

USER MANUAL

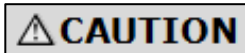
OXYGEN

DIAL FLOWMETER



PM2300RFCV-8CE

SAVE THESE INSTRUCTIONS



Federal (USA) law restricts this device to sale by or on the order of a physician.



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RECEIVING / INSPECTION

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

INTENDED USE

The Dial Flowmeter is intended to provide selected doses of medical oxygen to a patient.

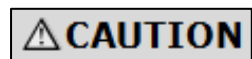
READ ALL INSTRUCTIONS BEFORE USING

This manual instructs a Patient to install and operate the Dial 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.

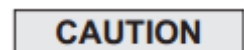
SAFETY SYMBOL DESCRIPTION



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



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



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



CONSULT ACCOMPANYING DOCUMENTS



CONSULT ACCOMPANYING DOCUMENTS (CE)



Symbol for "USE NO OIL"



Symbol indicates the device complies with the requirements of Directive 93/42/EEC concerning medical devices and all applicable International Standards.

WARNING

- Use this Dial 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.

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 product.
- **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.
- **DO NOT** attempt to repair the Dial Flowmeter.
- NO FLOW is delivered when the indicating pointer ▼ is pointing to “OFF”.
- There is NO FLOW between settings. Flow is available only at the listed settings.

CAUTION

- Only personnel instructed and trained in its use should operate this Dial Flowmeter.
- Ensure 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	PM2300RFCV-8CE
Gas	Oxygen
Inlet Pressure	10 to 26 psi (0.69 to 1.79 bar)
Graduations	0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 7, 8
Flow Range	0 – 8 lpm 0 – 4 lpm
Transport / Storage Requirements	-40°F to 140°F (-40°C to 60°C) 95° Humidity

NOTE: Storage/Transport outside the specified range may cause damage to the Dial Flowmeter. The effect on accuracy of flow due to variations in ambient temperature is standard accuracy +7.3% @ 32°F (0°C) and -3.0% @ 104°F (40°C).

Duration (Hours)		
Liter Flow lpm	Reservoir Size (LOX)	
	35 liter	45 liter
.5	1003	1290
1	501	645
1.5	334	430
2	250	322
2.5	200	258
3	167	215
4	125	161
5	100	129
6	83	107
7	71	92
8	62	80

Duration (Days)		
Liter Flow lpm	Reservoir Size (LOX)	
	35 liter	45 liter
.5	41	53
1	20	26
1.5	13	17
2	10	13
2.5	8	10
3	7	9
4	5	6
5	4	5
6	3	4
7	3	3
8	2	3

Accuracy			
LPM Setting	Flow Range		
.5	.450	-	.550
1	.900	-	1.10
1.5	1.35	-	1.65
2	1.80	-	2.20
2.5	2.25	-	2.75
3	2-70	-	3.30
4	3.60	-	4.40
5	4.50	-	5.50
6	5.40	-	6.60
7	6.30	-	7.70
8	7.20	-	8.80

NOTE:

The accuracy of flow may be:

- Outlet resistance
- Inlet pressure is out of specification
- Ambient temperature out of specification

Specifications are subject to change without prior notice.

OPERATING INSTRUCTIONS

WARNING

- Read this User Manual before installing or operating the Dial Flowmeter.
- This product contains magnetic, ferrous material that may affect the results of an MRI.
- **To avoid injury to patient:** ALWAYS confirm prescribed flow before administering to patient and monitor flow on a frequent basis.
- **DO NOT** immerse Dial Flowmeter in any kind of liquid. This will cause damage to the Flowmeter and will void the warranty.

CAUTION

- Inspect the Dial Flowmeter for visual damage before use, DO NOT USE if damaged.
- Missing or illegible labels must be replaced, contact DEHAS.

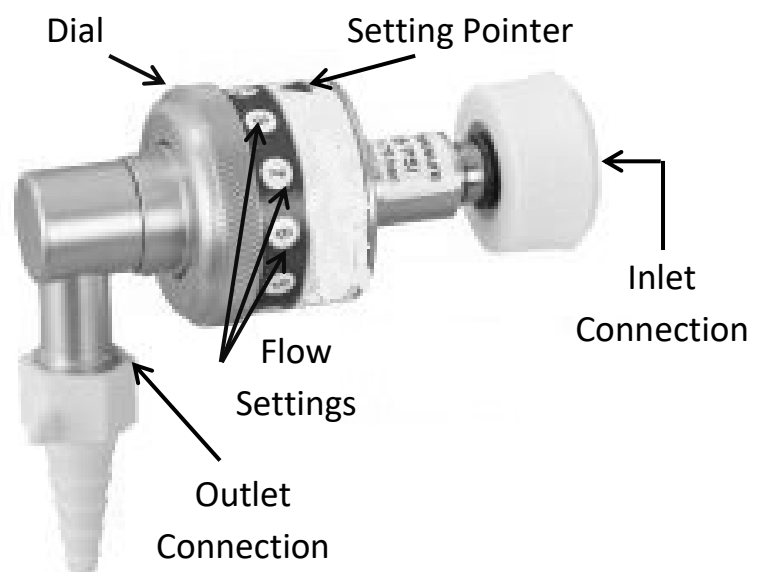
NOTE: DEHAS strongly recommends the use of kink proof patient tubing.

1. Turn dial to the "OFF" position.
2. Connect the Dial Flowmeter to an Oxygen Source 10 - 26 psi (0.69 - 1.79 bar).
3. Set flow by aligning the setting pointer with a specific setting on the dial.

NOTE:

The accuracy of flow may be:

- Outlet resistance
- Inlet pressure is out of specification
- Ambient temperature out of specification.



CLEANING INSTRUCTIONS

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

TROUBLESHOOTING

If the Dial Flowmeter fails to function, consult the Troubleshooting guide below.

If the problem cannot be corrected, consult your Provider or DEHAS.

Problem	Probable Cause	Remedy
No flow	<ul style="list-style-type: none">• Dial Flowmeter set in "OFF" position• Dial Set between settings• Internal failure	<ul style="list-style-type: none">• Turn to desired setting• Move dial to flow setting• Return to manufacturer
Dial will not turn / Hard to turn	<ul style="list-style-type: none">• Dial seized	<ul style="list-style-type: none">• Return to manufacturer
Will not shut off	<ul style="list-style-type: none">• Dial Flowmeter not in "OFF" position	<ul style="list-style-type: none">• Turn dial to the "OFF" position
Flow out of tolerance	<ul style="list-style-type: none">• Inlet pressure is outside of inlet range	<ul style="list-style-type: none">• Use ONLY on a 10-26 psi (0.69-1.79 bar) oxygen source

RETURNS

Returned products require a Returned Goods Authorization (RGA) number. ANY product returned to DEHAS must be packaged in sealed containers to prevent damage. DEHAS will not be responsible for goods damaged in transit. Return Policy available on the Internet, www.dehas.de.

DECLARATION OF CONFORMITY



DEHAS Medical Systems GmbH
Wesloer Straße 107-109
23568 Lübeck

GERMANY



Dial Flowmeter
PM2300RFCV-8CE



Classification: IIb

Classification criteria: Clause 3.2 Rule 11 of Annex IX of MDD

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documents are retained under the premises of the manufacturer and the notified body.

Directives: General Application Directives: (MDD) Medical Device Directive, Council Directive 93/42/EEC Of 14 June 1993 Concerning Medical Devices, Directive 2007/47/EC Of The European Parliament and of the Council of 5 September 2007 and 2010/35/EC Transportable Pressure Equipment Directive.

Applied Standards: DIN EN 15223-1
DIN EN ISO 14971
DIN EN ISO 15001
DIN EN ISO 15002

Notified Body: DNV Medcert GmbH /  0482

Address: Pilatuspool 2, 20355 Hamburg; GERMANY

Certification Registration No's: 4153DE410200327 Date of Expiry: 05/2024

Devices already manufactured: SN traceability via Device History records

Validity of DOC: 27-03-2020 to Date of Expiry

Manufacture Representative: Quality Manager

Position: Manager, Quality System/ISO Representative

Date of Issue: 03-04-2020

LIMITED WARRANTY AND LIMITATION OF LIABILITY

DEHAS warrants that the Medical Gas Dial Flowmeter (the Product) will be free of defects in workmanship and/or material for the following periods:

One (1) year from shipment

Should any failure to conform to this warranty appear within the applicable period, DEHAS shall, upon written notification thereof and substantiation that the goods have been stored, installed, maintained and operated in accordance with DEHAS' 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 DEHAS 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.

DEHAS 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 provide above shall constitute fulfillment of all liabilities of DEHAS whether based on contract, negligence, strict tort or otherwise.

DEHAS reserves the right to discontinue manufacture of any product or change product materials, designs, or specifications without notice.

DEHAS reserves the right to correct clerical or typographical errors without penalty.