

HAND HELD NITROUS® INSTRUCTIONS FOR USE "MASK"

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.

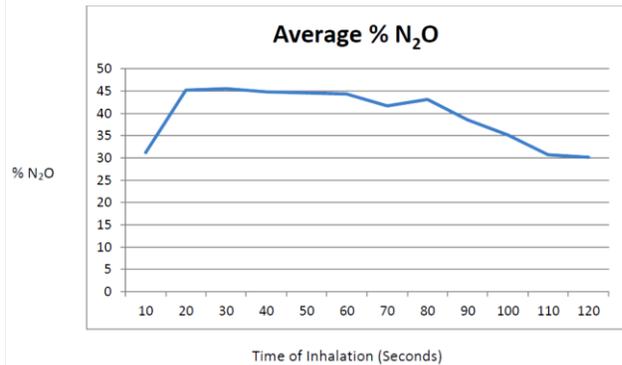
Hand Held Nitrous® is for supplemental use only and to be used in addition to existing anesthetics only. Do not attempt to use this device as the sole source of analgesia or to modify existing analgesic protocols.

DOSING:

Percent N₂O: Maximum 46.8%: Average 39.6%
Limit to two doses per patient per day in adults.
For patients ages three (3) and up, limit one dose per patient per day in children.

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

Average percent nitrous oxide delivered over 120 seconds using mask.



ASSEMBLY:

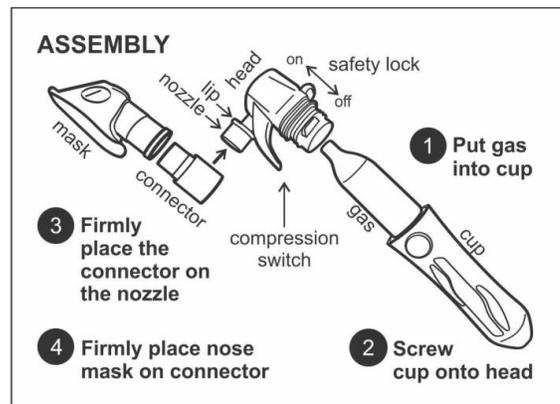
1. Place the gas cylinder inside the cup as shown. Always use new gas cylinder and mask supplied by Strata Medical Innovations. All gas is USP Medical Grade.

2. Confirm the threads are matched (MATCH YELLOW ARROWS) and firmly screw cup with full cylinder onto the head until in stops. Firmly turn one quarter turn further. 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).

3. Firmly place the connector on the nozzle.

4. Firmly place the mask on the connector



Safety lock feature (if desired):

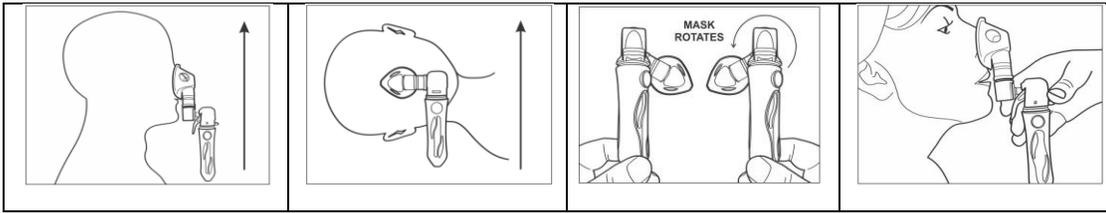
Move the safety lever to the "up" position to lock the compression switch. To unlock the compression switch, move the safety lever into the "down" position. Gas can only be dispensed when the safety lock is in the unlocked "down" position.

WHO CAN RECEIVE HAND HELD NITROUS:

Any patient that 1) is over three years of age and 2) is not pregnant, that is about to receive a procedure with local anesthetics or numbing gels, is about to have an uncomfortable exam or injection or that shows any form of short term discomfort or nervousness.

GAS ADMINISTRATION:

- ⚠ WARNING: FAILURE TO HOLD THE DEVICE VERTICAL (WITHIN 35° EITHER DIRECTION) MAY RESULT IN ICE BURN. MASK ROTATES.
- ⚠ WARNING: NEVER USE THE INHALER WITHOUT THE MASK, ICE BURN MAY OCCUR
- ⚠ WARNING: PATIENT WILL HEAR A HISSING NOISE AND SEE AND FEEL A COLD WHITE MIST. THIS IS NORMAL.



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 patients 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.

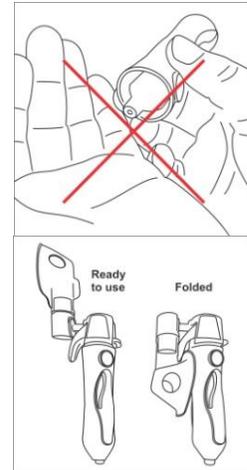
Ready the patient: To Calm the patient: If you are administering the gas to calm the patient, make sure the patient is sitting down and follow the instructions below. If administering the gas to **reduce pain for an exam or procedure:** the patient must be sitting down or lying down and prepped for the 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.

Give as much of the gas to the patient as possible. Failure to properly administer the gas may result in no effects. Fully compress the compression switch to release the gas. The amount of gas is limited; outcomes may vary pending inhalation depth, age and sex of patient.

Always hold the inhaler vertical (within 35° in either direction), regardless of head position. The mask rotates for this purpose (see drawings)

Adults:

- Without administering gas, place the mask gently over the nose (or mouth) of the patient and instruct patient to inhale **deeply and slowly** two to three times through the nose (patient practice step), The patient must maintain deep slow breathing throughout gas administration.
- First Inhalation: When the patient is ready to inhale, **fully** press the compression switch and release gas. The patient must inhale deep and slow. With the lungs full of gas, adults are instructed to **hold their breath for as long as possible then breathe out slowly**. Stop gas flow when the patient is holding their breath.
- Remaining Inhalations: Immediately after the patient exhales, **fully** compress the switch continuously until remaining gas is gone. Instruct the patient again to breathe deep and slow. It will take approximately 180 seconds for all gas to be depleted.
- If at any time the gas stops flowing, quickly release and press the compression switch.
- The effects of the gas should be observed within 3 to 5 inhalations. **Repeat process using another dose if effect is not seen.** Limit to two doses per patient per day. Stay with the patient and make sure the patient does not stand or ambulate for at least 5 minutes.



Children

Same as above but do not required the child to hold their breath after first inhalation and only give one dose per patient per day.

REMOVING GAS CYLINDER:

- ⚠ WARNING: HAVE TRASH RECEPTICLE IN THE IMMEDIATE VACINITY BEFORE REMOVING CYLINDER
- ⚠ WARNING: FAILURE TO RELEASE ALL GAS BEFORE REMOVING CYLINDER MAY RESULT IN ICE BURN.
- ⚠ WARNING: YOU MAY HAVE THE IMPRESSION THAT THE CYLINDER IS EMPTY BUT IT MAY NOT BE. GAS LEFT IN THE CYLINDER 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.

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 mask. The inhaler may also be cold to the touch. This is normal

CLEANING INHALER BETWEEN PATIENTS AND TRANSPORTING

The mask is disposable and is discarded. The white filter/muffler extending from the connector must be wiped down with 70⁰ isopropyl alcohol between patients. Saturate a cotton swab and wipe down the top and side of the filter/muffler as well as the inhaler itself. The inhaler is designed to be transported with a new cylinder placed 'upside down" in the cup and the mask folded under the compression switch (see drawing). The folded inhaler and mask is small enough to fit in your pocket.

OTHER IMPORTANT INFORMATION:

Storage:	Store gas/mask and inhaler in a cool dry place and under lock and key to avoid abuse.
Emergency Equipment:	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)
Who Administers the Gas	The gas must be administered by a licensed health care professional. The health care professional insures the inhaler is

	held vertical regardless of the head position of the patient, that the remaining unused gas is expelled into the air, and the used cylinder is disposed of directly into the garbage without touch the cylinder.
Patient Prepping & Starting Gas	Product can be used while waiting for a procedure, just before the procedure or during the procedure, depending on what is being performed. Regardless of the position of the patient head the inhaler MUST be held vertical.
When to Start Procedure or Exam:	Perform the most painful portion of the procedure or exam when the patient is at his or her deepest level, which will be after 3 to 5 deep inhalations (depending on how deep they inhale).
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. The amount of gas is safely limited to 16 grams (8.6 liters). If the patient does not feel they have received enough gas after the first dose, release all remaining gas and use another dose and mask
Gas Effect / Patient Observation:	ANALGESIA: Analgesia is defined herein as an induced depression of consciousness during which 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. 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.
Patient Care:	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 forage 6) can communicate on his/her own
First Aid :	In the event of any problem immediately stop inhalation and allow the patient to breath fresh air. If breathing continues to be difficult, give oxygen. In case of frostbite, obtain medical treatment immediately.
Time to take effect:	Less than 60 seconds
How long effect lasts:	Approximately 5 minutes, at which time the patient will be back to normal.
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 mask is supplied non- sterile. The inhaler is re-usable. The gas cylinder and mask are disposable.
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 N2O gas cylinder and mask are disposable. The inhaler is reusable up to 150 times. Always use a new N ₂ O gas cylinder & mouth piece supplied by Strata Medical for each patient.
Gas Purity	Never use gas from another source. Strata Medical N ₂ O gas meets United States and European Pharmacopoeia standards for medical grade gas purity.

WARNINGS AND PRECAUTIONS (READ CAREFULLY):

- Warning:** Patient must be sitting or lying down BEFORE using this product. Falling or loosing balance may occur. Health care professional must stand next to the patient during use and for up to 5 minutes after use.
- Warning:** Instruct the patient to stop inhalation immediately if they feel any discomfort or nausea.
- 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 canister as frostbite may occur. NOTE: Empty canister will be cold.
- 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 PERFORMAMCE ISSUES

	Authorized Representative		Manufacturer:
	ARAZY GROUP GmbH Am Kalkofen8, Wollstadt, 61206 Germany Tel: +49 60 34 90 59 49 -0 Fax: +44 1923 859 810 - 9		Strata Medical Innovations 3706 76th Street, Lubbock, Texas 79423 Tel / Skype: 1 + 806 787-0756 Fax: 806-793-3177



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

