INDICATIONS FOR USE:

Hand Held Nitrous® is an inhaler intended to create short term supplemental analgesia 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, lacerations, botulinum toxin injections, cystoscopies, administering locals for dental carries, vasectomies, etc.

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 Instructions: The graph below shows the amount of gas delivered over 120 seconds for adult (closed) and children (open) dose configurations.

### Adults:

**Instructions:** Always use a new N₂O gas cylinder & mouthpiece supplied by Strata Medical. Assemble inhaler with N₂O cylinder as instructed below. Leave label on air hole of mouthpiece (closed, see graph above). Ready the patient for procedure. The health care professional performing the procedure should be in the room and ready to begin procedure.

Without administering gas, instruct patient to make a seal around mouth piece with lips and inhale deeply and slowly several times (patient practice step). ALWAYS HOLD THE INHALER VERTICAL REGARDLESS OF HEAD POSITION, the mouthpiece rotates for this purpose. After observing the patient slowly breathing in and out several times, holding the device vertical, begin gas flow by squeezing the compressing switch when the patient inhales. Remind patient to inhale deeply and slowly. A hissing noise will be heard for the first few seconds and a white mist may be observed, this is normal. Squeeze compression switch continuously until patient is ready to begin procedure (after the first 3 to 5 inhalations, pending on inhalation depth). Patient may NOT require all the gas. **Optional step:** to conserve gas, stop gas flow during first two exhalations then release gas continuously thereafter. To stop gas flow simply release compression switch.

After use, holding inhaler vertical, expel all remaining gas into the air, unscrew the cup from head (a hissing noise may be heard) and empty cylinder directly into trash without touching or holding the used gas cylinder. Discard mouthpiece.

**Dose:** **Percent N₂O:** Average 71.2% which drops to 31.8% in 60 seconds. Limit to two gas cylinders total per procedure* per day

### Children:

**Instructions:** Remove sticker from hole of mouthpiece, leave both holes open continually (see graph above), follow instructions for adults. Do not apply the optional step to conserve gas.

**Dose:** **Percent N₂O:** Average 57.0% which drops to 29.3% in 60 seconds. Limit to one gas cylinder per procedure per day.

* vasectomies, bilateral nipple reconstructions and other work performed on multiple locations on the body

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| **Storage:** | Store gas/mouthpiece and inhaler in a cool dry place and under lock and key to avoid abuse. |
| **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) |
| **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:** | 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).

Gas Effect / Patient Observation: 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 for age 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_2O 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_2O gas cylinder and mouthpiece are disposable. The inhaler is reusable up to 150 times. Always use a new N_2O gas cylinder & mouth piece supplied by Strata Medical for each patient.

Gas Purity: Never use gas from another source. Strata Medical N_2O gas meets United States and European Pharmacopoeia standards for medical grade gas purity.

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**ASSEMBLY:**

1. Firmly push mouthpiece on inhaler nozzle until it hits the lip.

2. Place the gas cylinder inside the cup as shown.

3. Confirm the threads are matched accordingly and firmly screw cup with full cylinder onto the head until in stops. Firmly turn one quarter turn further. You may hear a slight hissing sound. 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 and start again. Note, if the cylinder is punctured, let the gas escape, replace with a new cylinder and start again.

Hand-Held Nitrous® is ready for use.

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. N_2O can ONLY be dispensed when the safety lock is in the unlocked “down” position.

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**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 you should experience. 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. First I will ask you to pretend to inhale the gas by creating a seal with your lips around the mouthpiece and asking you to inhale deep and slow without gas. After I notice you get the feel of the inhaler, I will allow the gas to flow while you inhale. Let me fill your lungs with the gas. Slowly inhale and exhale about 8 to 10 times - completely expand your lungs. Stop taking the gas if you feel any discomfort or nausea by gently pushing my hand away. Do you have any questions?”

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**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.

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**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.

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.

Warning: Patient must be lying down or be in a semi-prone position 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 (sold separately).

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>
<thead>
<tr>
<th>Authorized Representative</th>
<th>Manufacturer:</th>
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<tbody>
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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