

Operating and Maintenance Manual

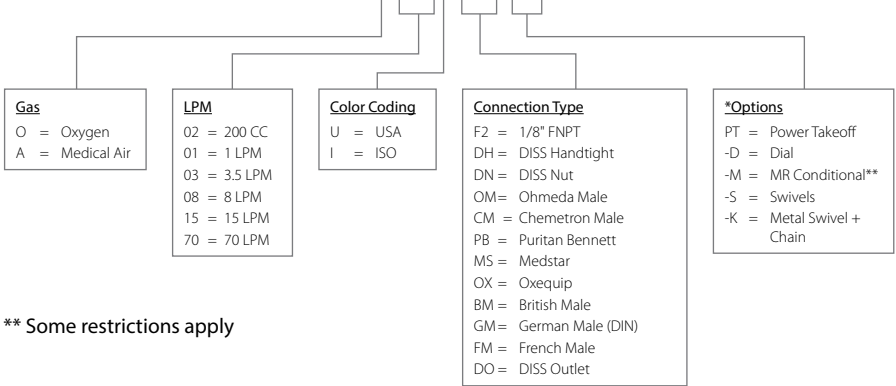
Flowmeter



Amico

Models

FMX-XXY-XX(YY)*



** Some restrictions apply



CAUTION: United States federal law restricts this device to sale by or on the order of a physician.

User Responsibility

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.


Symbols Glossary



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.



Manufacturer - Indicates the medical device manufacturer (ISO 15223-1 5.1.1).



Catalog Number - Indicates the manufacturer's catalogue number so that the medical device can be identified (ISO 15223-1 5.1.6).



Serial Number - Indicates the manufacturer's serial number so that a specific medical device can be identified (ISO 15223-1 5.1.7).



USE NO OIL.



For pediatric/neonatal use.



MR Conditional - An item with demonstrated safety in the MR environment within defined conditions (ASTM F2503-23).

Receiving Inspection

Remove the Flowmeter from the packaging and inspect for damage. If there is any damage, **DO NOT USE** and contact your provider.



WARNING: To minimize the risk of explosion or fire:

- **DO NOT** use or store 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

Intended Use

Used to control and measure gas flow rate of medical gases supplied by a medical gas supply system directly to a patient.



WARNING: Use Flowmeters only for their **Intended Use** as described in this manual.

Specifications

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

Flow Range	Increments	Accuracy	Flood
0 - 200 CC	25 CCM (Starts at 25 CCM)	± 20 CCM	500 CCM MAX
0 - 1 LPM	0.1 LPM (Starts at 0.1 LPM)	± 0.1 LPM	2.5 LPM MAX
0 - 3.5 LPM	0.125 LPM (From 0.125 to 1 LPM)	± 0.125 LPM or ± 10% of Reading (whichever is greater)	45 LPM MAX
	0.25 LPM (From 1 to 3.5 LPM)		
0 - 8 LPM	0.5 LPM (Starts at 0.5 LPM)	± 0.5 LPM, or ± 10% of Reading (whichever is greater)	50 LPM MIN
0 - 15 LPM	0.5 LPM (From 1 to 5 LPM)	± 0.5 LPM, or ± 10% of Reading (whichever is greater)	50 LPM MIN
	1 LPM (From 6 to 15 LPM)		
0 - 70 LPM	5 LPM (Starts at 10 LPM)	± 10% of Reading	75 LPM MIN

Specifications

Flood is the output of the Flowmeter when the flow indicator is beyond the highest calibrated graduation. The Flood range is as indicated on the Flowmeter labeling.

Transport / Storage Requirements: -4°F to 140°F (-20°C to 60°C).

Note: Storage or transport outside the specified range may cause damage to the Flowmeter.

The gas and inlet pressures are indicated on the Flow Tube or Flowmeter body.

The above Flowmeter models are calibrated at a specified inlet pressure of 70°F (21°C) standard atmospheric pressure. International models are calibrated per specifications marked on Flow Tube or Flowmeter body.



MR WARNING: This product contains a magnetic, ferrous material that may affect the result of an MRI.

MRI Safety Summary

THIS SECTION APPLIES TO MR CONDITIONAL LABELED FLOWMETERS ONLY.



Devices with this label indicates that it is MR Conditional and can be used in an MR Environment.

All products identified as MR Conditional have been observed to maintain proper functionality during exposure to static magnetic fields of not less than 300 Gauss in the fringe field area of a 3.0 Tesla MRI system.

As per ASTM F2052, the largest deflection measurement across all devices tested yield allowable maximum spatial gradients of 8.93 T/m (893 gauss/cm) for 1.5 T systems, and 4.46 T/m (446 gauss/cm) for 3.0 T systems.



WARNING:

- This product should not be used directly inside of the MR System (e.g., inside the bore of the scanner).
- The device must be securely attached to a wall Gas Outlet.
- To ensure MR compatibility, only adapters and fittings tested and designated by Amico Patient Care for the configurations listed as MR conditional should be used. Any substitution or change must be evaluated in accordance with your hospital policy.
- Device must be kept MR Conditional if serviced or replaced.
- This information must be kept with the device.

Operating Instructions



WARNING: Read this User Manual before installing or operating the Flowmeter.



CAUTION: Flowmeters must be operated with the Flow Tube in a vertical, upright position.



CAUTION: Only personnel instructed and trained in its use should operate this Flowmeter.

CAUTION: The Pediatric Models including 0-200 CC and 0-1.5 LPM contains a glass Flow Tube which is fragile. Special care should be observed to avoid breaking the Flow Tube.



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

1. Turn Flowmeter off by turning knob fully clockwise.



CAUTION: Overtightening the knob when turning the Flowmeter off will cause damage.



WARNING: The Flow Tube specifies the gas and pressure required. The accuracy will be affected if a different pressure, other than the one specified, is used.

2. Connect the Flowmeter to the appropriate gas source. The appropriate gas and pressure are specified on the Flow Tube or Flowmeter body.



CAUTION: Ensure all connections are tight and leak free.



CAUTION: Only use an oxygen-safe leak detector.



CAUTION: 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.

3. Verify that the Float Ball is at the very bottom of the Flow Tube.

NOTE: If the Float Ball is not at the bottom of the Flow Tube, the Flowmeter could be leaking. Please contact Amico Patient Care Corporation.

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.



WARNING: ALWAYS confirm prescribed flow before administering to a patient and monitor the flow on a frequent basis.

6. Adjusting the flow beyond the last calibrated indicator line will result in an undetermined flow.

7. To obtain maximum flush flow, turn knob fully counterclockwise.

NOTE: Any flow beyond the highest calibrated line on the Flow Tube with unrestricted flow is Flood/Flush flow.

Cleaning Instructions



CAUTION:

- **DO NOT** autoclave
- **DO NOT** gas sterilize with EtO (Ethylene Oxide)
- **DO NOT** immerse Flowmeter in any kind of liquid

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

Recommended and tested cleaning products are: 99% Isopropyl Alcohol and Clorox Healthcare Bleach Germicidal Wipes.

The use of commercial grade cleaners are preferred over household cleaners that may contain dyes and fragrances. These chemicals can affect the quality of the flowmeter.

3. Wipe dry with a clean cloth.

Maintenance and Prevention

Before and after each use, **inspect the flowmeter for damage.**



WARNING: When changing connectors on the Flowmeter for service or replacement, NEVER attach connectors of a different gas. Doing so may result in patient injury or damage to the equipment.



CAUTION: Disconnect Flowmeter from gas supply before servicing.

Troubleshooting Guide

Problem	Probable Cause	Remedy
Will not shut off	Leak	Replace valve orifice
Knob won't turn	Seized valve	Replace valve assembly
Accuracy out of specification	Incorrect gas supply pressure	Confirm gas supply pressure of 50 PSI
No gas flow	Gas supply depleted	Replenish gas supply
	Inlet or outlet obstructed	Clear obstruction

Flowmeter Assemblies

Figure 1: 3.5 LPM, 8 LPM, 15 LPM Flowmeters

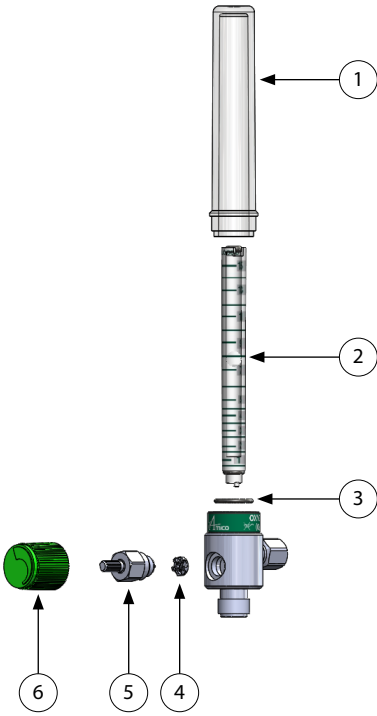
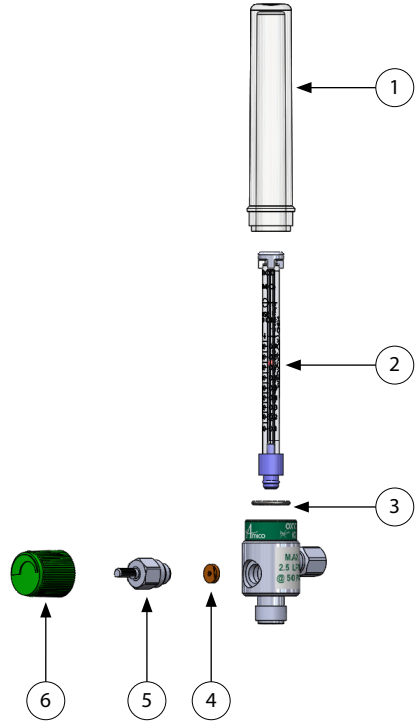


Figure 2: 200 CCM & 1 LPM Flowmeters



Item #	Description	Qty	Model(s)				
			02	01	03	08	15
			200 CC	1 LPM	3.5 LPM	8 LPM	15 LPM
1	Plastic Hood	1	FMX-HOOD				
2	Inner Tube Module OXY	1	FMO-02-INRTB-MOD	FMO-01-INTRB-MOD	FMO-03-INRTB-MOD	FMO-08-INTRB-MOD	FMO-15-INRTB-MOD
	Inner Tube Module AIR		N/A	N/A	N/A	N/A	FMA-15-INRTB-MOD
3	Hood Bottom O-Ring	1	H-OR-020X145V-75A				
4	Orifice for Needle Valve	1	FMX-ORF-PN		FMX-ORF-LRG		
5	Needle Valve Module	1	FMX-NDL-VLV-MOD-PN		FMX-NDL-VLV-MOD		
6	Knob (Oxygen USA/Green)	1	FMO-KNB-GRN				
	Knob (Oxygen ISO/White)		FMO-KNB-WHT				
	Knob (Medical Air USA/Yellow)		N/A	N/A	N/A	N/A	FMA-KNB-YLW
	Knob (Medical Air ISO/Black)		N/A	N/A	N/A	N/A	FMA-KNB-BLK



Warranty Policy - Flowmeters

This Product is sold by Amico Patient Care Corporation, a Richmond Hill Corporation (the "Company") under the express terms of the warranty set forth below.

For a period of three (3) years (or for a period of five [5] years in North America only) from the date the Company ships this Product to the customer, this Product is warranted to be free from functional defects in materials and workmanship and to conform in all material respects to the description of the Product contained in the operation manual, so long as this Product is properly operated under conditions of normal use, regular periodic maintenance and service is performed and repairs are made in accordance with the operation manual.

Within this period, Amico Patient Care Corporation will repair or replace any part which is proven to be defective at the Company's costs. All shipping and installation costs will be borne by the Customer after the first twenty four (24) months after receipt of the Product.

This warranty shall not apply if the Product has been repaired or altered by anyone other than the Company or an authorized dealer, or if the Product has been subjected to abuse, misuse, negligence or accidental damage. Should the parts be repaired or replaced by an authorized technician in accordance to the Company's operation manual, the warranty will continue to be applied.

This warranty is extended only to the initial customer with respect to the purchase of this Product directly from the Company or from an authorized dealer as new merchandise. Dealers are not authorized to alter or amend the warranty of any Product described in this agreement unless previously authorized in writing by the Company.

This warranty is expressly in lieu of any other warranties, express or implied, including any warranty of merchantability or fitness for a particular purpose. The Company shall not be liable for incidental, collateral, consequential or special damages including, but not limited to: lost profits or loss of use. The Company's liability, in the aggregate, shall not exceed the purchase price of the product.

As determined at the sole discretion of the Company, Products which qualify under the warranty will be repaired or replaced, at the Company's option, and returned to the Customer via ground delivery. The Company reserves the right to stop manufacturing any product or change materials, designs or specifications without notice.

All claims for warranty must first be approved by Amico Patient Care Corporation's Customer Service Department at: SOT-CSR@amico.com or 905.764.0800. Upon approval, the Customer Service Department will issue a Return Goods Authorization (RGA) number. An RGA must be obtained prior to commencement of any warranty claim.

Amico Patient Care Corporation | 122A East Beaver Creek Road, Richmond Hill, ON L4B 1G6, Canada
Toll Free Tel: 1.877.462.6426 | Toll Free Fax: 1.866.440.4986 | Tel: 905.764.0800 | Fax: 905.764.0862
Email: sot-csr@amico.com | www.amico.com