

Equinox® Advantage

Nitrous Oxide/Oxygen Analgesic Gas Mixing and Delivery System



USER MANUAL

Made in Canada by
O-Two Medical Technologies Inc.
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1. INTRODUCTION

1.1 INDICATIONS FOR USE

The Equinox[®] Advantage N₂O/O₂ Analgesic Gas Mixing and Delivery System is intended to administer an adjustable mixture of Nitrous Oxide analgesic gas and Oxygen, on demand, to a conscious, spontaneously breathing patient.

The device is suitable for use in:

- Pre-hospital (emergency medical) use, and
- In-hospital use (ER, Labor and Delivery etc.)

1.2 CONTRAINDICATIONS

The contraindications for this device include, but may not be limited to:

- Hypersensitivity to the medication
- Head injuries with impaired consciousness
- Maxillofacial injuries
- Artificial, traumatic or spontaneous pneumothorax
- Air embolism
- Middle ear occlusion, ear infection
- Decompression sickness
- Abdominal distension / intestinal obstruction

NOTE: Nitrous Oxide/Oxygen (N₂O/O₂) mixtures must never be used in any condition where air is trapped in the body and expansion (up to 3x original size) would be dangerous. For example, it will exacerbate pneumothorax and increase pressure from any intracranial air. Air in any other cavities such as the sinuses, middle ear and abdomen may also expand.

1.3 PRODUCT DESCRIPTION/PRINCIPLES OF OPERATION

Two input connectors are provided on the device for the connection of pressure regulated gas sources of nitrous oxide and oxygen. The device has only one control for turning ON or OFF. When it is turned ON, the output of N₂O/O₂ gas mixture will only be activated by an inspiratory effort by the patient. The output of N₂O/O₂ gas mixture can be selected among various percentages as follows:

Setting	1	2	3	4	5	6	7	8
O ₂ %	25	40	50	60	70	75	90	100
N ₂ O %	75	60	50	40	30	25	10	0

The gas specific built-in alarm systems will generate both visual and audible alarms should either the nitrous oxide or oxygen input fall below 40 PSI, and the device will be automatically shut off should the oxygen input fall below 35 PSI. Both visual indicator and audible alarm circuits for both gasses are powered by oxygen only to prevent dumping nitrous oxide gas into atmosphere during alarm cycling.

If Oxygen Supply runs out or shuts off, the device will automatically shut off; however the device will continue to provide atmospheric room air on demand to the patient.

An Oxygen Enrichment function allows the healthcare professional to provide a constant flow of 100% oxygen to the patient.

Note: The **O-Two Equinox[®] Advantage** System is considered a critical device, and its components considered critical components. Only those individuals trained in the operation of nitrous oxide/oxygen analgesic gas delivery systems should use this equipment. Thoroughly review the instruction manual before use.

1.4 WARRANTY

WARRANTY

O-Two Medical Technologies Inc. products are manufactured from the finest quality materials. Each individual part is subject to strict quality control tests to ensure exceptionally high standards. The manufacturer warrants to the purchaser of the **O-Two Equinox[®] Advantage** N₂O/O₂ Analgesic Gas Mixing and Delivery System that its component parts are free from defects in material and workmanship for a period of two years from the date of purchase. The manufacturer will replace and /or repair all parts of the device at its option for two years from the date of purchase at no cost to the purchaser, upon the notification of the defects, in writing by the purchaser. All shipping costs shall be borne by the purchaser. The manufacturer shall be liable under this warranty only if the device and its parts have been used and serviced in the normal manner described in the instruction manual. There are no other expressed or implied warranties. This warranty gives no specific legal rights. You may also have other rights which may vary according to local regulations.

1.5 SAFETY PRECAUTIONS

The **O-Two Equinox[®] Advantage** System is designed to be operated as indicated herein. Only personnel trained in its use should operate this device. Carefully read this manual prior to operation and use.

The following precautions should always be observed:

1. CAUTION: US FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.
2. WHEN THE UNIT IS IN USE, DO NOT SMOKE OR USE NEAR OPEN FLAME EITHER DURING OPERATION OR WHEN CHANGING THE CYLINDER.
3. THE NITROUS OXIDE CYLINDER SHOULD BE OPERATED IN AN UPRIGHT POSITION. IF THE NITROUS OXIDE CYLINDER IS IN A VALVE-DOWN POSITION WHILE THE POST VALVE IS OPEN, LIQUID MAY BE EXPELLED THROUGH THE VENT PASSAGES. THIS LIQUID, NITROUS OXIDE, CAN CAUSE BURNS BY FREEZING ON EXPOSED SKIN.
4. ALWAYS TURN ON CYLINDER VALVE SLOWLY AND FULLY.
5. IT IS RECOMMENDED TO USE CYLINDERS THAT ARE AT LEAST 1/4 FULL.
6. IF THE ALARM SOUNDS CONTINUOUSLY, IMMEDIATELY DISCONTINUE USE AND SHUT OFF THE GAS SUPPLY.
7. WHEN NOT IN USE, ALWAYS TURN OFF THE CYLINDER.
8. NEVER ALLOW OIL OR GREASE TO COME INTO CONTACT WITH ANY PART OF THE CYLINDER, REGULATOR OR **EQUINOX[®] ADVANTAGE** SYSTEM. GAS MIXER HAS BEEN DEGREASED FOR OXYGEN SERVICE PRIOR TO DELIVERY. OXYGEN COMPATIBLE LUBRICANTS HAS BEEN USED ON O-RINGS.
9. DO NOT DISASSEMBLE ANY PART OF THE UNIT EXCEPT WHERE DESCRIBED IN THIS MANUAL AS ANY UNAUTHORIZED DISASSEMBLY WILL INVALIDATE THE WARRANTY.
10. AFTER USE, ALWAYS ENSURE THAT ALL COMPONENTS ARE CLEANED IN ACCORDANCE WITH THE INSTRUCTIONS PROVIDED IN THIS MANUAL.

11. ALWAYS USE THE CHECK LIST TO ENSURE THAT ALL COMPONENTS ARE REASSEMBLED CORRECTLY AND THAT ALL ITEMS ARE REPLACED.
12. NEVER ATTACH THE FACEMASK TO THE PATIENT USING A HEAD HARNESS.
13. AFTER USE, ALWAYS ENSURE THAT A GAS CYLINDER WITH SUFFICIENT VOLUME IS ATTACHED BEFORE RETURNING THE UNIT TO ITS NORMAL STORAGE POSITION.
14. BEFORE USE ON A PATIENT, THE OXYGEN CONCENTRATION OF THE DELIVERED GAS SHOULD BE CHECKED AT THE SETTING INTENDED FOR USE.
15. IT IS RECOMMENDED TO USE OXYGEN MONITOR WHENEVER THE GAS MIXER IS IN USE BY CONNECTING IT TO THE PATIENT CIRCUIT.
16. MEDICAL GASES MUST BE DRY AND FREE FROM DUST AND OIL.

1.6 PERFORMANCE SPECIFICATIONS

Minimum Flow rate	120 L/min
Exhalation Resistance	0 to 6 cmH ₂ O @ 60 L/min
Inhalation Resistance	0 to -6 cmH ₂ O @ 60 L/min
Oxygen Concentrations (±5 %V/V at Minimum Demand Flow 20 L/min)	25, 40, 50, 60, 70, 75, 90,100%
Input Pressure	50 to 70 PSI (3.5 - 4.8 Bar)
Low Input Pressure Alarm	40 ±1 PSI (2.7 Bar)
Device Cut-off Pressure	35 ±2 PSI (2.4 Bar)
Demand Valve Triggering Pressure	-1.5 to -2.5 cmH ₂ O
Oxygen Enrichment Flow	30 ± 5 L/min
Operating Temperature	41 ⁰ F to 104 ⁰ F (5 ⁰ C to 40 ⁰ C)
Storage Temperature	-40 ⁰ F to 140 ⁰ F (-40 ⁰ C to 60 ⁰ C)
Input Connection	Refer to Appendix 1
Patient Connector	15/22 mm

Patient Circuit (Single use)	c/w 30 mm Scavenging port
Patient Valve Dead Space	8 ml
Weight	4.4 lb. (2.0 Kg)
Dimensions W x D x H	9.27" x 7.6" x 4.4" 236 x 194 x 112 mm

2. PREPARATION FOR USE

2.1 COMPONENT LIST

Ensure that all the following components have been received:

- [1] Operating Manual
- [2] **O-Two Equinox[®] Advantage** System
- [3] Single Use Patient Circuit with Mouth Piece
- [4] Oxygen Supply Hose
- [5] Nitrous Oxide Supply Hose

If any components are missing from the shipping carton, call the supplier immediately.

2.2 PRE-USE FUNCTIONAL CHECKS

Along with the contents of the shipping cartons you will require the following items to enable you to undertake the pre-use functional check:

- [1] Nitrous oxide and oxygen pressure sources with 60 PSI output capable to provide a minimum of 100 L/min at no less than 42 PSI (2.9 Bar).
- [2] Vacuum generator w/30 L/min flowrate.

Leak test

Having connected the supply hoses (ISO 5359 compliant) to the regulators (refer section 3.1 for CONNECTION OF HOSES), ensure that the **O-Two Equinox[®] Advantage** System ON/OFF selector is in the OFF position and turn on the N₂O and O₂ Gas source. Using a mild soap solution, spray the input connections to the device to check for leaks. If any leak is present, tighten the connection and re-test. Once no leakage is confirmed, turn the **ON/OFF** control to the **ON** position.

Reverse gas flow test

Equinox[®] Advantage is designed to meet “reverse flow” requirement of ISO 11195. It is recommended to test the reverse flow as follows before use:

Connect one gas at a time to the corresponding input connector, spray the other input connector, no bubbles allowed from this connector.

Testing of the Individual Features of Equinox[®] Advantage System

The following features can be individually tested or measured using calibrated pressure gauge and flowmeter during the pre-use Functional Check:

[1] Demand Valve Function

Apply a vacuum to the patient connector equivalent to a flow rate of 30 L/min for a minimum of 1 second. The demand valve will provide a flow rate equivalent to that demanded. Remove the vacuum from the patient connector; the flow from patient connector should stop.

NOTE: 1. Ensure performing this test using the single use patient circuit for this device otherwise the demand valve will free flow.

2. The vacuum source can be as simple as a 500 ml calibration syringe.

[2] Low Input Pressure Alarms

NOTE: To fully test this function it is necessary to have a supply regulator with an adjustable output pressure and a release valve (Not supplied). Checking of the alarm can be undertaken by simply slowly closing the cylinder valve.

With the adjustable outlet pressure regulator set with an outlet pressure of 50 PSI, gradually reduce the outlet pressure of the regulator to around 40 PSI while slowly releasing the gas until you hear the Low Input Pressure Alarm activate. For the nitrous oxide alarm the pulsed tone frequency is set at a low frequency of approximately 60 BPM. For the low oxygen alarm, the pulsed

tone frequency is set at high frequency of approximately 120 BPM.

When low pressure alarm is activated, the Gas Supply Status Indicator should cycle at the same rate of the alarm.

[3] Low Input Pressure Shut Off

Continue decrease oxygen regulator outlet pressure to around 35 PSI, the device should be automatically shut off.

[4] Oxygen Enrichment Button

When pressed with the ON/OFF switch set to ON, Oxygen should flow out of the patient circuit.

[5] Oxygen Concentration

If required, the percentage of the oxygen concentration of the delivered gas can be determined by:

- a. Connecting an oxygen monitor to the output connector of the Advantage using a T-Connector.
- b. Utilizing a 1 Liter calibrated syringe connected to the output of the Advantage, draw 5 full breaths (1 Liter each) from the unit.
- c. Check the corresponding reading of the oxygen percentage, ensure the reading falls within +/- 10% of the preset value.

3. OPERATING INSTRUCTIONS

3.1 CONNECTION OF HOSES

The **Equinox[®] Advantage** System is designed to operate on medical nitrous oxide and oxygen from either cylinders or piped-in system. The inlet fittings on the device are non-interchangeable fittings specifically for nitrous oxide and oxygen.

The device is designed to operate under 50 - 70 PSI input pressures for both gas supplies.

In case of failure in gas input systems, **Equinox[®] Advantage** is equipped with internal pressure regulators that can handle input pressure up to 1.5 times the design input pressure without having damage to internal components.

The nitrous oxide supply hose provided shall be attached to the N₂O input connection on the left side of the device when facing it. The oxygen supply hose provided shall be attached to the O₂ input connection on the right side of the device. Tighten the supply hoses “Finger tight” only – DO NOT USE A WRENCH (fig 1).

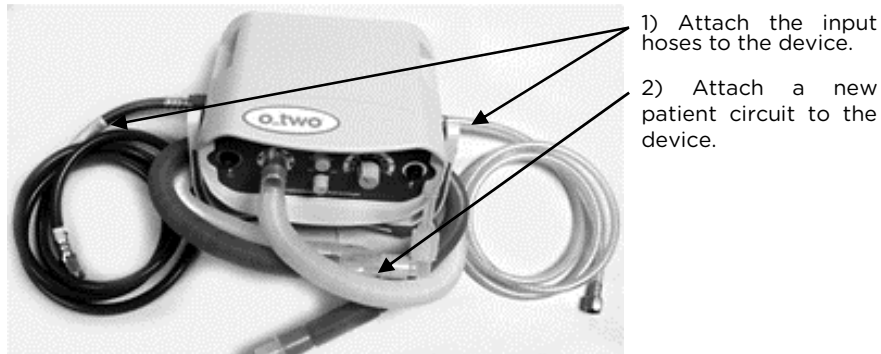


Fig.” 1” Connecting the Supply hoses and Patient Circuit

WARNING: Using a wrench or excessive force in tightening the supply hose may damage the seal or the thread of the connection.

The patient circuit is attached to the gas outlet on the front panel of the control module by simply pushing the 22 mm taper over the outlet.

3.2 ON/OFF SELECTOR

ON/OFF SELECTOR controls the device in either normal operating function or shut off.

3.3 DEMAND VALVE

The device is equipped with a Demand System enabling spontaneously breathing patients to demand preselected mixture percentage of nitrous oxide and oxygen.

An inspiratory effort by the patient will open the demand valve and preselected percentage mixture of nitrous oxide and oxygen will flow to the patient at a rate in line with their inspiratory effort.

3.4 LOW INPUT PRESSURE ALARMS

Gas Supply Status Indicators

Located on the front panel, the O₂ visual indicator shows green

when oxygen is supplied to the unit and N₂O visual indicator shows green when nitrous oxide is supplied to the unit. Used in conjunction with the Low Input Pressure alarms, these indicators provide additional reference for the operator as to the gas supply status.

Low Input Pressure Alarms

The alarm system will generate a 45 to 75 BPM visual (flashing Green/Black) and an audible alarm should nitrous oxide input fall below 40 PSI. Should the oxygen input pressure fall below 40 PSI, a 90 to 150 BPM visual (flashing Green/Black) and audible alarm will be generated.

3.5 LOW INPUT PRESSURE SHUT OFF

The device will automatically shut off should oxygen input pressure fall below 35 PSI. This indicates that the drive gas is now exhausted to the point where the device will no longer function correctly.

When only oxygen is applied, the device will not shut off, and an audible alarm will be activated with cycled N₂O visual Indicator.

When only nitrous oxide is applied, the device will automatically shut off with O₂ gas supply indicator showing black and no audible alarms activated. However the Equinox[®] Advantage will continue to allow the patient to breathe through the device on atmospheric room air.

3.6 100% OXYGEN ENRICHMENT SUPPLY

If at any time 100% Oxygen Enrichment is desired, press the Oxygen Enrichment button to activate “100% Oxygen” supply.

The Oxygen Enrichment function is designed to provide 30 L/min of 100% oxygen in order to flush any residual gas from the patient circuit following the completion of the patient treatment.

When the device ON/OFF switch is set to the “OFF” position or the device not connected to an oxygen supply, the Oxygen Enrichment function is disabled.

Warning

The Oxygen Enrichment function should never be used to provide positive pressure ventilation to non-breathing patients.

3.7 GAS MIXTURE SELECTION

This selector allows the user to choose between 8 different combinations of Oxygen and Nitrous Oxide mixtures.

4. PREVENTIVE MAINTENANCE AND SERVICING

4.1 ROUTINE MAINTENANCE

To ensure proper operation of the **O-Two Equinox[®] Advantage**, regular inspection and checking of the device and accessories for correct function should be undertaken by a responsible member of staff. It is recommended that a preventive maintenance record be maintained for each unit.

It is recommended that the routine preventive maintenance be carried out and the **Equinox[®] Advantage** mixer be returned to O-Two Medical Technologies or its authorized service center for maintenance and service every 2 years as follows:

Monthly checking

This check is to ensure that all of the accessories and device components are present, the nitrous oxide and oxygen cylinders (if used) are full and that the device is in working order.

Function checking

The device should be checked for proper function and mixing percentage (oxygen concentration) at least every six months, and more frequently in high use applications. Units with test pressures outside of the ranges listed in the product specifications should not be used.

Any malfunction unit should be returned to the manufacturer or an authorized service center since this product is not designed for field disassembly or service. Unauthorized repairs will nullify the product warranty.

Level II service

The device shall be returned to the manufacturer or a service center authorized by the manufacturer for Level II service every 2 years.

Manufacturer full service

The device shall be returned to O-Two Medical Technologies for Manufacturer Full Service every 6 years.

	Description	Procedure	Criteria	Schedule	By
PM	Visual inspection	User Manual Chapter 4.1 Monthly checking	Device in work order, gas tanks are full, no missing item	Monthly	User
PM	Leak test	User Manual Chapter 2.2	No leak observed	Every 6 months	User
PM	Function check	User Manual Chapter 2.2 [1] - [5]	Within specification	Every 6 months	User
Servicing	Level II service	Service manual	Meet product specifications	Every 2 years	Manufacturer/service center
Servicing	Full service	Service manual	Meet product specifications	Every 6 years	Manufacturer

4.2 CLEANING

Routine cleaning of the device shall be undertaken to maintain the device in a clean condition.

Patient circuit with mouth piece of the device is intended for single use and shall be discarded after each patient use in accordance with local protocols and replaced with a new circuit.

All other components should be wiped clean with a mild soap solution or hard surface disinfectant suitable for the materials of manufacture of the device. Under no circumstances should the complete unit be allowed to be soaked or immersed in cleaning solutions.

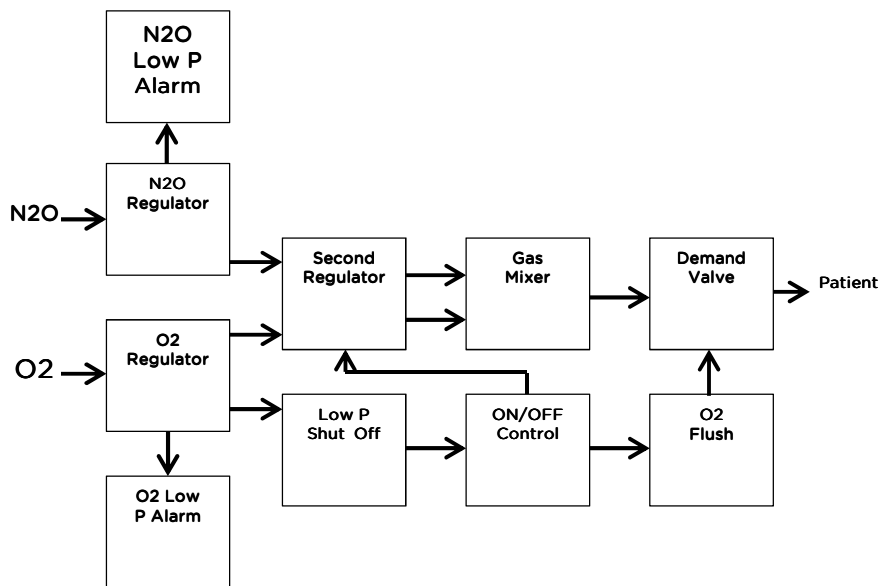
Detailed cleaning procedures are as follows:

1. Ensure that the device is disconnected from the gas supply source.

2. Remove N₂O and O₂ input hoses and wipe clean with a mild soap or hard surface disinfectant. Ensure no cleaning solution enters the hoses.
3. Remove the single patient use circuit from the device and dispose of safely in accordance with local protocols.
4. The enclosure of the device can be wiped over with a soft cloth and mild soap solution or hard surface disinfectant. Ensure no cleaning solution enters the input fittings.
5. If there is ingrained contamination a soft bristled brush may be used.
6. Dry all components thoroughly.
7. Attach a new patient circuit and connect the unit to gas supply to check function prior to packaging for emergency use.

WARNING: Do not attempt to clean and sterilize any components that are designated as disposable.

5. Schematic flow diagram



6. REPLACEMENT PARTS & ACCESSORIES

01CV8028-Cs	O-Two Medical Single-Use Relieve / Advantage 6 Foot Circuit with Scavenger Hose and Adapter with Mouthpiece	Case/10
17MP1997	O-Two 90° (Male to Female) adjustable Oxygen (O ₂) DISS elbow assy	Each
17MP1998	O-Two 90° (Male to Female) adjustable Nitrous Oxide (N ₂ O) DISS elbow assy	Each
01FM4999	Universal Facemask	Case/12

Oxygen Hoses*

01FV4303-AFNR	O-Two 6 Foot (1.85 Meter) O ₂ Supply Hose with AFNOR probe and 9/16" DISS Nut Device Connection	Each
01FV4303-AGA	O-Two 6 Foot (1.85 Meter) O ₂ Supply Hose with AGA probe and 9/16" DISS Nut Device Connection	Each
01FV4303-CZCH	O-Two 6 Foot (1.85 Meter) O ₂ Supply Hose with CZECH probe and 9/16" DISS Nut Device Connection	Each
01FV4303-DIN	O-Two 6 Foot (1.85 Meter) O ₂ Supply Hose with DIN probe and 9/16" DISS Nut Device Connection	Each
01FV4303-DISS	O-Two 6 Foot (1.85 Meter) O ₂ Supply Hose with 9/16 DISS Nut and 9/16" DISS Nut Device Connection	Each
01FV4303-UNFR	O-Two 6 Foot (1.85 Meter) O ₂ Supply Hose with UNIFOR probe and 9/16" DISS Nut Device Connection	Each
01FV4303-BM	O-Two 6 Foot (1.85 Meter) O ₂ Supply Hose with BRITISH probe and 9/16" DISS Nut Ventilator Connection	Each

Nitrous Oxide hoses*

01FV4303-AFN-N2O	O-Two 6 Foot (1.85 Meter) N ₂ O Supply Hose with AFNOR Gas Supply Fitting and N2O DISS Nut Device Connection	Each
01FV4303-AGA-N2O	O-Two 6 Foot (1.85 Meter) N ₂ O Supply Hose with AGA Gas Supply Fitting and DISS Nut Device Connection	Each
01FV4303-CZCH-N2O	O-Two 6 Foot (1.85 Meter) N ₂ O Supply Hose with Czech Gas Supply Fitting and DISS Nut Ventilator Connection	Each
01FV4303-DIN-N2O	O-Two 6 Foot (1.85 Meter) N ₂ O Supply Hose with DIN Nut and DISS Nut Device Connection	Each
01FV4310	O-Two 6 Foot (1.85 Meter) N ₂ O Supply Hose with DISS Gas Supply Fitting and DISS Nut Device Connection	Each
01FV4303-UNF-N2O	O-Two 6 Foot (1.85 Meter) N ₂ O Supply Hose with UNIFOR Gas Supply Fitting and DISS Nut Device Connection	Each
01FV4303-BM-N2O	O-Two 6 Foot (1.85 Meter) N ₂ O Supply Hose with BRITISH Gas Supply Fitting and DISS Nut Device Connection	Each

*Select the hose connection type for the country of use

MANUFACTURERS AND DISTRIBUTORS OF:

- o_two™ e-Series Electronic Transport Ventilators
- o_two™ CAREvent® Range of Automatic Transport Ventilators
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- o_two™ N₂O/ O₂ Administration Systems
- o_two™ Oxygen Demand Valves & Demand Valve Resuscitators
- o_two™ Line of Pressure and Flow Regulators

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