

HAND HELD NITROUS® INSTRUCTIONS FOR USE - ADULT AND PEDIATRIC "DISPOSABLE NOSE CANNULA"

INDICATIONS FOR USE:

Hand Held Nitrous® is a nitrous oxide inhaler intended to create short term supplemental analgesia (pain and anxiety reduction) to patients undergoing minor medical procedures by delivering a approximately 16 grams (8.6 liters) of medical grade nitrous oxide over a total of 180 seconds (3 minutes) of inhalation time. The effects of the gas are limited to approximately five (5) minutes and are not intended to last the entire length of the procedure. For use in children ages three (3) and up and adults of all ages. Do not use if you are pregnant, or think you may be pregnant. Hand Held Nitrous can be used while waiting for a procedure (anxiety) or immediately before or during the procedure (pain).

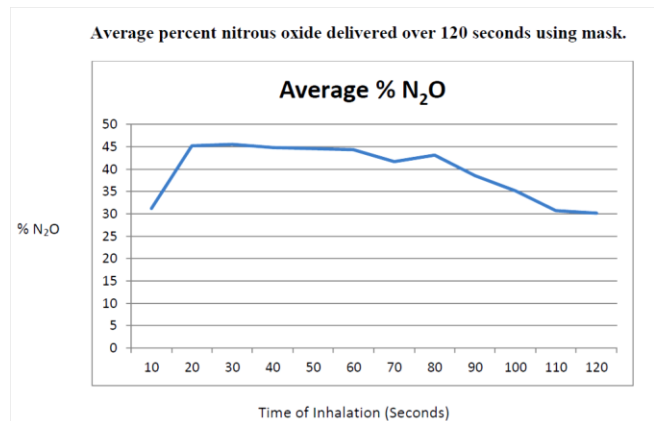
Minor procedures include mole removal, laceration suturing, botulinum toxin injections, cystoscopies, administering local injections and other minor medical office procedures.

Hand Held Nitrous® is for supplemental use only and to be used in addition to existing anesthetics only. Do not attempt to use this device as the sole source of analgesia or to modify existing analgesic protocols.

DOSING:

Percent N₂O: Maximum 46.8%: Average 39.6%
 Adults: Limit to two cylinders per patient per day.
 Children: Ages three and up, limit one cylinder per patient per day.

- ⚠ WARNING: NOT FOR RECREATIONAL USE.**
- ⚠ WARNING: THIS DEVICE MUST BE USED UNDER THE DIRECTION OF A LICENSED HEALTH CARE PROFESSIONAL.**
- ⚠ WARNING: READ AND FOLLOW ALL INSTRUCTIONS, WARNINGS AND PRECAUTIONS CAREFULLY ESPECIALLY IN REOMAVAL OF THE USED CYLINDER.**
- ⚠ WARNING: PRODUCT IN-SERVICING IS HIGHLY ENCOURAGED FOR ALL USERS**



WHO CAN RECEIVE HAND HELD NITROUS:

All patients that are over three years of age, not pregnant and that are about to 1) receive a procedure with local anesthetics or numbing gels, 2) are about to have an uncomfortable exam or injection/s or 3) that show any form of short term discomfort or nervousness while in your care. Product can be used while waiting for a procedure, just before the procedure or during the procedure.

EXPOSURE LIMITS





Under "worse case" conditions, this product can create a nitrous oxide time weighted average (TWA) exposure rate of approximately 4 ppm (parts per million) using 15 doses over an 8 hour time period. OSHA exposure limit levels of < 25 ppm TWA are considered safe.

GAS ADMINISTRATION (READ CAREFULLY):

- ⚠ WARNING: HOLD THE DEVICE VERTICAL (WITHIN 35° EITHER DIRECTION). FAILURE TO HOLD VERTICLE MAY CAUSE FREEZING LIQUID TO DRIP FROM INHALER.**
- ⚠ WARNING: NEVER USE THE INHALER WITHOUT THE NOSE CANNULA, ICE BURN MAY OCCUR**
- ⚠ WARNING: PATIENT WILL HEAR A HISSING NOISE. THIS IS NORMAL.**
- ⚠ WARNING: ALWAYS USE A NEW GAS CYLINDER AND NEW NASAL CANNULA**

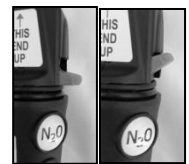
Confirm the threads are matched (MATCH YELLOW ARROWS) and firmly screw cup with full cylinder onto the head until in stops. Firmly turn two quarter turns to activate the cylinder. You may hear a brief hissing sound. If a continuous hissing sound is heard, screw another quarter turn.

Note: Never force the threads between the cup / head interface. If the threads are not lined up properly the inhaler will not function correctly. If this occurs, SLOWLY unscrew the cylinder in small increments. If the cylinder is punctured, you will hear a hissing sound. Stop: Do not unscrew further until all gas is released (when hissing noise stops). When all gas has escaped, replace with new cylinder and start again. Do not touch the used cylinder. Discard directly into garbage (see Removing Gas Cylinder below).

			
1. Place cannula in nose, around ears and under chin	2. Insert gas cylinder into cup	3. Match arrows, thread together until slight resistance, then two quick quarter turns	4. Insert tip of nozzle into cannula

Safety lock feature (if desired):

Move the safety lever to the "up" position to lock the compression switch. To unlock the compression switch, move the safety lever into the "down" position. Gas can only be dispensed when the safety lock is in the unlocked "down" position.



1. Room Check Air Flow: For small exam rooms, perform simple tasks to confirm air passes past the patient's face (first) and out the room (second). Simple tasks include positioning the table so that the patient's head is nearest the outgoing air vent turn on the air to the room when possible. If you're not sure where the air leaves the room consider leaving the door partially open.

2. Ready the patient:

Calming patient: Make sure the patient is sitting down and follow the instructions below.

Reducing pain for procedure: Patient must be sitting down or lying down and prepped for the procedure. The health care professional performing the procedure should be in the room and ready to begin procedure. Administer gas approximately 60 seconds before most painful step or portion of an exam. Follow the instructions below.

3. Failure to properly administer the gas may prohibit the effects of the gas. The amount of gas is limited outcomes may vary pending inhalation depth, age and sex of patient.

4. Who Administers the Gas (adults only):

Adults: Licensed health care professional or patient.

Children: Licensed health care professionals only.

5. How to Administer the Gas:

- A. Prepare dispenser and cylinder as shown in the table above (steps 1 through 5).
- B. Give dispenser to adult patient and show them how to activate the gas flow using green compression switch.
- C. Instruct patient they do not need to fully compress the compression switch the first inhalation; this may result in the nasal cannula pushing off the dispenser. Instruct patient to hold the device as vertical as possible.
- D. Note: Removing and replacing cylinders must be done by the health care professional only (see Removing Gas Cylinders, below).

Adults - Instruct Patients:

- A) Inhalations 1 through 5: Inhale and exhale through nose. Fill lungs with gas. Hold breath as long as possible. Breathe out slowly through nose. Stop gas administration when holding breath. After 5th inhalation continuously allow gas flow until gas is gone.
- B) Stop gas any time. Maximum of two cylinders per adult. Patient should be ready for procedure after 3 to 5 inflations. Health care professional may start procedure while the patient continues to inhale the gas.
- C) The patient must maintain deep slow breathing throughout gas administration.
- D) If at any time the gas stops flowing, quickly release and press the compression switch.
- E) Repeat process with second cylinder if desired. Note: see Removing Gas Cylinder below.

Children:

Same as above except:

- A) Maximum one cylinder per child
- B) Do not require children to hold their breath after inhalations

C) Do not allow children to self administer.

GAS EFFECTS / PATIENT SAFETY:

- A) The effects of the gas should be observed within 3 to 5 inhalations.
- B) Cognitive function and coordination may be impaired. The patient responds purposefully to verbal command, either alone or accompanied by light tactile stimulation. No interventions are necessary to maintain patent airway. Spontaneous ventilation is adequate and cardiovascular function maintained.
- C) Stay with the patient and make sure the patient does not stand or ambulate for at least 6 minutes.
- D) The patient is not to be left alone until the procedure or exam is complete and until all of the following patient parameters are met: Patient: 1) is not "dizzy" 2) can ambulate 3) has minimal nausea 4) is absent of respiratory distress 5) is alert and oriented as appropriate for age 6) can communicate on his/her own

REMOVING GAS CYLINDER:

- ⚠ WARNING: HAVE TRASH RECEPTICLE IN THE IMMEDIATE VICINITY BEFORE REMOVING CYLINDER**
- ⚠ WARNING: FAILURE TO RELEASE ALL GAS BEFORE REMOVING CYLINDER MAY RESULT IN ICE BURN.**
- ⚠ WARNING: YOU MAY HAVE THE IMPRESSION THE CYLINDER IS EMPTY BUT FREEZING LIQUID N₂O GAS MAY REMAIN IN THE BOTTOM OF THE CYLINDER. THIS RESIDUAL GAS IS EXTREMELY COLD AND WILL CAUSE ICE BURN. NEVER TURN THE USED CYLINDER UPSIDE DOWN IN YOUR HAND. NEVER TOUCH THE USED CYLINDER. DUMP USED CYLINDER DIRECTLY INTO TRASH WITHOUT TOUCHING OR HOLDING THE CYLINDER.**



Cylinder: After use, while holding inhaler vertical, expel all remaining gas into the air before removing cylinder. If you attempt to remove the cylinder and you hear a hissing noise, STOP, let all gas release before continuing unscrewing the cup. Dump used cylinder directly into trash without touching or holding the cylinder. Do not turn the cylinder upside down in your hand. Discard cannula. The inhaler may be cold to the touch. This is normal.

Nose Cannula: Discard the nose cannula after each use.

CLEANING INHALER BETWEEN PATIENTS AND TRANSPORTING:

The cannula is disposable and is discarded. Saturate a cotton swab and wipe down the top and side of the inhaler. The inhaler is designed to be transported with a new cylinder placed 'upside down' in the cup.


OTHER IMPORTANT SAFETY INFORMATION:

Storage:	Store gas/mask and inhaler in a cool dry place and under lock and key to avoid abuse.
Emergency Equipment And First Aid	Typically oxygen will not be administered during the procedure; however it is recommended in case of an adverse event requiring oxygen administration. Emergency equipment suggested: an oxygen source with a regulator and flow meter and options for supplemental oxygen administration (e.g., nasal cannula or simple face mask), a positive pressure ventilation system (e.g., Ambu bag with mask attached), suction, and advanced airway equipment. These should be appropriately sized for the patient(s) In the event of any problem immediately stop inhalation and allow the patient to breath fresh air. If breathing continues to be compromised, give oxygen. In case of frostbite, obtain medical treatment immediately.
Stopping Gas:	Not all patients will require all the gas. Patient and health care professional can stop administration of gas at any time for any reason. It is recommended but not required that all gas be administered if it does not interfere with the procedure, however, most patients will respond to the gas in the first 60 seconds or less if the gas is properly administered. Stop administration if the patient signals they have had enough. Stopping is optional if the health care professional can see the patient has had enough gas but no signal has been giving by the patient to stop.
Gas Effect / Patient Observation:	Note: Inspiratory concentrations of nitrous oxide are a function of inspiratory flow rates and may differ between patients therefore the effects of nitrous oxide and concentration of nitrous oxide depend on how much of the gas the patient inhales. The patient will appear relaxed and breathing will slow. Patient may appear sleepy but will be able to hear and react to light tactile stimulation. Outcomes may vary pending inhalation depth, age and sex of patient.
Contraindications:	Not for use for patients under three years of age or if you are pregnant. Health care professional: If you are pregnant or think you may become pregnant do not administer this gas.
Federal law:	Caution: Federal law restricts this device to sale by or on the order of a licensed health care provider
Device	Inhaler and cannula is supplied non-sterile.
Exposure Limits	This product meets all OSHA, NIOSH and ACGIH exposure limits if used as instructed. Health care professionals should limit their exposure to 15 doses per 8 hour day to stay below exposure limits. Hand Held Nitrous should only be used in a well vented room no smaller than 12x10x9 and the distance from the patients face is 23 +/- 2 inches.
Disposable / Re-usable	The N ₂ O gas cylinder and cannula are disposable. The inhaler is reusable up to 150 times.
Gas Purity	Never use gas from another source for this device. Strata Medical N ₂ O gas meets United States and European Pharmacopoeia standards for medical grade gas purity. The gas cylinder and inhaler are CE Marked.

WARNINGS AND PRECAUTIONS (READ CAREFULLY):

- Warning:** Use only USP medical grade nitrous oxide supplied with a disposable mouth piece specifically designed for this device.
- Warning:** Health care professional: If you are pregnant or think you may become pregnant do not administer this gas.
- Warning:** Do NOT point the device at your eyes.
- Warning:** Hand-Held Nitrous[®] is only to be used by or under the supervision of a licensed health care professional.
- Warning:** Never expose the user directly to the nozzle or bare cylinder as frostbite may occur.
- Warning:** Administration of nitrous oxide may be hazardous or contraindicated. For use only by or under the supervision of a licensed practitioner who is experienced in the use and administration of nitrous oxide and is familiar with the indications, effects, dosages, methods, and frequency and duration of administration, and with the hazards, contraindications, and side effects and the precautions to be taken. CFR 21:201.161 (call Strata Medical for more information).
- Warning:** It is illegal to inhale Nitrous Oxide in many states except for medical reasons. In some states only professionals licensed to use Nitrous Oxide can use this product and therefore distribution is limited (call your gas supplier for more information).

NOTIFY SMI EU REPRESENTATIVE BELOW OF ANY PRODUCT COMPLAINTS OR PERFORMANCE ISSUES

<table border="1" style="display: inline-table;"> <tr> <td style="padding: 5px;">EC</td> <td style="padding: 5px;">REP</td> </tr> </table>	EC	REP	Authorized Representative ARAZY GROUP GmbH Am Kalkofen8, Wollstadt, 61206 Germany Tel: +49 60 34 90 59 49 -0 Fax: +44 1923 859 810 - 9		Manufacturer: Strata Medical Innovations 3706 76th Street, Lubbock, Texas 79423 Tel / Skype: 1 + 806 787-0756 Fax: 806-793-3177
	EC	REP			



Temperature Limitations (Store gas between 50 and 75°C)



Lot number appears on N2O gas cylinder



Do not reuse mask or gas cylinder



Use before (see labeling on mask / gas box)



Consult Instructions for Use

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