June 2017

<u>Nitrous Oxide/Oxygen</u> - *Analgesia/Sedation for Office Procedures*

Procedures & Protocol

a) Safety & Effects of Nitrous Oxide :

Nitrous Oxide, (dinitrous oxygen, N2O) or "laughing gas" has been utilized for decades in both Dentistry & pediatric procedures, with unparalleled safety documented in hundreds of studies during millions of cases. It was first produced in the 1800's. It can provide effective **ANALGESIA** (pain relief), **ANXIOLYSIS** (sedation, relaxation, euphoria), and **AMNESIA** (decreased recall of event) for short office procedures. It is the least potent of all the inhalational agents. The experience should be pleasant. It is usually used in conjunction with local anesthesia (e.g. Xylocaine).

The analgesic effect is similar to 10 - 15 mg. of morphine, but unlike narcotics, it does not cause apnea (reduced drive to breathe). The sedation effect is minimal, akin to a "2 beer high". No extra sedation medications are usually needed. The patient should be capable of verbal communication throughout the entire procedure. No airway assistance is needed, and the cough/gag reflex is maintained. The gas is not irritating to mucous membranes, so it can be safely used in asthmatics and people with reactive airways. The patient holds his own mask, and should be instructed on how to maintain a good seal over the face (encompassing both the chin & nose); so that the patient is receiving the prescribed dose of Nitrous. The patient may experience some numbness or tingling in the fingers. The mask & tubing systems are designed so that the expired air is removed by the scavenger, and the patient (or staff) is not re-breathing his own expired breaths. If the patient becomes too relaxed, he will ease his hold on the mask and it will fall away from the face, thus he will breath room air and the level of sedation will decrease. The Nitrous sedation can be stopped at any time by simply removing the mask or by turning off the nitrous and letting the patient breath 100% oxygen.

Ambient room air that we normally breathe, is approx. 20% Oxygen, and 80% Nitrogen. Nitrous Oxide (dinitrous oxygen) is colorless, sweet smelling, non irritative, and is heavier than room air (so it sinks to the floor). With the Nitrouseal® system, the Nitrous can only flow if Oxygen is also flowing. If the oxygen runs out the nitrous will stop flowing and the flowmeter will alarm. These flowmeters are very robust and have many fail safes built into them. *The minimum concentration of oxygen deliverable is 30%. It is not possible to deliver a lower concentration of oxygen than 30%.* Due to poor solubility in the body's tissues (not stored in tissues), the effects of Nitrous **dissipate very quickly**, usually within 1 -3 minutes. Usually during this time 100% Oxygen is supplied. Likewise, the onset of therapeutic effects of Nitrous occur very quickly, within 3 minutes. There are **no persisting sedative effects; there is complete cognitive recovery.** So this form of office analgesia/sedation is very safe in the elderly, those with altered cognitive states (such as Dementia), and those who have difficulty with arranging transportation and must drive themselves to/from the office.

Side Effects: The commonest is **Nausea & Vomiting**, & occurs in up to 2% of patients (less than the typical effect of a narcotic). This can be minimized by:

- a) Keeping the .patient NPO (no food/drink) for 2 hours before the procedure time.
- **b**) Keeping the sedation light.
- c) Providing adequate oxygen.
- **d**) Sitting the patient up slowly after the procedure.

*There are NO ALLERGIES to Nitrous/Oxygen gas

Signs of over- sedation: (none are permanent)

1] Nausea, Vomitting, 2] Trouble staying awake, 3] Glassy Eyed, 4] Drooping Eyelids 5] Numbness around the mouth, 6] Ataxia (gait disturbance)

There are **NO Negative Effects** on: Cardiovascular System (or interaction with medications), Respiratory system, or Muscular system. No effects on Cancers (does not worsen or cause them). Safe in labor, and 3rd trimester of pregnancy. While there are no documented teratogenic effects by Nitrous on patients or staff, it is still an accepted routine to not expose women in the early stages of pregnancy to any drugs or chemicals.

Contraindications to the use of Nitrous:

- 1) Pregnancy $(1^{st} \& 2^{nd} \text{ trimester} \text{up to } 24 \text{ weeks}).$
- 2) Severe 'oxygen dependant' Emphysema (OK in typical COPD or Asthma).
- 3) Recent (within 2 weeks) Sinus or Inner ear infection or surgery.
- 4) Recent (within 2 weeks) Retinal surgery.
- 5) Recent Bowel obstruction (OK if person "passing gas" normally).
- 6) Scuba diving within 24 hrs. A diver (can already have extra Nitrogen gas in their blood).
- 7) Theoretical: severe Vitamin B12 deficiency.

b) Patient Preparation:

- 1) Consent Signed
- 2) Patient made aware of added COST for Nitrouseal apparatus & gas
- 3) NPO (no food/drink) for 2 hours prior to procedure
- 4) May have light, low fat food more than 2 hours before procedure
- 5) Patient should not be take, or be prescribed any other sedatives for the procedure unless under special circumstances & authorized by Medical Provider.
- 6) Patient may take a mild oral analgesic within 2 hrs. of procedure with a sip of water, such as Acetaminophen (Tylenol), or Anti-inflammatory (Ibuprofen, Motrin, Alieve)
- 7) Reassure the patient that the Nitrous will afford them a more pleasant experience (mild temporary sedation, relaxation, euphoria, and perhaps amnesia), and that they will be continuously monitored throughout the procedure by trained staff.
- 8) Let patient know that the Medical providers in the office have completed a special Nitrous training course, and that all staff are trained in emergency procedures, including BCLS and the use of providing oxygen.

c) Nitrouseal® Set up:

- 1) The Nitrouseal® system is FDA-cleared, fully licensed, and designed with multiple fail safe systems.
- 2) Turn MINISCAV[™] scavenger pump on, connected to tank system, and exhaust tubing connected to wall outlet (save the small plug!) Remember, neither the patient nor the staff are breathing any expired gases.
- 3) Oxygen (green) & Nitrous (blue) tanks turned on (counter-clockwise, with attached special wrench), & check pressures. A full oxygen tank should read 2000 PSI. If at or below 200, it should be turned off (clockwise), unscrewed & removed, and replaced with a full cylinder. The Nitrous tank should read 750 PSI. Because it is in a liquid state & not gas (like the O2), the pressure will not fall until it is <20% full. Then it should be turned off (clockwise), unscrewed & disconnected, and replaced with a fresh tank.</p>
- 4) It is advisable with the Nitrous tank to place a marked tape with the number of total procedures performed on that tank, so we can judge our usage and be prepared to exchange tanks in advance. Typically 20 cases can be performed with a single Nitrous tank assuming that each case is run at 50% nitrous and lasts 15 minutes. Only 5 6 cases on average will use up an oxygen tank.
- 5) Gas tanks cannot be misplaced on the manifold unit, due to the Pindex safety system (the small pin holes on the tanks, & the supporting pins on the tank holder are different for Oxygen & Nitrous).
- 6) Always check that you have at least one full spare tank of both nitrous & oxygen, before starting any procedure.

- 7) If oxygen tank runs out, the Nitrous flow will automatically stop, and the unit will alarm to notify you. It is impossible to run the flowmeter at less than 30% O2
- 8) Instruct the patient on how to hold the Nitrouseal® full-face mask, and observe that the mask cushion forms a good seal under the chin & over the nose. Do not encourage patient to talk during the procedure except to answer questions (talking will loosen the seal).
- 9) Turn on the Oxygen flow, to inflate the reservoir bag to approx. 2/3 3/4 full, before placing mask on patient. The bag holds 3 liters of gas for reserve. The flow may need to be altered depending on the size the patient's breath (Tidal volume), and rate of breathing. The patient should breathe 100% oxygen for one (1) minute prior to starting nitrous.
- 10) Start the Nitrous at 30%, and titrate the dose by increasing 10% every 3 minutes until the desired level of analgesia/sedation is achieved (typically 40 60%). Maximum dose of Nitrous is 70% (which will correspondingly supply a minimum 30% oxygen). Patients taking chronic narcotics or sedatives may require a higher nitrous dose than anticipated.
- 11) At the termination of procedure, turn off Nitrous, and let the patient breathe 100% oxygen for up to three (3) minutes, and then turn off all the tanks (and record pressures remaining). With the tanks screwed to off position (clockwise), bleed the lines for a minute, and finally the MINISCAV[™] scavenger pump can be turned off, and disconnected from the wall exhaust.
- 12) *Be sure to replace the occluding plug in the wall exhaust.

d) Contacts:

 Airgas - (supply gases & they own the tanks<u>- E CYLINDER</u> size) 14301 Mono Way, Suite C, Sonora, Office TeL.:209-536-0369, Fax 209-536-0401 (Matt Oliver. Cell 209-663-9047) Contact: Tim Solis, Regional Specialist, Cell-916-870-3380, <u>tim.solis@airgas.com</u> CUSTOMER SOLUTIONS TEAM: 800-336-4004

Dave Larson, VP Airgas, 216-496-1249, davidlarson@airgas.com

 2) Nitrouseal® - (supplies disposable mask and breathing circuit set) Sedation Systems LLC, 2471 McMullen Booth Rd., Suite 316, Clearwater, FL 33759. Tel.: 727-744-5145, 888-959-5288 Contact: Michael Bender – Manager. *Use Purchase Order emailed to: Info@Sedationsystems.com

Anesthesiologist (developer of Nitrouseal® system): **Dr. Ramsey Nashed Cell: 727-418-6622, Dr.RNashed@SedationSystems.com**

Advanced Urology – Eric R. Freedman, M.D.