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O-Two Equinox® Relieve Analgesic Gas Delivery System

O-Two Equinox® Advantage Adjustable Analgesic Gas Delivery System

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Your Representative is:



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For your nearest Authorized O-Two Medical Technologies Distributor North America call Toll Free: **1-800-387-3405**



O-Two Equinox® Relieve Nitrous Oxide/Oxygen Analgesic Gas Mixing and Delivery System



01EQ1000 USER MANUAL

Made in Canada by O-Two Medical Technologies Inc. Part Number: 15PL2175 Rev.6 Jan. 2017

5. REPLACEMENT PARTS & ACCESSORIES

Oxygen Hoses*

O1FV43O3-AFNR O-Two 6 Foot (1.85 Meter) O2 Supply Hose with AFNOR probe and 9/16" DISS Nut Device Connection Each O1FV43O3-AGA O-Two 6 Foot (1.85 Meter) O2 Supply Hose with AGA probe and 9/16" DISS Nut Device Connection Each O1FV43O3-CZCH O-Two 6 Foot (1.85 Meter) O2 Supply Hose with CZECH probe and 9/16" DISS Nut Device Connection Each O1FV43O3-DIN O-Two 6 Foot (1.85 Meter) O2 Supply Hose with DIN probe and 9/16" DISS Nut Device Connection Each O1FV43O3-DISS O-Two 6 Foot (1.85 Meter) O2 Supply Hose with 9/16 DISS Nut and 9/16" DISS Nut Device Connection Each O1FV43O3-UNFR O-Two 6 Foot (1.85 Meter) O2 Supply Hose with UNIFOR probe and 9/16" DISS Nut Device Connection Each O1FV43O3-BM O-Two 6 Foot (1.85 Meter) O2 Supply Hose with BRITISH probe and 9/16" DISS Nut Ventilator Connection Each

Nitrous Oxide hoses*

O1FV43O3-AFN-N2O O-Two 6 Foot (1.85 Meter) N₂O Supply Hose with AFNOR Gas Supply Fitting and N2O DISS Nut Device Connection 01FV4303-AGA-N2O O-Two 6 Foot (1.85 Meter) N₂O Supply Hose with AGA Gas Supply Fitting and DISS Nut Device Connection Each O1FV43O3-CZCH-N2O O-Two 6 Foot (1.85 Meter) N₂O Supply Hose with Czech Gas Supply Fitting and DISS Nut Ventilator Connection Each **01FV4303-DIN-N2O** O-Two 6 Foot (1.85 Meter) N₂O Supply Hose with DIN Nut and DISS Nut Device Connection Each 01FV4303-DISS-N20 O-Two 6 Foot (1.85 Meter) N₂O Supply Hose with DISS Gas Supply Fitting and DISS Nut Device Connection Each 01FV4303-UNF-N2O O-Two 6 Foot (1.85 Meter) N₂O Supply Hose with UNIFOR Gas Supply Fitting and DISS Nut Device Connection Each **01FV4303-BM-N2O** O-Two 6 Foot (1.85 Meter) N₂O Supply Hose with BRITISH Gas Supply Fitting and DISS Nut Device Connection Each

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^{*}Select the hose connection type for the country of use

1. INTRODUCTION

1.1 INDICATIONS FOR USE

The O-Two Equinox® Relieve N_2O/O_2 Analgesic Gas Mixing and Delivery System is intended for delivering a 50/50% mixture of nitrous oxide and oxygen, on demand, to a conscious, spontaneously breathing patient.

The device is suitable for use in:

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

1.2 CONTRAINDICATIONS

- 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 (N_2O/O_2) 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 gut may also expand.

1.3 PRODUCT DESCRIPTION/PRINCIPLES OF OPERATION

The device provides two input connectors for connection with nitrous oxide and oxygen cylinders through pressure regulators. The device has only one control for turning ON or OFF the device. When it is turned ON, the output of N_2O/O_2 gas mixture will only be activated by an inspiratory effort by the patient. The output of N_2O/O_2 gas mixture is pre-set at 50/50%. Neither the patient nor medical personnel are able to adjust, eliminating the risk of delivering a hypoxic mixture.

The gas specific built-in alarm systems will generate both visual and audible alarms should either the nitrous oxide or oxygen input fall below 37 PSI.

Detailed cleaning procedure is as follows:

- 1. Ensure that the device is disconnected from the gas supply source.
- 2. Remove N_2O and O_2 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.

4. SERVICING

4.1 ROUTINE MAINTENANCE

To ensure proper operation of the O-Two Equinox® Relieve System 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 service record be maintained for each unit. This check is to ensure that all of the accessories and device components are present, the nitrous oxide and oxygen cylinders are full and that the device is in working order.

The device should be checked 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. O-Two Medical products are not designed for field disassembly or service outside that indicated in this manual. Any malfunctioning units should be returned to the manufacturer or an Authorized O-Two Medical Technologies Service Center. Unauthorized repairs will nullify the product warranty.

4.2 CLEANING

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

The patient circuit and mouth piece of the device are 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.

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.

The device is also equipped with a secondary "fail safe" circuit that will activate an alarm and shut off the device should internal malfunction occur in the mixer or any internal hoses rupture or kink.

If either the Nitrous Oxide or Oxygen Supply runs out or is shut off, the device will automatically shut off; however the patient will be able to breathe atmospheric room air through the emergency air intake.

Note: The **O-Two Equinox® Relieve** 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® Relieve 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® Relieve** 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. <u>CAUTION:</u> 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. DO NOT USE IF THE INPUT PRESSURE LOWER THAN 50 PSI.
- 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 O-Two Equinox® Relieve SYSTEM.
- 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 IN THE CARRYING CASE.
- 12. AFTER USE, ALWAYS ENSURE THAT A FULL GAS CYLINDER IS ATTACHED BEFORE RETURNING THE UNIT TO ITS NORMAL STORAGE POSITION.
- 13. NEVER ATTACH THE FACEMASK TO THE PATIENT USING A HEAD HARNESS.

3.3 DEMAND VALVE

The device is equipped with a Demand System enabling spontaneously breathing patients to demand 50/50% nitrous oxide and oxygen.

An inspiratory effort by the patient will open the demand valve and 50/50% 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 O_2 visual indicator shows green when oxygen is supplied to the unit and N_2O 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 60 BPM visual (flashing Green/Black) and an audible alarm should nitrous oxide input pressure fall below 41 PSI. Should the oxygen input pressure fall below 41 PSI, a 120 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 either nitrous oxide or oxygen input pressure fall below 37 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 automatically shut off, and an audible alarm will be activated with cycled N_2O visual Indicator. When only nitrous oxide is applied, the device will automatically shut off with O_2 gas supply Indicator showing black and no audible alarms activated.

If either the Nitrous Oxide or Oxygen Supply runs out or is shut off, the device will allow the patient to breathe on atmospheric room air through the emergency air intake.

3. OPERATING INSTRUCTIONS

3.1 CONNECTION OF HOSES

The **O-Two Equinox® Relieve** System is designed to operate on medical nitrous oxide and medical oxygen from either a cylinder or piped-in system.

The inlet fittings on the device are non-interchangeable DISS fittings specifically for nitrous oxide and oxygen.

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

The nitrous oxide supply hose provided shall be attached to the N_2O input connection on the left side of the device. The oxygen supply hose provided shall be attached to the O_2 input connection on the right side of the device. Tighten the supply hoses "Finger tight" only – DO NOT USE A WRENCH (fig 1).

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.

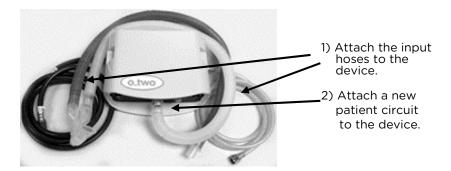


Fig 1. Connecting the Supply hoses and Patient Circuit

3.2 ON/OFF SELECTOR

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

1.6 PERFORMANCE SPECIFICATIONS

Minimum Flow rate	
Exhalation Resistance	0 to 6 cmH ₂ O @ 60 L/min
Inhalation Resistance	0 to -6 cmH ₂ O
Our construction	@ 60 L/min
Oxygen ConcentrationInput Pressure	
input Fressure	(3.5 to 4.8 Bar)
Demand Valve Triggering	(0.0 to 20.)
Pressure	1.5 to -2.5 cmH ₂ O
Operating Temp	41°F to 104°F
CI T	$(5^{\circ}C \text{ to } 40^{\circ}C)$
Storage Temp	40°F to 140°F (-40°C to 60°C)
Nitrous Oxide Input	(-40 C to 60 C)
Connection	CGA1040 DISS
Oxygen Input Connection	CGA1240 DISS
Patient Connector	
Patient Circuit	
Dationt Value Dand Crass	Scavenging port
Patient Valve Dead Space Weight	53 oz. (1.5 Kg)
Dimensions W x D x H : (inches)	
	226x168x99
` ,	

2. PREPARATION FOR USE

2.1 COMPONENT LIST

Having unpacked the O-Two Equinox® Relieve System from its shipping carton, use the following list to ensure that all components have been received:

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

NOTE: If any components are missing from the shipping carton, immediately call the supplier quoting the packing slip number, your original purchase order number and the description of the item which is missing.

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 with 30 L/min flowrate

Leak Test

Having connected the supply hoses to the regulators (refer section 3.1 for CONNECTION OF HOSES), ensure that the O-Two Equinox® Relieve ON/OFF selector is in the OFF position and turn on the N₂O and O₂ supplies. 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

O-Two Equinox® Relieve 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 the O-Two Equinox® Relieve System

The following features can be individually tested during the preuse Functional Check:

- Demand Valve Function [1]
- [2] Low Input Pressure Alarm
- Γ31 Low Input Pressure Shut Off

[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 either nitrous oxide or oxygen regulator outlet pressure to around 35 PSI, the device should be automatically shut off.