

HAND HELD NITROUS® INSTRUCTIONS FOR USE "MOUTHPIECE"

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 limited 16 grams (8.6 liters) of medical grade nitrous oxide over a total of 120 seconds 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.

Minor procedures include mole removal, laceration suturing, botulinum toxin injections, cystoscopies, administering locals for dental carries 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:

Adult: Percent N₂O: Average 71.2% which drops to 31.8% in 60 seconds (Solid Line)
Limit to two gas cylinders total per procedure*per day.

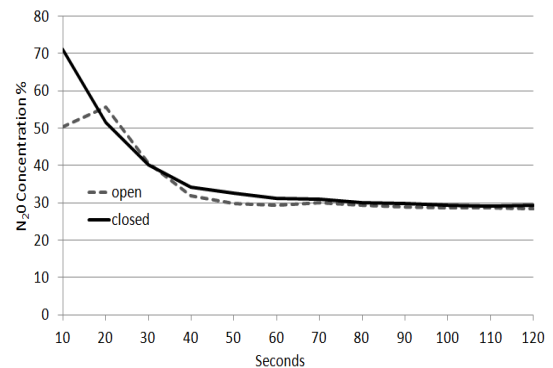
Children Percent N₂O: Average 57.0% which drops to 29.3% in 60 seconds (Dotted line)
Limit to one gas cylinder per procedure per day.

⚠ WARNING: NOT FOR RECREATIONAL USE.

⚠ THIS DEVICE MUST BE USED UNDER THE DIRECTION OF A LICENSED HEALTH CARE PROFESSIONAL ONLY.

⚠ READ AND FOLLOW ALL INSTRUCTIONS, WARNINGS AND CAUTIONS CAREFULLY.

Average N₂O Percent Concentration with Mouthpiece
Air Holes Opened and Air Holes Closed



ASSEMBLY:

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

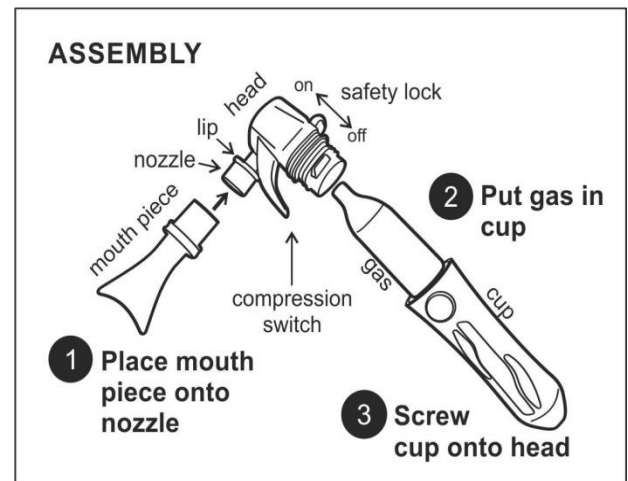
2. Confirm the threads are matched (MATCH ARROWS) and firmly screw cup with full cylinder onto the head until in stops. Firmly turn one quarter turn further. You may hear a brief hissing sound. If a continuous hissing sound is heard, screw another quarter turn.

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 mouthpiece on the nozzle.

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.



GAS ADMINISTRATION:

Always hold the inhaler vertical regardless of head position. The mouthpiece rotates for this purpose.

⚠ WARNING: FAILURE TO HOLD THE DEVICE VERTICAL MAY RESULT IN ICE BURN.

⚠ WARNING: NEVER USE THE INHALER WITHOUT THE MOUTHPIECE, ICE BURN MAY OCCUR

⚠ WARNING: PATIENT WILL HEAR A HISSING NOISE AND SEE A WHITE MIST. THIS IS NORMAL.

Ready the patient for procedure. The patient must be sitting down or lying down. The health care professional performing the procedure should be in the room and ready to begin procedure. Stand by the patient during and after gas administration for at least 5 minutes.

The goal is to give as much of the gas to the patient as possible. The amount of gas is limited. Use gas wisely.


- Without administering gas, place the mouthpiece gently onto lips (or mouth) of the patient and instruct patient to inhale **deeply** and **slowly** two to three times through the mouthpiece (patient practice step), maintain deep slow breathing throughout gas administration.

- When the patient is ready to inhale, **holding the inhaler vertical**, press the compression switch and release gas. A **hissing sound** will be heard and a **white mist** may be seen, this is normal. In adults, after the first inhalation of gas, instruct the patient to **hold their breath** for as long as possible then breathe out slowly. Stop gas flow when the patient is holding their breath.
- Immediately after the patient exhales, administer the gas continuously until all gas is released. Instruct the patient to breathe deep and slow continually until the gas is gone.
- 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 procedure per day.

Children: remove label from the mouthpiece air hole. Do not instruct the patient to hold their breath.

REMOVING GAS CYLINDER:

 **WARNING: FAILURE TO RELEASE ALL GAS BEFORE REMOVING CYLINDER MAY RESULT IN ICE BURN.**

 **WARNING: NEVER TOUCH THE USED CYLINDER. NEVER TURN THE USED CYLINDER UPSIDE DOWN IN YOUR HAND. GAS LEFT IN THE CYLINDER MAY CAUSE ICE BURN. DISCARD DIRECTLY INTO TRASH WITHOUT TOUCHING THE CYLINDER.**

After use, while holding inhaler vertical, expel all remaining gas into the air before removing cylinder. Dump used cylinder directly into trash without touching or holding the cylinder. Do not turn the cylinder upside down in your hand. Discard mouthpiece. The inhaler may also be cold to the touch. This is normal

OTHER IMPORTANT INFORMATION:

Storage:	Store gas/mouthpiece 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 mouthpiece), a positive pressure ventilation system (e.g., Ambu bag with mouthpiece 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	Administer gas approximately 60 seconds before most painful portion of procedure. Ready the patient by making sure he/she is properly prepped for the procedure and sitting back or in the prone or semi-prone position BEFORE administering the gas. The patient, person performing the procedure, and the person administering the gas, must all be ready before administering the gas. Regardless of the position of the patient head the inhaler MUST be held vertical.
When to Start Procedure:	Perform the most painful portion of the procedure 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 mouthpiece
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. 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.
Patient Practice Step:	Place the mouth piece on the lips of the patient, instruct them to make a seal with their lips and let them breath a few times through the air hole/s WITHOUT administering gas. This helps the patient get the feel of the inhaler. When the patient is ready let the patient exhale one more time, when inhaling, administer the gas
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 mouthpiece is supplied non- sterile. The inhaler is re-usable, cleaning may be performed using alcohol (70% solution) and paper towels.
Exposure Limits and Venting	This product meets all OSHA, NIOSH and ACGIH exposure limits if used as instructed. If you would like to monitor N ₂ O levels at your facility, contact us. Health care professionals should limit their exposure to 15 doses per 8 hour day. No special venting or scavenging equipment is required.
Disposable / Re-usable	The N ₂ O gas cylinder and mouthpiece 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.

WHAT TO COMMUNICATE TO THE PATIENT:


When the device, patient and attending health care professional are ready to start, confirm the patient wants nitrous oxide and read:

“I am about to give you nitrous oxide. The more of the gas you inhale the less pain (or anxiety) you should experience. You only have 120 seconds of inhalation time. Use the gas wisely. You will continue to be awake and you will be able to hear what is happening around you. The effects of the gas will last only a few minutes. Please do NOT attempt to get off the table and please hold still for your procedure. You must breathe deep and slow while the gas is being administered. First I will ask you to pretend to inhale the gas by inhaling deeply and slowly without gas. After I notice you get the feel of the inhaler, I will allow the gas to flow while you inhale. You will hear a **hissing noise** and see a **white mist**. This is normal. Adults only: Hold your breath after the first inhalation for as long as you can, then slowly breathe out. After the first inhalation, breathe slowly and deeply until the rest of the gas is gone. Stop taking the gas if you feel any discomfort or nausea by gently pushing my hand away. Do you have any questions?”

WARNINGS AND PRECAUTIONS (READ CAREFULLY):

- Warning:** This device must always be used in the vertical (upright) position, regardless of head position - no exceptions. The mouth piece rotates on the nozzle for this purpose.
- Warning:** Press the compression switch and release all remaining gas BEFORE removing used cylinder.
- Warning:** Compressed gas becomes extremely cold when dispensed; NEVER touch the used cylinder with your hand. Discard directly into the trash without touching the cylinder. Do NOT turn the used cylinder upside down in your hand.
- Warning:** A loud hissing noise will be heard for the first few seconds of administration. This is normal.
- Warning:** A white mist may be observed coming from the mouth and nose of the patient. This is normal. Gas is being wasted if this occurs.
- Warning:** Patient must be sitting or lying down BEFORE using this product. Falling or losing 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:** Hand-Held Nitrous[®] supplements existing analgesics and does NOT take the place of local or general anesthesia.
- 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).
- Warning:** You must not drive any vehicle for at least 10 minutes after use of this device. If driving must be performed after the 15 minute wait, short distance driving (less than 15 minutes) is strongly encouraged.

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: 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 mouthpiece or gas cylinder



Use before (see labeling on mouthpiece / gas box)



Consult Instructions for Use