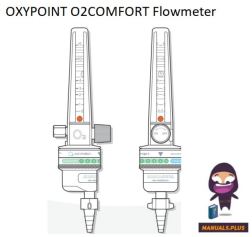
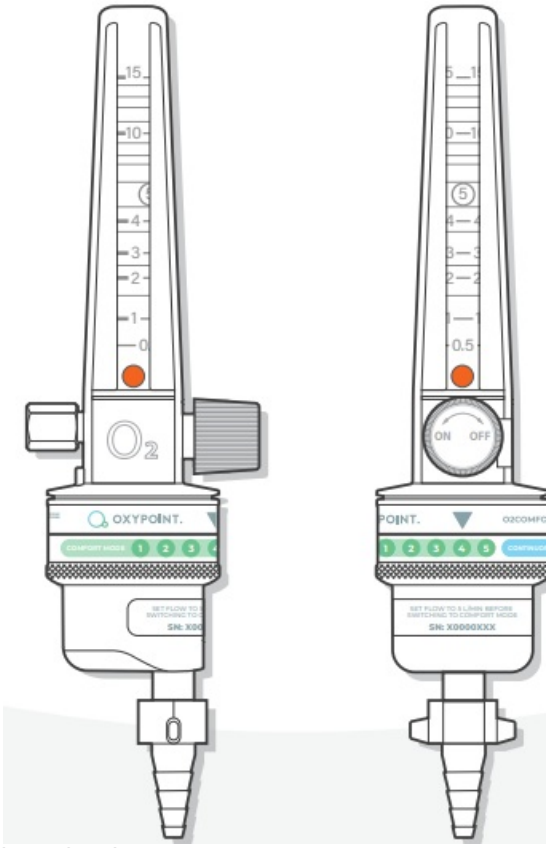


OXYPOINT O2COMFORT Flowmeter User Manual

Contents

OXYPOINT O2COMFORT Flowmeter



READ ALL INSTRUCTIONS PRIOR TO USE

This manual contains important information on the O2COMFORTTM Flowmeter. You should read this document carefully, so that you can use this flowmeter safely and correctly. Ensure that you read and understand all instructions in this manual, before using the flowmeter. If you do not understand these instructions, or if you have any additional questions, please contact your supplier or Oxypoint NV before use.
Remove the O2COMFORTTM Flowmeter from the packaging and inspect the device to make sure it is not damaged. Do not use the flowmeter if you notice any kind of damage and contact your supplier or Oxypoint NV. Do not try to repair the flowmeter yourself. All repairs must be carried out by Oxypoint NV or by a party authorised by Oxypoint NV.

INTENDED USE

The O2COMFORTTM Flowmeter is designed to regulate the oxygen delivery mode and the flow rate settings during oxygen therapy. The flowmeter is not intended as a system that takes over/replaces the patient's spontaneous breathing. The device may only be used by trained personnel, authorised to administer a prescribed dose of medical oxygen to oxygen-dependent patients. The user can use the flowmeter to make the switch between continuous and comfort mode. In comfort mode, the flowmeter functions as an dosing system, which maintains the moisture balance of the nasal and oral mucosa. In continuous mode, the device functions like a traditional flowmeter.
The device is designed for connection to an oxygen system with an inlet pressure of 5 bar (72,5 psi). When used with the correct nasal cannula, the flowmeter (in any setting) always adds 100% oxygen to the patient's spontaneous breathing, providing the device is connected to an oxygen system with an oxygen concentration of 100%.

SAFETY LABELS

WARNING	The WARNING label indicates potentially hazardous situations, which could result in death or serious injury if they are not avoided.
CAUTION	The CAUTION label indicates potentially hazardous situations, which could r esult in minor or moderate injury if they are not avoided.
ATTENTION	The ATTENTION label indicates potentially hazardous situations, which coul d result in property damage if they are not avoided.
CE	This symbol indicates compliance with directive 93/42/EEC concerning medical devices and all applicable international standards on CE-marked de vices.

LIST OF ABBREVIATIONS

l/min	(Therapy level in continuous) litres per minute
l/minequiv	(Therapy level in comfort) litres per minute equivalent
FiO2	Fraction of inhaled oxygen (%)

RESPONSIBILITIES OF THE USER

The user is responsible for all defects that manifest through improper use, poor maintenance, incorrect repairs, damage or adaptations carried out by anyone other than your authorised supplier or Oxypoint NV. The flowmeter functions as described in this user manual, as long as the product is handled, mounted, maintained and repaired in a way that meets the instructions provided. It is recommended, but not mandatory, that the flowmeter is checked annually. If the flowmeter is -or appears to be- damaged or defective, it must not be used. When detecting parts that are defective, missing, worn, deformed or polluted, immediate repair or replacement of the product is required. The flowmeter must not be modified without prior written permission from Oxypoint NV

WARNING

- Always follow the ISO and EIGA standards for Medical Gas Products and Oxygen Handling.
- Only connect the flowmeter to a system with medical oxygen gas. Never fit connectors for a different gas to the flowmeter. This could pose a hazard to the patient and/or lead to damage to the device.
- Ensure that all connections are securely tightened and leakage-free prior to use. When testing for leaks, onl y use substances that are safe to use in combination with medical oxygen gas.
- The flowmeter must only be used with the Thorpe tube in a vertically upward position.

WARNING

- Never use the flowmeter when flammable anaesthetics are present.
- Never use grease, oil, organic lubricants or flammable material near the flowmeter, and never apply these s ubstances to the flowmeter. Wash and dry your hands before use.
- Smoking is strictly forbidden in an area where medical oxygen gas is used.
- Never ignite a flame, or use flammable or explosive substances, near the flowmeter.

OPERATING PRINCIPLE

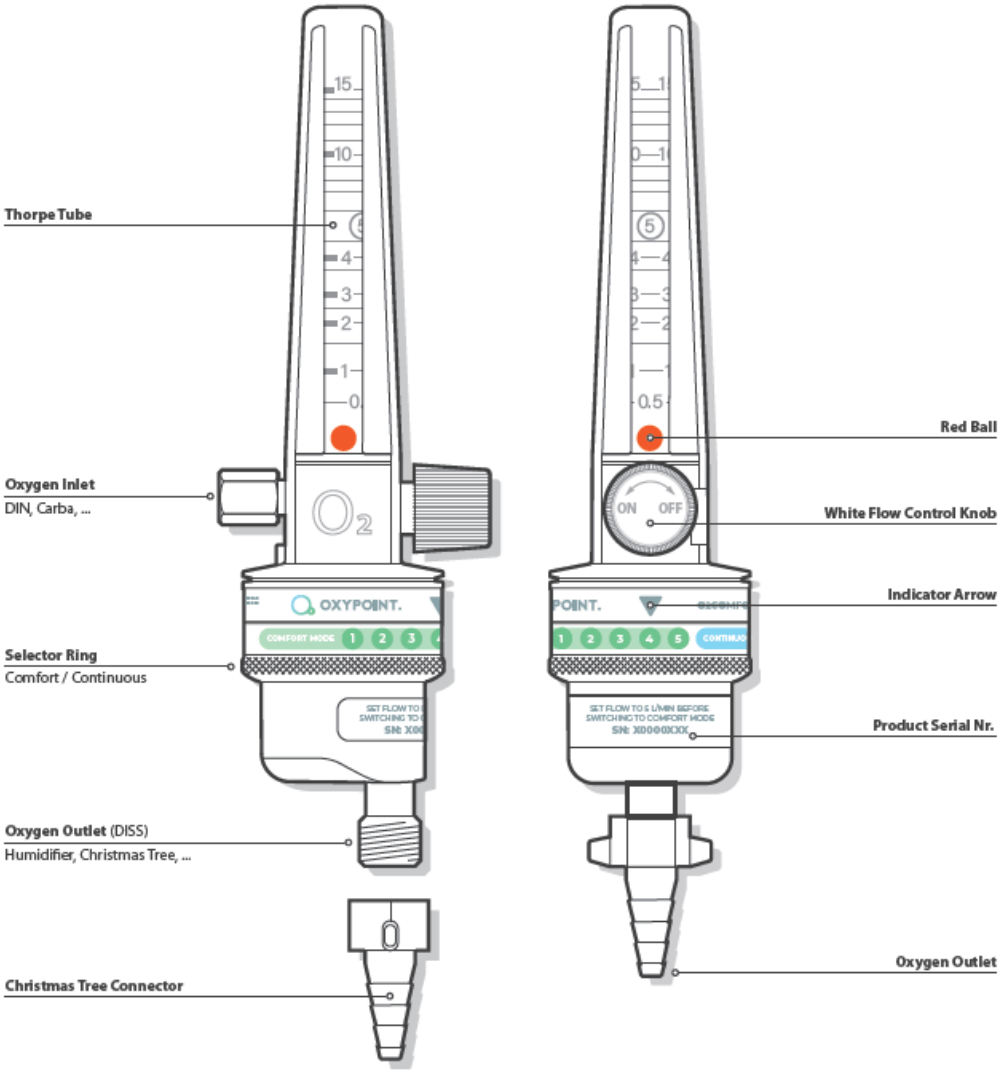
The O2COMFORTTM Flowmeter is a combination of a traditional counter-pressure compensated Thorpe tube flowmeter and a comfort dosing system. Using the selector ring, oxygen therapy can be set to either continuous or comfort mode.
In continuous mode, the device operates like a traditional Thorpe tube flowmeter. Flow rates for this mode are

indicated from 0 to 15 l/min and can be set by turning the white flow control knob. The Thorpe tube has a logarithmic scale, meaning flow rates from 0 to 5 l/min can be adjusted per half a litre and flow rates from 5 to 15 l/min per 1 litre. By turning the knob completely counterclockwise, it is possible to administer up to 24 l/min in flush flow. Flush flow is any flow rate above the highest indication line of the Thorpe tube. In comfort mode, the device operates like a dosing system. Here, the flowmeter delivers a dose of oxygen during the first phase of inhalation. The delivery is triggered by the patient's spontaneous breathing. Using the selector ring the therapy can be set from 1 to 5 l/minequiv. These settings provide a FiO2 equivalent to the settings of 1 to 5 l/min in continuous mode. The dosing system also has a constant minute volume. This principle regulates the pulse intensity so that the same amount of oxygen is delivered to the patient every minute.

PATENTED TECHNOLOGY

The operating principle of the O2COMFORTTM Flowmeter is patented technology. The following patent numbers apply to the flowmeter: EP2707072, CA2835301, US2014076321, US6752152, and US7089938.

COMPONENT DESCRIPTION



PRODUCT SPECIFICATIONS

Inlet pressure	5 bar (72.5 psi)
Comfort flowrate	1, 2, 3, 4 and 5 l/minequiv
Continuous flowrate	Indicated from 0 to 15 l/min: 0 to 5 per half liter, 5 to 15 per 1 liter. Up to 24 l/min fl ush flow
Oxygen use in comfort mod e	Position 1 = 0.260 l/min; position 2 = 0.420 l/min; position 3 = 0.560 l/min; position 4 = 0.700 l/min; position 5 = 0.860 l/min
Comfort mode precision	Within ± 15% of the pulse intensity with each breath
Continuous mode precision	From 0.5 to 5 ± 0.25 l/min; from 5 to 15 ± 0.5 l/min
Trigger method	Negative pressure during nasal inhalation
Breathing frequency	Up to 35 breaths per minute (constant minute volume)
Normal working range	Temperature: 1.7°C to 40.6°C (35°F to 105°F); Height: sea level to 3048 m (0 to 1 0,000 ft)
Deviant working range	Effect on flow accuracy as a result of changes to ambient temperature: +7.3% at 0°C (32°F) and -3.0% at +40°C (104°F)
Storage conditions	Temperature: -40°C to 60°C (-40°F to 140°F) Maximum humidity: 95% non-conde nsing
Administering requirement	A standard type nasal cannula for adults with a single-lumen connection

WARNING

- The flowmeter is calibrated to an inlet pressure of 5 bar at 21°C (70°F) and standard atmospheric pressure (as indicated on the Thorpe tube). These specifications can be amended without prior notification.

- The accuracy may be affected if the temperature of the medical oxygen gas deviates from 21°C and/or the i nlet pressure deviates from 5 bar.

- The flowmeter contains magnetic, ferrous material. This may affect the results of an MRI examination.

OPERATING INSTRUCTIONS

Inspect the O2COMFORTTM Flowmeter for damage before and after every use. Do not use the device if any form of damage is observed. If there is no visible damage, then correctly connect the flowmeter to an outlet of an oxygen system with an inlet pressure of 5 bar. Follow the steps below to ensure correct use:

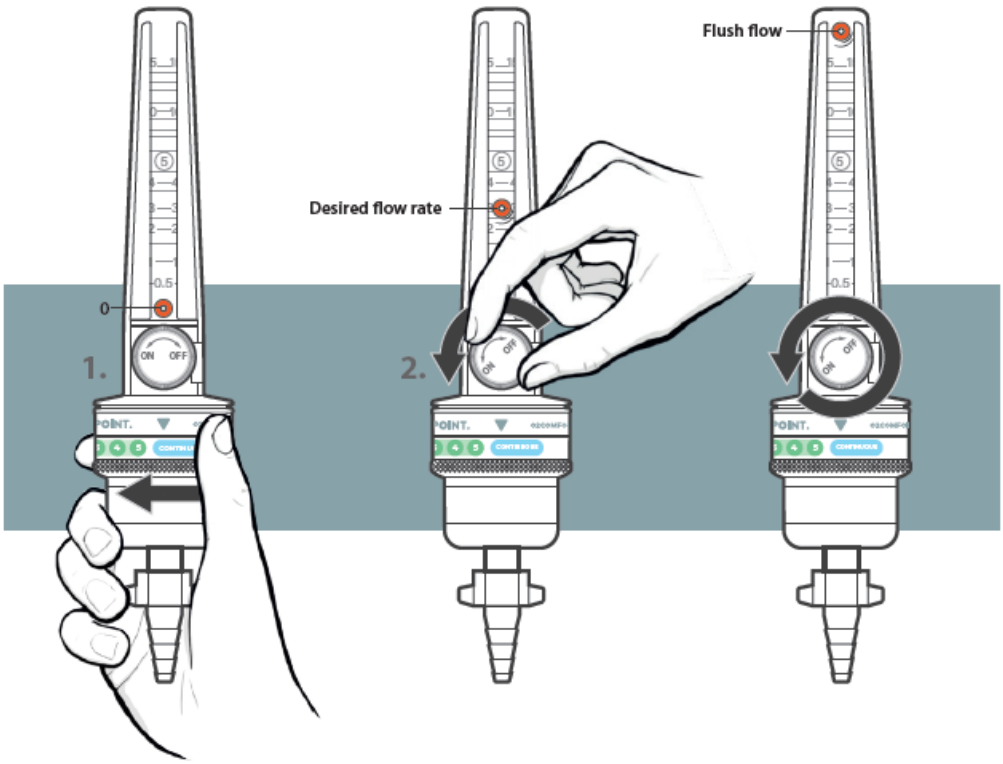
Choose therapy mode

If the patient has a prescribed therapy level of ≤ 5 l/min, both continuous and comfort mode can be selected for oxygen administration. If required, a switch from one mode to the other is possible during treatment. The correct way to set therapy in both modes, is described on pages 8 and 9. Do not use a humidifier when administering oxygen in comfort mode. When setting therapy to comfort mode: if the prescribed therapy level is a whole number, choose the comfort position with a value equal to the prescribed level (e.g. if the patient has a prescribed therapy level of 4 l/min, then select position 4 in comfort mode) When setting therapy to comfort mode: if the prescribed therapy level is not a whole number, choose the comfort position with the first higher whole value as the prescribed level (e.g. if the patient has a prescribed therapy level of 2.5 l/min, then select position 3 in comfort mode).

CAUTION
• Do not connect a standard-type nasal cannula to the oxygen outlet of the flowmeter until after setting the therapy level. • Do not obstruct the oxygen outlet and ensure that the nasal cannula is not pinched or clamped. This could be harmful to both the patient and the device. • Do not use a pediatric nasal cannula or an oxygen mask in comfort mode. • Ensure that the *Christmas Tree* connection is firmly screwed onto the flowmeter.

Set therapy level in continuous mode

1. Turn the selector ring all the way to the left until the indicator arrow is above the green ‘continuous ’ flow.
2. Turn the white flow control knob to obtain an appropriate flow rate. Bring the centre of the red ball to the same height as the indication line on the Thorpe tube, that equals the prescribed therapy level.
   Turn the white flow control knob fully counterclockwise to obtain maximum flush flow.

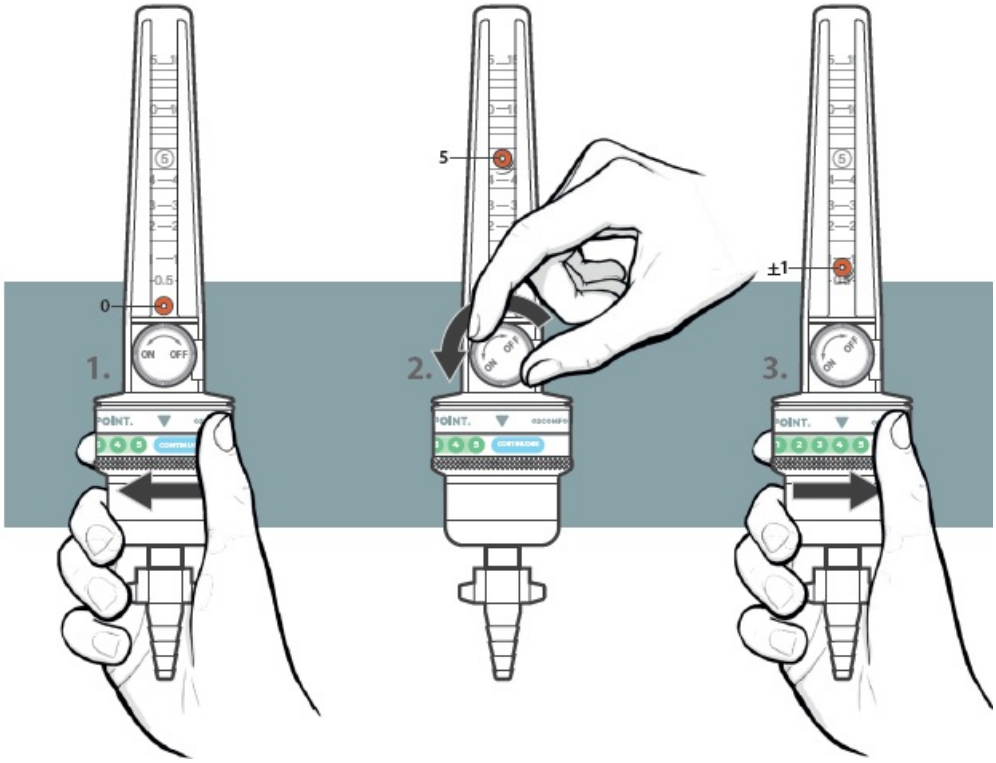


Set therapy level in comfort mode

1. Turn the selector ring all the way to the left until the indicator arrow is above the green ‘continuous flow’.
2. Turn the white flow control knob to obtain an appropriate flow rate. Bring the centre of the red ball to the same height as the indication line on the Thorpe tube, which equals 5 l/min. Do not adjust the position of the white

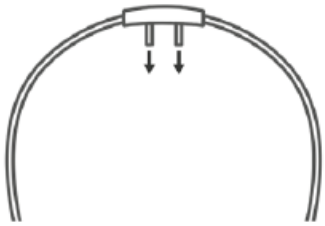
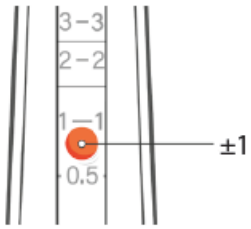
flow control knob after this step.

3. Turn the selector ring to the right until the indicator arrow is above the desired therapy level (position 1 to 5).



Verify the respiration

For oxygen therapy in comfort mode, regularly check if the patient is breathing through the nose. This can be done both auditive and visually.

AUDITIVE CONTROL	VISUAL CONTROL
	
The nasal cannula produces a soft 'puff' sound with each oxygen pulse/breath.	When breathing through the nose, the red ball floats between 0.5 and 1.

Verify the saturation

Regularly check the patient's oxygen saturation level, during oxygen therapy in both continuous and comfort mode. Increase or decrease the therapy level if necessary. Therapy adjustments in comfort mode are always made in increments of 1.

Therapy weaning

The oxygen therapy can be weaned in continuous mode by setting a lower flow rate using the white flow control knob. The oxygen therapy can be weaned in comfort mode by setting the selector ring to a lower position.

Stop the oxygen flow

For both comfort and continuous mode, the oxygen flow can be shut off manually by turning the white flow control knob completely clockwise. In comfort mode, the oxygen flow also stops automatically, if the device is not triggered by the patient's spontaneous breathing. As a result, no oxygen will be lost to the ambient air in comfort mode.

Inspect after closing

Confirm for both closing methods, that the red ball is completely at the bottom of the Thorpe tube, after shutting off the oxygen flow. If this is not the case, a leak may be present. Contact your supplier or Oxypoint NV if this situation occurs.

ATTENTION

- Operate the white flow control knob with care. Too much force may cause damage to the device.

WARNING

- Always check the prescribed therapy level prior to administering the treatment to prevent injury.
- Check the therapy level and the oxygen saturation level of the patient regularly during the treatment.
- When selecting a setting above the highest indicator line on the Thorpe tube, the therapy level is no longer measurable.
- If labels are missing, illegible or require replacing, contact your supplier or Oxypoint NV.
- Do not adjust the position of the white flow control knob, after setting the comfort mode.
- Do not use a humidifier when administering oxygen in comfort mode.
- The flowmeter does not deliver oxygen when the indicator arrow is placed between two positions in comfort mode.
- Inform the patient that in comfort mode, oxygen is only delivered at the beginning of the inhalation.
- The comfort mode does not trigger when patients breathe through the mouth or for patients with a shallow b reathing pattern.

TROUBLESHOOTING

If the flowmeter does not function properly, consult the troubleshooting guide below for the probable causes and a solution. Consult your supplier or Oxypoint NV, if the problem persists.

PROBLEM	PROBABLE CAUSE	REMEDY
	The flowmeter is not correctly attached to an oxygen outlet	Plug in the flowmeter until a click is obser ved

The flowmeter Does not deliver any flowrate	The oxygen flow is turned off	Follow the procedure on p8 or p9
	The selector ring is set between two positions	Place the selector ring in the correct position
The flow meter does not trigger in comfort mode	The nasal cannula is not connected	Correctly connect the cannula
	The nasal cannula is kinked	Replace the cannula
	A humidifier is connected	Remove the humidifier
	The patient's breathing is too shallow or through the mouth	Ask the patient to breathe firmly through the nose
	The comfort mode is not suitable for this patient	Switch to continuous mode
The patient is desaturating in comfort mode	The comfort mode has not been set correctly	Follow the procedure on p9
	The patient's breathing is too shallow or through the mouth	Ask the patient to breathe firmly through the nose
	Due to an extension tube, the oxygen dose arrives later in comfort mode	Increase the therapy level (Pay attention to patients at risk of carbo narcosis)

ATTENTION

- Do not attempt to repair the device in case of a defect or a problem.
- All repairs must be carried out or authorised by Oxypoint NV, or by a party authorised by Oxypoint NV.

CLEANING INSTRUCTIONS

1. Prior to cleaning, remove all connections from the flowmeter.
2. Clean the exterior surface of the flowmeter using a cleaning cloth dampened with a mild detergent and water. Do not spray anything directly onto the flowmeter.
3. Wipe the exterior surface of the flowmeter dry using a clean cloth.
4. Store the flowmeter in a dust-free environment, free of oil, grease or other sources of contamination.

CAUTION
• Never clean the flowmeter using volatile organic solvents. • Never autoclave the flowmeter, or gas sterilize it with ethylene oxide (EtO). • Never immerse the flowmeter in any kind of liquid. • Avoid dropping the flowmeter or placing it somewhere where it could fall and/or become damaged.

RETURNING THE PRODUCT

To prevent damage, all returns must be sent in sealed, protective packaging. Oxypoint NV is not responsible for damage that occurs during transport. Contact Oxypoint NV for all details regarding the return policy.

RECYCLING INSTRUCTIONS

The O2COMFORTTM Flowmeter and its packaging contain no hazardous materials. No special precautions need to be taken for disposing of the device and/or its packaging. Please recycle.

MANUFACTURER'S WARRANTY AND LIABILITY LIMITATION

The Oxypoint O2COMFORTTM Flowmeter is manufactured exclusively by Precision Medical, Inc. in the United States of America. Precision Medical, Inc. warrants that the Product will be free of defects in workmanship and/or material for two years from the date of shipment. Should any failure to conform to this warranty appear within the applicable period, Precision Medical, Inc. shall, upon written notification thereof via Oxypoint NV 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.

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DECLARATION OF CONFORMITY

- Precision Medical Inc.
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  - The Netherlands
  - **Phone**: +31 (0)70.345.8570
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- REF EasyPulse Flow Conserver / Flowmeter 19MFA
- **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 as amended by all subsequent directives.

Notified Body:	Lloyd's Register LRQA	1330 Enclave Pkwy, Suite 200 Houston, TX 77077
Certification Registration No's:	10055119	Date of Expiry: 5 February 2023
Devices already manufactured:	SN traceability via Device History Records	
Validity of DOC:	6 February 2018 to Date of Expiry	
Manufacture Representative:	James Parker Signature:	Digitally signed by James Parker Date: 2018.02.09 08:08:14 -05'00'
Position:	Manager, Quality System/ISO Representative	
Date of Issue:	6 February 2018	

contact

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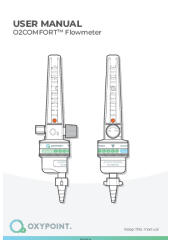
Documents / Resources

	OXYPOINT O2COMFORT Flowmeter [pdf] User Manual O2COMFORT Flowmeter, O2COMFORT, Flowmeter

References

- User Manual