

## Proposed hypoxic “O<sub>2</sub>” pipeline algorithm

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### Disclaimer:

The discussion and proposed algorithm below are based on anesthesia machine designs used in the United States and may not be appropriate for designs that adhere to different regional or national standards and practices.

### Diagnosis:

Fault 2 on the Virtual Anesthesia Machine ([www.anest.ufl.edu/vam](http://www.anest.ufl.edu/vam)) is a hypoxic O<sub>2</sub> pipeline condition (gas mix-up) where N<sub>2</sub>O, instead of O<sub>2</sub>, is inadvertently supplied to the O<sub>2</sub> pipeline. This fault recently occurred in New Haven, CT in January 2002 and killed 2 patients. Even though an anesthesia machine was not involved in the New Haven cases, the root cause is applicable and clinically relevant to anesthesia machines.

### Observations/consequences:

1. N<sub>2</sub>O is supplied, instead of O<sub>2</sub>, via the O<sub>2</sub> flow meter
2. N<sub>2</sub>O is supplied, instead of O<sub>2</sub>, when pressing the “O<sub>2</sub> flush” valve
3. The “O<sub>2</sub> failsafe” device is fooled and allows delivery of a hypoxic gas mixture
4. The “hypoxic guard” device (O<sub>2</sub> proportioning device) does not prevent delivery of a hypoxic gas mixture
5. N<sub>2</sub>O is used as the drive gas, instead of O<sub>2</sub>, during mechanical ventilation
6. N<sub>2</sub>O, that is now the drive gas, is vented directly to the room in most anesthesia ventilators with gas driven bellows
7. The O<sub>2</sub> analyzer, if present, alarms when FiO<sub>2</sub> drops below alarm threshold
8. The pulse oximeter, if present, alarms when SpO<sub>2</sub> drops below alarm threshold
9. Initially, end-tidal CO<sub>2</sub> will be normal if ventilation (not oxygenation) is adequate
10. Airway pressure will be normal if ventilation is adequate

### Itemized discussion points related to above observations and consequences:

1. Color coding of cylinders, hoses and gas connectors and Diameter Index Safety System (DISS) and Pin Index Safety System (PISS) are among the safety features designed to prevent gas mix-ups. These safety features help but are not foolproof. Behind the walls, gas piping is generally not color-coded and thread-indexed allowing accidental misconnection of pipes. Furthermore, there has been a reported instance where a bulk O<sub>2</sub> tank was misfilled by an overzealous employee who defeated the safety mechanism [needs reference]. In the recent New Haven case, the pins preventing hook-up of an O<sub>2</sub> line to an N<sub>2</sub>O outlet were allegedly missing.
2. The O<sub>2</sub> flush valve is supplied by gas in the “O<sub>2</sub>” pipeline if (a) the O<sub>2</sub> pipeline is connected and (b) if the O<sub>2</sub> pipeline is connected and the O<sub>2</sub> cylinder is also open. The O<sub>2</sub> flush valve is supplied by the O<sub>2</sub> cylinder if the O<sub>2</sub> pipeline is disconnected and the O<sub>2</sub> cylinder is connected, open and not empty.
3. The “O<sub>2</sub> failsafe” (a misnomer because it does not fail in a safe mode) failed because it relies solely on loss of pressure in the O<sub>2</sub> pipeline to activate. If the pressure of non-O<sub>2</sub> gas in an O<sub>2</sub> pipeline is adequate, the “O<sub>2</sub> failsafe” will not activate.
4. The “hypoxic guard device” fails because its design (mechanical or pneumatic) assumes that the gas in the O<sub>2</sub> pipeline is oxygen.
5. The ventilator bellows drive gas is usually pure O<sub>2</sub> or pure O<sub>2</sub> entraining room air. The O<sub>2</sub> making up all or part of the drive gas is supplied from (a) the O<sub>2</sub> pipeline if connected and (b) the O<sub>2</sub> pipeline if the O<sub>2</sub> pipeline is connected and the O<sub>2</sub> cylinder is also open. The ventilator drive gas is supplied by

the O<sub>2</sub> cylinder if the O<sub>2</sub> pipeline is disconnected and the O<sub>2</sub> cylinder is connected, open and not empty.

6. Most gas-driven anesthesia ventilators vent their drive gas directly to ambient air. The Datex-Ohmeda 7900 ventilator is an exception and vents the bellows drive gas to the scavenging system and will therefore not vent the N<sub>2</sub>O drive gas, during an O<sub>2</sub>/N<sub>2</sub>O mix-up, to ambient air.
7. The use of an O<sub>2</sub> analyzer is not guaranteed or mandated at all locations where O<sub>2</sub> is delivered. For example, an O<sub>2</sub> analyzer may not be used in conscious sedation cases where the patient is generally not intubated but is instead supplied with supplemental O<sub>2</sub> via nasal prongs. Such was apparently the case in the New Haven incident. If an O<sub>2</sub> analyzer is not used, there will be no low FiO<sub>2</sub> alarm to warn of the gas mix-up
8. If an O<sub>2</sub> analyzer is not in use or defective, the patient becomes the “FiO<sub>2</sub> monitor” and a low SpO<sub>2</sub> alarm will eventually trigger from hemoglobin desaturation. The SpO<sub>2</sub> alarm is, in this scenario, a late indicator of a problem with oxygenation and more importantly, a non-specific indicator. The clinician may conceivably look first to the patient’s physiology or condition (such as old age or advanced sickness) to diagnose the cause of the low SpO<sub>2</sub> alarm, wasting precious minutes. This is allegedly what happened in New Haven where the first fatality on a Friday may have been attributed to old age. A younger fatality on the following Tuesday prompted a thorough investigation that found an O<sub>2</sub> pipeline connected to an N<sub>2</sub>O outlet.
9. The washout of CO<sub>2</sub> (ventilation) is based on the minute volume (tidal volume times respiratory rate) of gas, not on the species of the gas. Therefore, if minute ventilation is adequate, there will be no ET/CO<sub>2</sub> alarm to help in early diagnosis. Eventually, there will be no O<sub>2</sub> to support production of CO<sub>2</sub>.
10. Airway and peak airway pressures are primarily determined by the tidal volume and the lung characteristics of the patient such as resistance and compliance. The rise in airway pressure during mechanical inspiration is dependent on the tidal volume of gas, not the species of the gas, such that airway pressure will be normal during a gas mix-up.

#### **Further discussion**

A hypoxic O<sub>2</sub> pipeline already present at the start of a first case of the day will be detected if the clinician performs a pre-use check according to the 1993 FDA Anesthesia Apparatus Checkout Recommendations. Specifically, step 9c [Reinstall (O<sub>2</sub>) sensor in circuit and flush breathing system with O<sub>2</sub>] and step 9d [Verify that monitor now reads greater than 90%] of the 1993 FDA pre-use check recommendations will raise a warning that something is amiss and potentially help to identify the hypoxic O<sub>2</sub> pipeline condition.

The footnote at the end of the 1993 FDA pre-use check recommendations states that “If an anesthesia provider uses the same machine in successive cases, these steps (*9c and 9d included because there is an asterisk next to step 9 – authors’ addition*) need not be repeated or may be abbreviated after the initial checkout.” Thus, if the gas in an O<sub>2</sub> pipeline becomes hypoxic after the first case of the day, an abbreviated pre-use check per the 1993 FDA recommendations for a following case of the day may not detect the low FiO<sub>2</sub> associated with a hypoxic O<sub>2</sub> pipeline condition.

The 1993 FDA pre-use check also does not guard against gas in the O<sub>2</sub> pipeline becoming hypoxic in the middle of a case. While this may appear far-fetched, we have been informed of such a case in a military hospital where the central O<sub>2</sub> supply was actually a bank of O<sub>2</sub> H-cylinders in the cellar. A medical orderly was tasked with monitoring the pressure gauges on the O<sub>2</sub> cylinders and opening a new H-cylinder when the one being used was nearing exhaustion. The new “O<sub>2</sub> cylinder” that was opened while cases were proceeding was misfilled with Argon and multiple fatalities occurred at different anesthetizing locations.

Most developed countries have guidelines for testing O<sub>2</sub> outlets after construction or renovation and before they are used. This system too has been reported to fail. In one reported instance, the O<sub>2</sub> outlets after the addition of 3 new ORs were correctly plumbed and passed when tested. Subsequently, the O<sub>2</sub> outlets were repositioned and during repositioning of the outlets, the gas pipes were crossed. The O<sub>2</sub> outlets were not tested again after the repositioning and patient fatalities occurred in different anesthetizing locations.

**Recommended algorithm if a hypoxic O2 pipeline condition is suspected because of a low FiO2 alarm and/or reading that does not match the set FiO2:**

**Note that this implies that an O2 analyzer is being used:**

- (a) Call for help (the anesthesia technician, other clinicians)
- (b) Disconnect the patient from the circuit at the elbow connector with the gas sampling line still attached to the elbow connector
- (c) Ventilate (or ask for assistance to manually ventilate) with a self-inflating resuscitation bag (SIRB or “Ambu” bag) using room air. If the patient needs O2-enriched air, use O2 from a **stand-alone** O2 cylinder.
- (d) **Disconnect O2 pipeline** – audible alarm should sound confirming O2 pipeline disconnection
- (e) Open the O2 cylinder – audible sound should indicate that O2 cylinder is open and not empty
- (f) Press the oxygen flush button until the O2 analyzer displays rapidly increasing FiO2 values
- (g) Alert all other locations supplied by the same central oxygen supply
- (h) Reconnect breathing circuit to patient, resume ventilation (mechanical or spontaneous) using O2 from the O2 cylinder and order more O2 tanks
- (i) If extra O2 cylinders are not readily available and patient was previously being mechanically ventilated, ventilate manually using the reservoir bag to save the oxygen used as ventilator drive gas

**Recommended algorithm if an O2 analyzer is not being used:**

If an O2 analyzer is not being used, there will be no low FiO2 warning. The first indication of trouble will most likely be a low SpO2 alarm that is a late and non-specific warning. Because of the non-specificity of a low SpO2 alarm, there are many possible causes to be ruled out before a hypoxic O2 pipeline algorithm as outlined above can be initiated with certainty.

**Rationale and discussion for proposed algorithm when an O2 analyzer is available:**

- (a) At this point, for the hypoxic “O2” pipeline algorithm to be initiated, there is a low FiO2 alarm and/or a low FiO2 reading that does not match the set FiO2. The clinician should not wait for a low SpO2 alarm to respond because if the patient is pre-oxygenated before a gas mix-up occurs, it may be several minutes before SpO2 drops. The clinician should be taught to set the low FiO2 alarm close to the desired FiO2. Thus, if set FiO2 is 0.5, the low FiO2 alarm should be set at 0.4 or 0.45, not at 0.21. The clinician should trust the oxygen sensor and SpO2 monitor and not waste precious time verifying whether the O2 sensor reads correctly in room air (this should have been already done anyway during step 9a of the 1993 FDA pre-use check). Help should be called because additional hands and brains are helpful in managing a problem.
- (b) The primary responsibility of the clinician is to the patient, not debugging the suspected fault with the machine. Therefore, isolate the patient from the machine as soon as a machine malfunction is suspected. If the Y-piece needs to be closed off to debug the machine, use a 3-L reservoir bag as the “patient”. The gas sampling line should be left on the circuit when disconnecting from the patient so that in step (f) of the proposed algorithm, FiO2 can be monitored while flushing with O2.
- (c) Manual ventilation with a self inflating resuscitation bag (SIRB or “Ambu” bag) with room air containing 21% O2 is better than continued mechanical or manual ventilation (using the 3 L reservoir bag) with a hypoxic gas mixture when the objective is to re-establish oxygenation and a normal SpO2. If the patient requires O2-enriched air during ventilation with an SIRB or Mapleson system, do not use supplemental O2 from an auxiliary O2 flow meter or common gas outlet installed on the anesthesia machine because these auxiliary O2 outlets will also supply hypoxic gas if the O2 pipeline is still connected to the anesthesia machine.
- (d) The O2 pipeline has to be disconnected for O2 to flow from the reserve O2 cylinder. This step is in anticipation of step (e). O2 pipeline disconnection precedes opening the O2 cylinder so that hypoxic gas inflow into the machine is interrupted as soon as possible. Also, disconnecting the O2 pipeline before opening the cylinder will, in most anesthesia machines, generate an audible alarm that provides a confirmatory cue to the clinician that the correct pipeline (O2) has been disconnected. In the heat of the action, it may be possible that a clinician disconnects the N2O pipeline instead of the O2 pipeline

- such that opening the O<sub>2</sub> cylinder in the ensuing step does not help. If the O<sub>2</sub> cylinder is opened first, there will be no audible alarm when the O<sub>2</sub> pipeline is subsequently disconnected. The clinician may check that the O<sub>2</sub> pipeline pressure gauge reads zero to verify that the O<sub>2</sub> pipeline is disconnected.
- (e) The O<sub>2</sub> cylinder is opened to provide access to the reserve O<sub>2</sub> stored in the O<sub>2</sub> cylinder. An audible signal will be generated in most anesthesia machines to provide a confirmatory cue to the clinician that the O<sub>2</sub> cylinder has been opened and the anesthesia machine is now being supplied with O<sub>2</sub> from the O<sub>2</sub> cylinder. If the O<sub>2</sub> cylinder had been opened before the O<sub>2</sub> pipeline was disconnected, there would be no audible confirmatory cue that O<sub>2</sub> is flowing from the O<sub>2</sub> cylinder. The clinician may also check that the O<sub>2</sub> cylinder pressure gauge reads more than zero to verify that the O<sub>2</sub> cylinder is not empty.
  - (f) The hypoxic gas in the anesthesia machine piping and breathing circuit needs to be flushed out in anticipation of reconnecting the patient to the anesthesia machine. If the gas in the opened O<sub>2</sub> cylinder is O<sub>2</sub>, then FiO<sub>2</sub> will increase as the gas from the O<sub>2</sub> cylinder replaces the hypoxic gas. A circuit disconnected at the Y-piece also provides for faster flushing of the hypoxic gas from the circuit. An increase in FiO<sub>2</sub> when using gas from the O<sub>2</sub> cylinder confirms that that gas supplied by the O<sub>2</sub> pipeline is hypoxic. Now that the gas in the O<sub>2</sub> cylinder is confirmed to be O<sub>2</sub>, if the patient requires O<sub>2</sub>-enriched air during ventilation with an SIRB or Mapleson system and a stand-alone O<sub>2</sub> cylinder is not available, supplemental O<sub>2</sub> from an auxiliary O<sub>2</sub> flow meter or common gas outlet installed on the anesthesia machine may now be used if the O<sub>2</sub> pipeline remains disconnected from the anesthesia machine. The plumbing leading up to auxiliary O<sub>2</sub> outlets may be flushed of residual hypoxic gas by opening them momentarily prior to connection to the SIRB or Mapleson system. If time allows, a further confirmatory test may be performed by verifying that the measured FiO<sub>2</sub> corresponds to the flow meter settings or set FiO<sub>2</sub>. Fuel (galvanic) cell O<sub>2</sub> sensors are common in anesthesia machines and have a slow response time compared to the faster paramagnetic O<sub>2</sub> analyzers. The user should be patient when waiting for the FiO<sub>2</sub> to increase with these slow O<sub>2</sub> sensors.
  - (g) Simultaneous patient deaths in multiple anesthetizing locations supplied by the same oxygen central supply have been reported. Early detection in one room and prompt communication of the problem to other sites using oxygen from the same O<sub>2</sub> central supply may save lives and prevent multiple deaths. This proposed algorithm points out the need to develop procedures for alerting all locations (not limited to anesthetizing locations) in a hospital or institution supplied by a given O<sub>2</sub> central supply system as well as immediately informing the O<sub>2</sub> manufacturer so that other institutions supplied by the same manufacturer or plant may be warned in a timely manner.
  - (h) Volatile anesthetics cannot be safely delivered while ventilating with an SIRB or Mapleson system. If the surgical case is still in progress, reconnect the patient to the machine supplied with O<sub>2</sub> from the O<sub>2</sub> cylinder and resume inhalational anesthesia.
  - (i) As discussed above, O<sub>2</sub> makes up all or part of the drive gas for gas-driven anesthesia ventilators. To eliminate the oxygen consumed by gas-driven anesthesia ventilators and make the finite amount of gas in a back-up O<sub>2</sub> E-cylinder (660 L when full at 2,000 psig) last longer, the clinician should resort to manual ventilation if the expected case duration is close to or exceeds the calculated time to exhaustion of the O<sub>2</sub> E-cylinder. The time to exhaustion is calculated by dividing the residual O<sub>2</sub> volume in the cylinder by the rate of consumption of O<sub>2</sub>. Residual volume in liters (L) in an E-cylinder is calculated by dividing the cylinder pressure in psig by 2000 psig and multiplying by 660 L. For example, 1,000 psig represents  $(1000/2000) * 660 = 330$  L. The rate of consumption of O<sub>2</sub> during mechanical ventilation is the sum of the O<sub>2</sub> flow meter setting and the minute ventilation (tidal volume in L x respiratory rate in breaths/min). For example, if FGF is 0.5 L/min O<sub>2</sub> and 1.0 L/min N<sub>2</sub>O and VT is 0.7 L and RR is 10 bpm, then the minute volume is 7 L/min and the total O<sub>2</sub> consumption is 7.5 L/min. The expected time to exhaustion is thus approximately  $330 \text{ L} / 7.5 \text{ L/min} = 44$  minutes, ignoring the gas sampled by the gas analyzer and leaks.