider or Precision Medical, Inc.

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” listed above.

⚠WARNING

To avoid injury to patient:

- ALWAYS confirm prescribed flow before administering to patient and monitor flow on a frequent basis.
- **DO NOT** immerse the Flowmeter in any kind of liquid. This will cause damage to the Flowmeter and will void the warranty.

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 appropriate gas specific indexed fittings to connect Flowmeter to gas source. Use Oxygen connections for oxygen Flowmeters; use air connections for air Flowmeters.

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.

MAINTENANCE

DO NOT attempt to repair the Flowmeter. There are no user serviceable parts.

TROUBLESHOOTING

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

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): 8MFA

MDD Class: IIa

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:

<u>Document</u>	<u>Title</u>	<u>Edition</u>
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 ISO 15001	Anaesthetic and Respiratory Equipment - Compatibility with Oxygen	2003
EN 1041	Information supplied by the Manufacturer with Medical Devices	1998

Notified Body: TÜV Rheinland Products Safety GmbH  0197

EC Certificate No.: HD60019110 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 | 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.