USER MANUAL

(19MFA1001 Shown)

EASYPULSEFLOW
Conserver/Flowmeter

Models: 19MFA Series

SAVE THESE INSTRUCTIONS

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

PRECISION MEDICAL®

300 Held Drive
Northampton, PA 18067 USA
ISO 13485 Certified

Tel: (+001) 610-262-6090
Fax: (+001) 610-262-6080
www.precisionmedical.com

RECEIVING / INSPECTION

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

INTENDED USE

The *EasyPulseFlow* flowmeter is intended for use by physicians, respiratory therapists, and other hospital personnel to administer selected doses of medical oxygen to patients suffering from hypoxia due to various etiologies and disease processes. The device delivers via nasal cannula a FIO_2 of 100% oxygen at all settings when connected directly to 100% gas source. It is intended to be used as a device to provide continuous flow oxygen therapy or as an oxygen saving device that delivers pulsed volumes for oxygen therapy while reducing the drying of the patient airways.

READ ALL INSTRUCTIONS BEFORE USING

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

⚠ DANGER

This product is not intended as a life-sustaining or life-supporting device.

EXPLANATION OF ABBREVIATIONS

FIO_2	Fractional Concentration of Inspired Oxygen
DISS	Diameter Indexed Safety System
psi	Pounds Per Square Inch
l/min	Liters Per Minute
b/min	Breathes Per Minute
bar	Barometric Pressure

SAFETY INFORMATION - WARNINGS AND CAUTIONS

⚠ DANGER	Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.
⚠ 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”

CE
0473

Symbol indicates the device complies with the requirements of Directive 93/42/EEC.
(On CE marked Devices ONLY)

⚠ WARNING

- **ALWAYS** confirm prescribed dose before administering to patient and monitor on a frequent basis.
- Always follow ANSI and CGA standards for Medical Gas Products and Oxygen Handling (G-4).
- NO OXYGEN is delivered when the pointer ▼ is between settings.

⚠WARNING

- The *EasyPulseFlow* is not to be used in the Pulse mode by patients who breathe through their mouths.
- **DO NOT** use oils, greases, organic lubricants or any combustible materials on or near this product. Wash and dry hands properly prior to usage.
- **DO NOT** use a humidifier when administering Oxygen therapy on pulse settings.
- **DO NOT** use pulse settings while patient is sleeping unless continuous pulse oximetry is utilized.
- **DO NOT** smoke in an area where oxygen is being administered.
- The *EasyPulseFlow* is designed to operate with a single lumen, adult cannula with a maximum length of 7 foot (2.1 m).
- Flowmeter must meet specified inlet pressure range, see “SPECIFICATIONS”.
- To use Pulse, Flow Control Knob must be set to 5 l/min or greater.

⚠CAUTION

- Only personnel instructed and trained in its use should operate the *EasyPulseFlow*.
- The *EasyPulseFlow* contains magnetic, ferrous material that may affect the results of an MRI.
- **DO NOT** autoclave.
- **DO NOT** gas sterilize with EtO (Ethylene Oxide).
- **DO NOT** clean with aromatic hydrocarbons.
- Avoid dropping the *EasyPulseFlow* or placing it in a position where it could fall and become damaged.
- The *EasyPulseFlow* may not be able to detect all respiratory efforts of the patient. (Shallow breathers may not be able to trigger the *EasyPulseFlow*.)
- Operating the *EasyPulseFlow* outside its range of operating conditions may affect its accuracy and performance.

PRINCIPLES OF OPERATION

The Precision Medical, Inc. *EasyPulseFlow* is a combination of two (2) devices, a traditional Thorpe tube flowmeter and a pulse oxygen conserver. The *EasyPulseFlow* is designed to be used with low pressure oxygen systems at specified Inlet Pressure. It consists of a back pressure compensated Thorpe tube flowmeter, a conserving module, and a selector dial to choose between Continuous Flow mode or Pulse mode.

In the Continuous Flow mode the flowmeter operates similar to a traditional Thorpe tube flowmeter: the flow is determined by setting the flow control knob to the prescribed flow. In this mode it is capable of delivering metered flows from 0 to 15 l/min and up to 24 l/min at flush flow.

In the Pulse mode the device operates as an oxygen conserver. Settings of 1 through 5 are available and supply a similar FIO_2 to the patient as continuous flow. The conserving module controls the pulse size and timing to the patient. It supplies a pulse of oxygen at the beginning of each breath. This reduces the oxygen demand on the system and limits the drying of the airways. The oxygen is supplied to the patient through the nasal cannula.

SPECIFICATIONS

Inlet Pressure Range:	19MFA: 50 psi (3.4 bar) 19MFA AU: 4 bar (58.0 psi) 19MFA CI: 5 bar (72.5 psi)
Pulse Settings:	1, 2, 3, 4 and 5 (similar FIO_2 to continuous flow value)
Continuous Flow Range:	0-15 l/min metered (20-24 l/min max flush flow)
Pulse Accuracy:	Within ±15% of the nominal bolus value (at each breath rate)
Continuous Flow Accuracy:	±0.25 l/min from 0.5 l/min up to 5 l/min ±0.5 l/min from 5 l/min up to 15 l/min
Savings Ratio:	Up to 5.7:1
Trigger Method:	Negative inspiratory effort from patient inhalation

Breathing Frequency: Up to 35 b/min

Cannula Requirement: Maximum 7 foot (2.1 m) long standard adult single lumen nasal cannula.

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) . The 19MFA flowmeter models are calibrated at specified inlet pressures as stated on Flowtube, 70°F (21°C), standard atmospheric pressure.

Operating Conditions:

Temperature: 35°F to 105°F (1.7°C to 40.6°C)

Altitude: Sea level to 10,000 ft (0 to 3,048 m)

Storage Conditions:

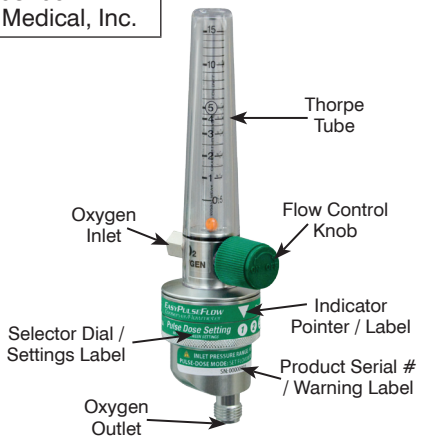
Temperature: -40°F to 140°F (-40°C to 60°C)

Maximum Humidity: 95% Noncondensing

COMPONENT DESCRIPTION

⚠CAUTION

Missing or illegible labels must be replaced, contact Precision Medical, Inc.



OPERATING INSTRUCTIONS

⚠WARNING

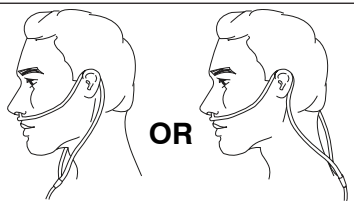
Read this User Manual before installing or operating the *EasyPulseFlow*.

CAUTION

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

⚠CAUTION

- **DO NOT** use pediatric, low flow nasal cannulas or oxygen masks with the *EasyPulseFlow*.
- **DO NOT** block the cannula connection or kink cannula tubing when the Conserver is in use, this may damage the *EasyPulseFlow*.



1. Verify order/need for oxygen administration.
2. Connect flowmeter to oxygen gas source, as stated on Flowtube.
3. Turn Selector Dial to align indicator pointer with Continuous Flow setting.
4. Turn Flow Control Knob to obtain appropriate flow rate.
   A. To **increase**, turn knob **counterclockwise**
   B. To **decrease**, turn knob **clockwise**
   C. Set flow by aligning center of Float Ball with indicator lines on flow tube.
   D. To obtain maximum flush flow, turn knob fully counterclockwise.

NOTE: *Flush flow is any flow above the last calibrated line on the Thorpe Flow Tube with an unrestricted flow, as per "SPECIFICATIONS".*

5. Connect oxygen administration equipment via DISS connector on bottom of flowmeter.
6. Assess effectiveness of oxygen therapy to the patient with pulse oximetry or arterial blood gas.
7. **If patient is stabilized on nasal cannula at ≤ 5 l/min, switch to pulse-dose mode as follows:**
   A. Remove any type of humidity bottle.
   B. Turn Flow Control Knob to obtain a continuous flow of 5 l/min or greater.
   C. Select pulse setting from 1 to 5, by turning the Selector Dial to align Indicator Pointer with pulse setting.
   NOTE: *DO NOT adjust Flow control knob on flowmeter.*
      i. Choose pulse setting equal to continuous flow setting (e.g. if patient is on 4 l/min continuous flow choose a pulse setting of 4).
      ii. If patient is on a ½ liter increment choose the next closest higher pulse setting (e.g. if patient is on 2½ l/min place patient on pulse setting of 3).
      iii. Instruct patient that oxygen will only flow during the first part of inspiration.
      iv. Assess patient/conserver interaction to assure pulsing is occurring.
   D. Re-assess patient's oxygenation status via pulse oximetry or arterial blood gas.
8. Amount of oxygen may be weaned either by decreasing the continuous flow rate on the Thorpe tube flowmeter if patient is on continuous flow or by decreasing the pulse of oxygen if on pulse mode. (If patient is on pulse mode, oxygen may only be decreased in increments of one (1)).
9. To turn off flowmeter, turn the Flow Control Knob fully clockwise.

NOTE: *If nasal cannula is disconnected while on pulse oxygen therapy. (The device should not pulse oxygen into the atmosphere.) Limit of three (3) pulses per minute .*

MAINTENANCE / CLEANING

1. Disconnect all connections before cleaning.

As needed:

2. Clean exterior surfaces of the *EasyPulseFlow* with a cloth dampened with mild detergent and water.
3. Wipe dry with a clean cloth.
4. Store the *EasyPulseFlow* in a clean area free of grease, oil, and other sources of contamination.

CAUTION

- **DO NOT** use cleaning solutions.
- **DO NOT** immerse the *EasyPulseFlow* in any kind of liquid.
- **DO NOT** attempt to repair the *EasyPulseFlow*.
- All repairs must be performed by Precision Medical, Inc. or Authorized Representative.

RETURNS

Returned products require a Returned Goods Authorization (RGA) number, contact Precision Medical, Inc. All returns must be packaged in sealed containers to prevent damage. Precision Medical, Inc. will not be responsible for goods damaged in transit. Refer to Precision Medical, Inc. Return Policy available on the Internet, www.precisionmedical.com.

Manuals available on our Website; www.precisionmedical.com

DISPOSAL INSTRUCTIONS

This device and its packaging contain no hazardous materials. No special precautions need to be taken when disposing the device and/or its packaging.

Please Recycle

TROUBLESHOOTING

If the *EasyPulseFlow* fails to function, consult the Troubleshooting Guide below. If problem cannot be solved, consult your Provider.

Problem	Probable Cause	Remedy
No flow/ pulse	• Flowmeter not securely attached to oxygen outlet • Thorpe tube flowmeter not turned ON • Selector Dial set between settings	• Securely attach flowmeter to oxygen outlet • Turn ON the Thorpe tube flowmeter using Flow Control Knob • Position Selector Dial at correct setting
Conserver not sensing breath	• Selector Dial set between settings • Cannula disconnected • Nasal cannula kinked • Humidity bottle in line • Cannula greater than 7 ft long • High flow cannula not being used	• Position Selector Dial at correct setting • Connect cannula • Replace cannula • Remove humidity bottle • ONLY use a 7 ft or less cannula • Replace cannula with a *high flow* cannula
Patient de-saturated in pulse mode	• Flowmeter set below 5 l/min in pulse mode • Device not sensing patient breath	• Increase flow ≥ 5 l/min • Change to continuous flow therapy

LIMITED WARRANTY
AND LIMITATION OF LIABILITY

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

Two (2) years from date of 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.

DECLARATION OF CONFORMITY

Precision Medical, Inc
300 Held Drive
Northampton PA 18067, USA

CE 0473

EC REP

Emergo Europe (European Office)
Molenstraat 15
2513 BH, The Hague
The Netherlands
Phone: +31 (0) 70.345.8570
Fax: +31 (0) 70.346.7299

REF

19MFA Series EasyPulseFlow

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

We hereby declare that an examination of the under mentioned production quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II, 3 of the Directive 93/42/EEC on medical devices.

We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0473 marking on those products listed above.

Applied Standards: *EN 980, EN 1041, EN ISO 14971, EN ISO 15001, EN ISO 15002, EN ISO 18779, ISO 13485*

Notified Body: Intertek AMTAC Certification Services Limited CE 0473
Address: Davy Avenue Knowlhill Milton Keynes MK5 8NL, UK
Certification Registration No's: 1126 CE
Date of Expiry: 26 July 2017
Devices already manufactured: S/N traceability Device History Records
Validity of DOC: 26 July 2012 to Date of Expiry
Manufacture Representative: Quality Manager
Position: Quality Systems/ISO Representative
Date of Issue: 26 July 2012

Tell us how we are doing!
Visit us at www.precisionmedical.com