MANUFACTURERS AND DISTRIBUTORS OF:

O-Two eSeries of Electronic Automatic Transport Ventilators
O-Two Single Use Open CPAP Systems
O-Two CAREvent® Range of Automatic Transport Ventilators
O-Two CAREvent® Range of Handheld Automatic Resuscitators
O-Two SMART BAG® MO “Controlled Flow” Manual Resuscitators
O-Two Oxygen Demand Valve and Demand Valve Resuscitators
O-Two Pressure Regulators
O-Two Equinox® 50% N_2O/50% O_2 Administration System
O-Two Equinox® Relieve Analgesic Gas Delivery System
O-Two Equinox® Advantage Adjustable Analgesic Gas Delivery System
O-Two First Response CPR Devices

Your Representative is:

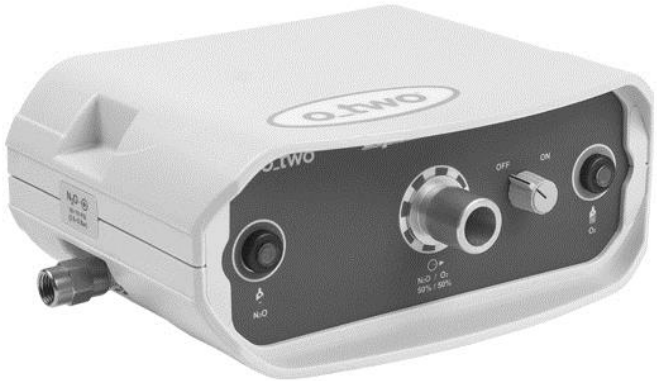
CE 0120

EC REP **MedNet GmbH**
Borkstrasse, 10
48163 Münster, Alemanha

O-TWO MEDICAL TECHNOLOGIES INC.
45A, Armthorpe Road, Brampton,
Ontario, Canada, L6T 5M4
Office: +1 905 792 OTWO (6896) Fax: +1 905 799 1339
Email: resuscitation@otwo.com Web: otwo.com

o_two controlled ventilation

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



01EQ1000
and
01EQ1000F

USER MANUAL

Made in Canada

Part Number: 15PL2175 Rev. 12 15 May, 2019

5. REPLACEMENT PARTS & ACCESSORIES

01CV8028-Cs	O-Two Single-Use Analgesic Gas Patient Circuit with Scavenger Hose and Adapter with Mouthpiece (Case/10)
17MP1997	90° (Male to Female) adjustable Oxygen DISS elbow
17MP1998	90° (Male to Female) adjustable Nitrous Oxide DISS elbow
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
01FV4303-AGA	O-Two 6 Foot (1.85 Meter) O_2 Supply Hose with AGA probe and 9/16" DISS Nut Device Connection
01FV4303-CZCH	O-Two 6 Foot (1.85 Meter) O_2 Supply Hose with CZECH probe and 9/16" DISS Nut Device Connection
01FV4303-DIN	O-Two 6 Foot (1.85 Meter) O_2 Supply Hose with DIN probe and 9/16" DISS Nut Device Connection
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
01FV4303-UNFR	O-Two 6 Foot (1.85 Meter) O_2 Supply Hose with UNIFOR probe and 9/16" DISS Nut Device Connection
01FV4303-BM	O-Two 6 Foot (1.85 Meter) O_2 Supply Hose with BRITISH probe and 9/16" DISS Nut Ventilator Connection

Nitrous Oxide hoses*

01FV4303-AFN-N2O	O-Two 6 Foot (1.85 Meter) N_2O Supply Hose with AFNOR Gas Supply Fitting and N2O DISS Nut Device Connection
01FV4303-AGA-N2O	O-Two 6 Foot (1.85 Meter) N_2O Supply Hose with AGA Gas Supply Fitting and DISS Nut Device Connection
01FV4303-CZCH-N2O	O-Two 6 Foot (1.85 Meter) N_2O Supply Hose with Czech Gas Supply Fitting and DISS Nut Ventilator Connection
01FV4303-DIN-N2O	O-Two 6 Foot (1.85 Meter) N_2O Supply Hose with DIN Nut and DISS Nut Device Connection
01FV4303-DISS-N2O	O-Two 6 Foot (1.85 Meter) N_2O Supply Hose with DISS Gas Supply Fitting and DISS Nut Device Connection
01FV4303-UNF-N2O	O-Two 6 Foot (1.85 Meter) N_2O Supply Hose with UNIFOR Gas Supply Fitting and DISS Nut Device Connection
01FV4303-BM-N2O	O-Two 6 Foot (1.85 Meter) N_2O Supply Hose with BRITISH Gas Supply Fitting and DISS Nut Device Connection

***Select the hose connection type for the country of use**

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.

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. If there is ingrained contamination a soft bristled brush may be used.
5. Dry all components thoroughly.
6. 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.

TABLE OF CONTENTS

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

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 (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 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.

.4. SERVICING

4.1 ROUTINE MAINTENANCE

To ensure proper operation of the O-Two Equinox® Relieve, 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 the routine preventive maintenance be carried out and the Equinox® Relieve mixer be returned to O-Two Medical Technologies or its authorized service center for maintenance and service every 2 years as follows:

	Description	Procedure	Criteria	Schedule	By
PM	Visual inspection	User Manual 4.1 Monthly checking	Device in work order, gas tanks are full, no missing item	Monthly	User
PM	Leak test	User Manual 2.2	No leak observed	Every 6 months	User
PM	Function check	User Manual 2.2 [1] - [4]	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

Monthly inspection
The device should be visual inspected and leak tested monthly to ensure that the components and accessories are present, the gas cylinders are full and the device is in working order.

Function check
The device should be checked for proper function and mixture output concentration at least every six months, and more frequently in high use applications. 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 an authorized service center 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.

3.6 FAILSAFE PROTECTION

The O-Two Equinox® Relieve System is equipped with a primary "Failsafe" protection circuit.

Should the output pressure differential of the internal mixer valve exceed 2 psi the "Fail Safe" protection circuit will activate, a continuous alarm will sound and the device will shut off.

Note: In Use, the drop in low input pressure may cause a difference in output pressure and trigger the Failsafe protection. In this case the shut off alarm will activate instead of the low pressure alarm.

When the device is turned off the Failsafe protection circuit is deactivated. Once initiated the alarm will continue its constant tone until the device is turned off or the pressure differential is resolved.

3.7 OUTPUT CONCENTRATION MONITORING

An oxygen monitor with alarm should be used to monitor the output of the N_2O/O_2 mixture. The monitor "Tee" piece is to be placed on the outlet of the mixer prior to the circuit being attached (fig 2).

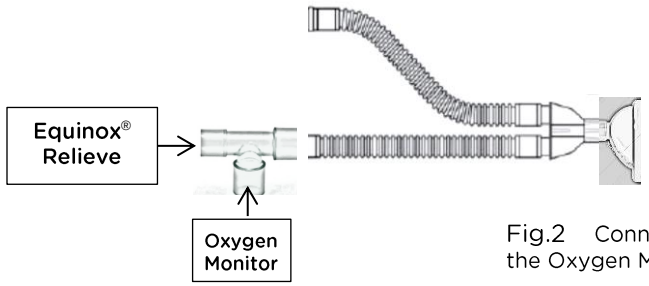


Fig.2 Connecting the Oxygen Monitor

NOTE: Placing an oxygen monitor in the above location will remove the additional monitoring line from becoming an issue for the patient if the "Tee" piece is placed proximal to the facemask. Additionally, the one-way valve system in the O-Two Equinox® circuit will prevent expired air from reaching the monitor.

The gas specific built-in alarm systems will generate both visual and audible alarms should either the nitrous oxide or oxygen input drop to 40 PSI, and the device will be automatically shut off should either the Nitrous Oxide or Oxygen input drop to 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.

The device is also equipped with a primary "failsafe" circuit (3.6) that will activate a continuous alarm and shut off the device should the output pressure differential from the mixer exceed 2 psi.

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. It shall only be used by patients under the guidance of those individuals trained in the operation of nitrous oxide/oxygen analgesic gas delivery systems. Thoroughly review the instruction manual before use.

The 01EQ1000F is fitted with an oxygen enrichment button to allow for the flushing of the system after 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 N_2O/O_2 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 a self-administered device. It shall only be used by patients under the guidance of qualified personnel trained in its use. Carefully read this manual prior to operation and use.

The following precautions should always be observed:

⚠ WARNINGS

1. WHEN THE UNIT IS IN USE, DO NOT SMOKE OR USE NEAR OPEN FLAME EITHER DURING OPERATION OR WHEN CHANGING THE CYLINDER.
2. NEVER ALLOW OIL OR GREASE TO COME INTO CONTACT WITH ANY PART OF THE CYLINDER, REGULATOR OR EQUINOX® RELIEVE SYSTEM. THE DEVICE HAS BEEN DEGREASED FOR OXYGEN SERVICE PRIOR TO DELIVERY.
3. EQUINOX® RELIEVE SYSTEM IS DESIGNED FOR PATIENT SELF-ADMINISTRATION.
4. NEVER ATTACH THE FACEMASK TO THE PATIENT USING A HEAD HARNESS.
5. IF THE ALARM SOUNDS CONTINUOUSLY, IMMEDIATELY DISCONTINUE USE AND SHUT OFF THE GAS SUPPLY.
6. IT IS RECOMMENDED THAT AN OXYGEN MONITOR BE USED WITH THIS DEVICE TO MONITOR THE GAS OUTPUT. HOWEVER, IF THERE IS A CONCERN THAT THE DEVICE HAS NOT UNDERGONE REGULAR MAINTENANCE, AT THE PRESCRIBED INTERVALS, IN ACCORDANCE WITH THIS MANUAL, THEN AN OXYGEN MONITOR SHALL BE USED.

CAUTIONS:

7. MEDICAL GASES MUST BE DRY AND FREE FROM DUST AND OIL.
8. 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.
9. IT IS RECOMMENDED TO USE CYLINDERS THAT ARE AT LEAST 1/4 FULL. ALWAYS TURN ON CYLINDER VALVE SLOWLY AND FULLY. WHEN NOT IN USE, ALWAYS TURN OFF THE CYLINDER.
10. AFTER USE, ALWAYS ENSURE THAT A GAS CYLINDER WITH SUFFICIENT VOLUME IS ATTACHED BEFORE RETURNING THE UNIT TO ITS NORMAL STORAGE POSITION.

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 and N_2O visual indicators turn green when oxygen and Nitrous Oxide are 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

At any time, if the input pressure of either gas drops to 40 PSI, a visual and audible Low Input Pressure alarm will be activated. The alarm will cycle 45 to 75 times per minute for Nitrous Oxide, or 90 to 150 times for Oxygen and the gas supply indicators will flash Green to black.

3.5 LOW INPUT PRESSURE SHUT OFF

The device will automatically shut off should the input pressure of either gas drop to 35 PSI. This indicates that the drive gas is now exhausted to the point where the device will no longer function correctly (see also the Note in 3.6).

NOTE: The shut off alarms will cease to function completely should the O_2 input pressure drop below 20 PSI.

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.

4 OXYGEN ENRICHMENT BUTTON (01EQ1000F only)

With the ON/OFF switch set to ON, a constant flow of oxygen will be supplied to the patient when the enrichment button is depressed.

NOTE: If the oxygen enrichment control is held depressed for an extended period the device may alarm. Releasing the button will cancel the alarm.

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 individual gas cylinders or piped-in medical gas systems.

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.

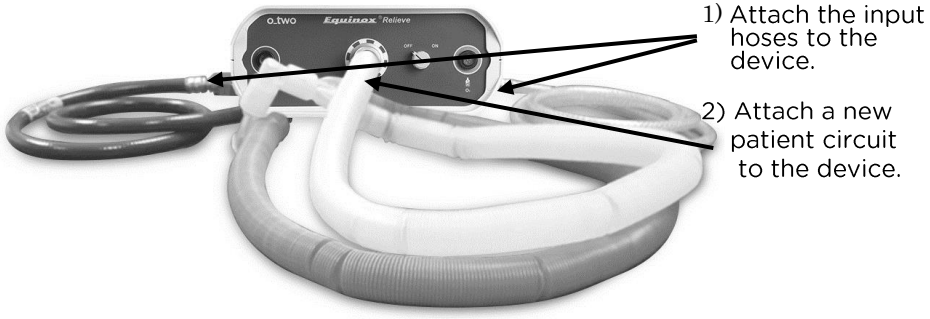


Fig 1. Connecting the Supply hoses and Patient Circuit

3.2 ON/OFF SELECTOR

The ON/OFF SELECTOR controls the device in either its normal operating mode or shut off.

11. AFTER USE, ALWAYS ENSURE THAT ALL COMPONENTS ARE CLEANED IN ACCORDANCE WITH THE INSTRUCTIONS PROVIDED IN THIS MANUAL.

12. DO NOT DISASSEMBLE ANY PART OF THE UNIT EXCEPT WHERE DESCRIBED IN THIS MANUAL AS ANY UNAUTHORIZED DISASSEMBLY WILL INVALIDATE THE WARRANTY.

13. BEFORE USE ON A PATIENT, THE OXYGEN CONCENTRATION OF THE DELIVERED GAS SHOULD BE CHECKED.

14. US FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

1.6 PERFORMANCE SPECIFICATIONS

Minimum Flow rate	120 L/min
Exhalation Resistance	0 to 6 cmH_2O @ 60 L/min
Inhalation Resistance	0 to -6 cmH_2O @ 60 L/min
Oxygen Concentrations	42.5- 57.5%
Oxygen Enrichment Flow (01EQ1000F only)	30 L/min
Input Pressure	50 to 70 PSI (3.5 - 4.8 Bar)
Low Input Pressure Alarm	40 ± 1 PSI (2.7 Bar)
Device Shut-off Pressure	35 ± 4 PSI (2.7 Bar)
Failsafe protection	~ 2 PSI differential pressure between O_2 and N_2O output gas. Prevents the output of high nitrous oxide concentrations
Demand Valve Triggering Pressure	-1.5 to -2.5 cmH_2O
Supply Hose Connections	Refer to Section 6
Device Input Connections	Nitrous Oxide: CGA1040 DISS Oxygen: CGA1240 DISS
Patient Connector	15/22 mm
Patient Circuit (Single use)	Dual limb circuit with one-way valves and 19 mm Scavenging Port Connection on the exhalation limb
Patient Valve Dead Space	32 ml
Operating Temperature	41^0F to 104^0F (5^0C to 40^0C)
Storage Temperature	-40^0F to 140^0F (-40^0C to 60^0C)
Weight	3.3 lb. (1.5 Kg)
Dimensions W x D x H	8.9"x6.6"x3.9" 226x168x99mm)

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
[6] Test 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:

- 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).
- A breathing simulator with 30 L/min demand flow over a minimum of 1 second. As an option, wall suction may be used to generate the 30 L/min flow however this is less accurate.

Leak Test

Having connected the supply hoses to the regulated gas supplies (refer to 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 N_2O and O_2 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

To test the reverse flow, connect one gas at a time to the corresponding input connector, spray the other input connector, no bubbles allowed from this connector.

Function test

The following features of the Equinox® Relieve System can be individually tested or measured using a calibrated pressure gauge and flowmeter during the Pre-use Functional Check:

[1] Demand Valve Function and Oxygen Concentration

Demand Valve function and oxygen concentration of the delivered gas can be determined by the following procedure:

a. Connect an oxygen monitor to the output connector of the Relieve using the "3-Way T" Connector test assembly supplied.
b. Utilizing a 1 Liter calibrated syringe, connect the syringe to the patient connection on the patient circuit connected to T-connector. Turn on the Relieve unit and activate the demand valve by cycling the syringe until the oxygen reading on the monitor has stabilized. Demand valve function is confirmed by a change in the reading on the monitor.

Setting	Acceptable Range
50%	40% – 60%

0

[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 may be undertaken by simply slowly closing the cylinder valve.

With the adjustable inlet pressure regulator set to a supply pressure of 50 PSI, gradually reduce the supply pressure of the regulator to around 40 PSI while slowly releasing the gas until you hear the Low Input Pressure Alarm activated. 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 corresponding Gas Supply Status Indicator will also cycle at the same rate of the alarm.

[3] Low Input Pressure Shut Off

Continue to decrease the outlet pressure of the regulator to around 35 PSI, the device should automatically shut off, and at the same time, in the event the N_2O pressure drops below 35 PSI, an additional continuous alarm will be activated.

[4] Oxygen Enrichment Button (01EQ1000F only)

The oxygen flow and concentration can be measured at the patient connection port using an O_2 monitor and flow meter.