Nitrous Oxide & Oxygen Gas Delivery System

CMI-0100-PNX-xxx

USER MANUAL

Made for CAREstream America | CMI-FORM-0100MAN-PNX V.9

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PRO-NOX™

Nitrous Oxide & Oxygen Delivery System

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1. WELCOME TO THE PRO-NOX™ NITROUS OXIDE DELIVERY SYSTEM

1.1 INTRODUCTION

The PRO-NOX Nitrous Oxide Delivery System is a pneumatically driven gas mixer designed to deliver a 50% Oxygen (O_2) and 50% Nitrous Oxide (N_2O) gas mixture to adult and pediatric patients for the relief of pain in a medical setting.

1.2 UNPACKING AND INSPECTION

Inspect packaging for damage – document any damage seen

Remove all contents from the PRO-NOX packaging, and ensure the following are included:

PRO-NOX Nitrous Oxide Delivery Mixer (Head Unit)
6-foot nitrous oxide high-pressure hose
6-foot oxygen high-pressure hose
Single-use patient circuit including mouthpiece and nose clip (x2)
Quick Reference Guide
Resources USB, Cylinder Wrench, and two (2) spare Bodok Seals
Regulators for N_2O and O_2 e-cylinder tanks
Patient Brochures

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

1.3 ABREVIATIONS AND SYMBOLS USED IN THIS MANUAL

N_2O	Nitrous Oxide
O_2	Oxygen
DISS	Diameter Index Safety System
PSI	Pounds per Square Inch pressure - equivalent to PSIG (gas) for the purposes of this manual
LPM	Liters per minute flow
cmH2O	Centimeters of water pressure
$^{\circ}C$	Degrees Celsius
$^{\circ}F$	Degrees Fahrenheit
mm	Millimeter
mL	Milliliter
lb	Pound
kg	Kilogram

⚠ 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, could result in minor or moderate injury or damage to equipment.

1.4 READ ALL INSTRUCTIONS PRIOR TO USE

⚠ CAUTION — Federal (USA) Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner) who has appropriate training and experience.

1.5 WARNINGS AND CAUTIONS

WARNING

- This device is restricted to sale by or on the order of a licensed healthcare practitioner
- Only trained, qualified medical personnel should operate this device
- Use this device only for its intended purpose as indicated in this manual
- Ensure absence of contra-indications before administering nitrous oxide
- Monitor patient closely while delivering nitrous oxide and afterward until effects are cleared
- Monitor patient oxygen saturations during administration of nitrous oxide, and discontinue use if oxygen saturations are not acceptable while patient is breathing on PRO-NOX
- DO NOT obstruct patient ambient-air inlet on back of machine
- If audible alarm sounds continuously, DISCONTINUE USE AND SHUT OFF SOURCEGAS
- DO NOT use this device or handle compressed gas near any open flame or other ignition source
- ALWAYS follow ANSI and CGA standards when handling compressed medical gases
- Servicing of this device should only be done by a qualified and authorized service technician. ANY UNAUTHORIZED DISASSEMBLY WILL INVALIDATE THEWARRANTY
- The nitrous oxide cylinder should be operated in an upright position. If it is in a valve-downposition while the cylinder valve is open, liquid may be expelled through the vent passages.This liquid nitrous oxide can cause burns by freezing exposed skin
- Never allow oil or grease to come into contact with any part of the cylinders, regulators orPRO-NOX device
- Where scavenging is being used, ensure the patient is maintaining a seal with themouthpiece or mask during exhalation
- *** NEVER HOLD THE MOUTHPIECE OR MASK IN PLACE FOR THE PATIENT OR USE A HEAD HARNESS.THE PATIENT MUST DO THIS ON THEIR OWN. IF THE PATIENT CANNOT, CONSIDER ALTERNATIVE FORMS OF ANALGESIA
- Turn off compressed gas source prior to storage of PRO-NOX device
- Store PRO-NOX in a clean, dry area when not in use
- NOT MRI COMPATIBLE
- Ensure all gas fittings are tight and leak free
- Adding components (filters, circuit extensions) to circuit may increase inspiratory resistance.If patient complains of difficulty in breathing through device, remove additional components
- Instruct patient to breathe out into mask or mouthpiece and to maintain seal throughout respiratory cycle
- Always open cylinder valves slowly and completely
- After use, always ensure that all components are cleaned or replaced in accordance with theinstructions provided in this manual
- Use this device in areas with appropriate ventilation to minimize atmospheric exposure to inhaled analgesic

1.6 INDICATIONS FOR USE

The PRO-NOX™ Nitrous Oxide and Oxygen 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.

1.7 CONTRAINDICATIONS

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

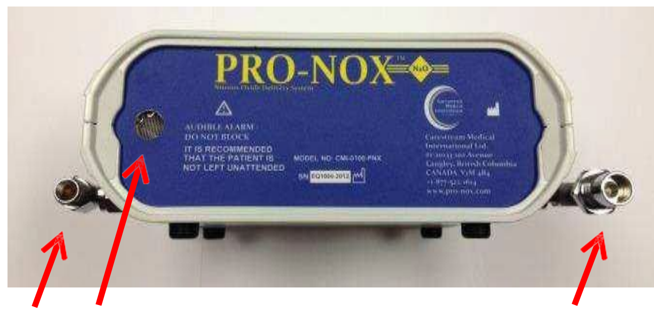
- Hypersensitivity to nitrous oxide mixtures
- Head injuries with impaired consciousness
- Maxillofacial injuries
- Artificial, traumatic or spontaneous pneumothorax
- Air embolism
- Middle ear occlusion, ear infection
- Decompression sickness
- Severe abdominal distension secondary to intra-abdominal air / intestinal obstruction
- Inability of patient to follow directions
- Inability of patient to hold own delivery device (mouthpiece or mask)

⚠ WARNING 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.

1.8 PRODUCT DESCRIPTION

The PRO-NOX™ System is designed to operate on medical nitrous oxide and medical oxygen from cylinders and/or medical gas piping systems. Supply gas shall be 50-70 PSI and able to supply 100 LPM flow at these pressures.

(2) (4) (1) (3)



(6) (7) (5)

(1) ON/OFF switch. With switch turned to ON and source gases connected, the demand valve will activate with -2.5 cmH2O inspiratory pressure. With switch in OFF position, the demand valve is inactive, and patient will breathe ambient air via opening at rear of device mixer (7)

(2) Nitrous Oxide and (3) Oxygen supply pressure indicators 'light up' green when pressurized with the indicated gas. These also serve as visual "flashing" indicators if low source gas pressure alarm is activated.

NOTE: the visual indicator will remain 'lit' with tank turned off if internals remain pressurized.

(4) Outlet of mixed PRO-NOX 50/50 gas to patient. 22mm OD connection for attachment of patient circuit

(5) DISS gas inlet connection for nitrous oxide source gas

(6) DISS gas inlet connection for oxygen source gas

The delivered gas mixture is pre-set at 50% nitrous oxide and 50% oxygen. Neither the patient, nor medical personnel, are able to adjust this ratio, 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 source pressure fall to 40 PSI, and the demand valve will no longer activate should either the nitrous oxide or oxygen source pressure drop to 35 PSI.

The device is also equipped with a primary "fail safe" circuit that will activate a continuous audible alarm and disable the demand valve should internal malfunction occur in the mixer or any internal hoses rupture or kink.

⚠ WARNING

THE PRO-NOX™ NITROUS OXIDE DELIVERY SYSTEM IS CONSIDERED A CRITICAL DEVICE, AND ITS COMPONENTS CONSIDERED CRITICAL COMPONENTS. ONLY THOSE MEDICAL PERSONNEL TRAINED IN THE OPERATION OF NITROUS OXIDE/OXYGEN ANALGESIC GAS DELIVERY SYSTEMS SHOULD USE THIS EQUIPMENT. THOROUGHLY REVIEW THE INSTRUCTION MANUAL BEFORE USE.

1.9 PERFORMANCE SPECIFICATIONS

(Minimum) Peak Flow rate	120 LPM
Inhalation Resistance	0 to -6 cmH_2O @ 60 LPM
Exhalation Resistance	0 to 6 cmH_2O @ 60 LPM
Input Pressure	50 – 70 PSI (3.5-4.8 Bar)
Oxygen Concentration	42.5 to 57.5%
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)
Fail Safe 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 cmH2O
Operating Temperature	41°F to 104°F (5°C to 40°C)
Storage Temp	-40°F to 140°F (-40°C to 60°C)
Nitrous Oxide Input Connection	CGA1040 DISS
Oxygen Input Connection	CGA1240 DISS
Patient Connector	15/22 mm
Patient Circuit (Single use)	Dual limb circuit with one-way valves and 19 mm Scavenging Port Connection and Filter
Patient Valve Dead Space	32 ml
Weight	3.3 lbs (1.5 Kg)
Dimensions W x D x H :	8.9” x 6.6” x 3.9” (226 x 168 x 99 mm)

2. PREPARATION FOR USE

2.1 PRE-USE ASSEMBLY

If the PRO-NOX™ is being mounted on a wall arm or rolling stand, attach mounting plate to the PRO-NOX™ unit as described in the instructions that come with the mount.

Attach high-pressure hoses to the appropriate inlet DISS connections on the PRO-NOX™.
*** HAND-TIGHT ONLY ***

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

Connect hoses to gas source (wall outlets or cylinder regulators).

Attach patient circuit to the patient outlet on the front of the PRO-NOX™. A bacterial/viral filter (ex. PharmaSystems Pharma Mini Filter) may be placed between the machine outlet and thepatient circuit. This filter should be changed with the patient circuit. Alternatively, placing the bacterial/viral filter between the patient valve head and the mouthpiece or mask will filter exhaled gases from the patient.

Attach scavenging tubing to exhalation port of patient valve using the scavenging connector and connect distal end of tubing to anesthetic gas scavenging system or (optional) PRO-NOX™ active scavenging system.

3. OPERATING INSTRUCTIONS

3.1 ON/OFF SELECTOR

In the ON position, a patient inspiratory effort will activate the demand valve and deliver the Nitrous Oxide/Oxygen gas mixture. In the OFF position, patient efforts will draw ambient air via the port on the back of the mixer device.

3.2 DEMAND VALVE

The device is equipped with a demand system providing a 50% nitrous oxide / 50% oxygen mixture to spontaneously breathing patients via the patient mouthpiece or mask.

An inspiratory effort by the patient will open the demand valve and the 50/50 gas mixture will flow to the patient matching the patient's inspiratory effort.

3.3 GAS SUPPLY VISUAL INDICATORS

Located on the front panel, the O_2 visual indicator shows green when oxygen is supplied to the unit at a sufficient pressure, and the N_2O visual indicator shows green when nitrous oxide is supplied to the unit at a sufficient pressure. Used in conjunction with the Low Input Pressure Alarms, these indicators provide additional reference for the operator as tothe gas supply status.

ON OFF

3.4 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 minutes for Nitrous Oxide, or 90 to 150 times for Oxygen. The Gas Supply Indicators will flash green to black.

Deep, fast inspiration may cause the low-pressure alarm to 'chirp' as the internal pressures drop due to high patient flow demand. This will cease as inspiratory flow demand slows. The patient should be encouraged to take slow deep breaths to maximize analgesic effect while minimizing hyperventilation.

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 note in Section 3.6)

The shut off alarms will cease to function completely should the O_2 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 from the back of the mixer device.

3.6 FAILSAFE PROTECTION

The PRO-NOX gas delivery system is equipped with a primary "Failsafe" protection circuit.

Should the output pressure differential of the internal mixer valve exceed 2 PSI, the "Failsafe" 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.

4. MAINTENANCE

4.1 ROUTINE CHECKS

Inspection of the PRO-NOX™ Nitrous Oxide Delivery System and checking of the device to ensure functioning Low Supply Pressure Alarms and Shut-offs should be performed on a regular basis, minimally every 6 months (see Section 4.3. PRE-USE FUNCTIONAL CHECKS), and it is recommended that a record of these checks be maintained for each unit. Beyond this, analysis of the patient gas mixture should be done once/year to ensure delivered gases are within specified range.

*** More in-depth testing of the alarm and shut-off thresholds should be performed with the use of adjustable pressure regulators whenever proper function of the safety mechanisms is questioned. Slowly decrease the source pressure while activating the demand valve until each safety feature is activated.

⚠ WARNING Units with test pressures or gas delivery outside of the ranges listed in the product specifications should not be used.

This PRO-NOX™ device is not designed for field service beyond that indicated in this manual. Any attempt to modify or repair this unit will make void the product warranty. If you have a unit that requires servicing, contact your local distributor prior to returning the unit.

	Description	Procedure	Criteria	Schedule	By
Preventative Maintenance	Visual Inspection	User Manual 4.3 Monthly Check	Device in working order, gas tanks are full, no missing items	Monthly	User
Preventative Maintenance	Leak Test	User Manual 4.3 “Leak Test”	No leak observed	Every 6 months	User
Preventative Maintenance	Function Check	User Manual 4.3 “Function Check”	Within specifications	Every 6 months	User
Servicing	Level II Service	Service Manual	Meet product specifications	Annually	Service Center
Servicing	Full Service	Service Manual	Meet product specifications	Every 6 years	Service Center

4.2 CLEANING PROCEDURES

Routine cleaning of the device shall be undertaken to maintain the device in a useable and sanitary condition.

Patient circuit is intended for single use and shall be discarded after each patient use in accordance with local protocols and replaced with a new circuit. The patient interface (mouthpiece or mask) shall be disposed of or cleaned between patients as indicated. Mouthpieces provided with the patient circuits are to be disposed of between patients.

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 the single patient use circuit from the device and dispose of safely in accordance with local protocols.
3. 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 or input fittings.
4. The PRO-NOX enclosure can be wiped over with a soft cloth and mild soap solution or hard surface disinfectant.
5. If there is ingrained contamination a soft bristled brush may be used.
6. Dry all components thoroughly.
7. Surface disinfection may be performed using disinfectant wipes compatible with polycarbonate materials. Ex. CaviWipes™ or Accel™ products with 0.5% accelerated hydrogen peroxide. Disinfect as per disinfection product instructions.
8. Attach a new patient circuit and connect the unit to the gas supply. Check function prior to packaging for emergency use.

⚠ WARNING

Do not attempt to clean or sterilize any components that are designated as disposable or single-patient-use as immersion of these items into a sterilizing solution can cause degeneration of the materials.

4.3 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 LPM at no less than 42 PSI (2.9 Bar)
- A breathing simulator with 30 LPM demand flow over a minimum of 1 second. As an option, wall suction may be used to generate the 30 LPM flow however this is less accurate. As a simple option a 1 Liter calibrated gas syringe may be used.

Leak Test

Having connected the supply hoses to the regulated gas supplies, ensure that the PRO-NOX ON/OFF selector is in the "Off" position and turn on the N_2O and O_2 supplies. Using 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 Glow 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 PRO-NOX Gas Delivery 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 PRO-NOX using a "3-way T" connector test assembly. (This can be purchased separately through your distributor.)
   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 PRO-NOX system 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 = 50% | Acceptable Range = 40% - 60%)

2. **Low Input Pressure Alarms**
   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 N_2O alarm, the pulsed tone frequency is set at a low frequency of approximately 60 BPM. For the low O_2 alarm, the pulsed tone frequency is set at a 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 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.

5. ACCESSORIES & CONSUMABLES

ITEM NAME	DESCRIPTION	PRODUCT CODE
Breathing Circuits (mouthpiece)	Patient breathing circuit with mouthpiece (box of 20)	WES-PROAESKIT
Breathing Circuits (Masks)	Patient breathing circuit with mask – SML, MED or LRG (box of 20)	WES-PROXXXKIT
Elbows	90° angled connector for patient breathing circuits (box of 20)	CC-Elbow
Noseclips	Padded noseclips for extra comfort	CC-PNClip
Pharma Mini Filter	Additional filter for patient breathing circuits (box of 25)	6126-25
CAREfilter	Staff/Patient filter and noseclip bundle (box of 20 or 100)	CARE-filter-20 CARE-filter-100
Patient Brochures	In-office patient education brochures (pack of 25)	PN110
N_2O Monitor Badge	Testing badge to monitor N_2O levels	N-10
PT Circuit	72” PT circuit with valve, filter, mouthpiece and noseclip (box of 20)	WES-9303
Cylinder Wrench	Air cylinder wrench for tanks	WES-0704
Bodok Seals	Washers for N_2O and O_2 regulators	200-120
Knob Assembly	Knob assembly for PRO-NOX mixer on/off switch	O2-OnOffKnobAssembly
Magenta Tubing	Disposable magenta tubing with 19 mm cuffs every 12” (sold in 100’ roll)	WES7-9019
Suction Tubing	Scavenger wall suction tubing – 1/4” x 20’ hose with straw connector	2954689
Rolling Stand	Mobile cart with basket, tank holders, handle and mounting plate	CMI-011A-PNX-KB
Wall Mount	Aluminum wall mounted 8” swing arm and stainless steel mounting plate	CMI-0120A-PNX
Active Scavenger	Active scavenger with 19 mm exhaled-gas inlet, 3/8 barb for suction hose attachment, flow control knob and collection bag. Pressure relief ports.	GD-1925

6.0 MANUFACTURER:

O-TWO MEDICAL TECHNOLOGIES INC.
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Brampton, Ontario, Canada, L6T 5M4
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CE **1639**

EC REP

MedNet EC-REP IIb GmbH
Borkstrasse, 10
48163 Münster, Germany

7.0 WARRANTY

CAREstream America warrants to the purchaser of this PRO-NOX™ Nitrous Oxide Delivery System that it is free from defects in material and workmanship for a period of two years from the date of purchase. This warranty is extended only to the original purchaser of this product from CAREstream America or an authorized PRO-NOX™ distributor.

In the event of a defect, malfunction, or failure of this PRO-NOX™ unit within the two-year period, and upon notification of the defect in writing by the purchaser, CAREstream America will repair or replace the product (at the sole discretion of CAREstream America) at no cost to the purchaser. All shipping costs shall be borne by the purchaser.

This warranty shall be void if the equipment is damaged as a result of abuse, neglect, accident, or failure to follow operating or maintenance instructions.

This warranty shall become void if any repairs or alterations to the warranted product beyond that described in the user manual are undertaken without the prior authorization of CAREstream America.

Under no circumstances will CAREstream America be liable for consequential damage, loss, or expense arising directly or indirectly from the use of this device.

This warranty is given in lieu of all other warranties expressed or implied, and CAREstream America neither assumes, nor authorizes any person to assume on CAREstream America's behalf, any liability beyond that stated herein. This warranty gives no specific legal rights. You may also have other rights which may vary according to local regulations.