

Anesthesia Machines Perils and Pitfalls

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Anesthesia Machine Safety

- Lots of new designs/improvement
- Safer than ever

Failed Exhalation Valve Causes Problem

Healthy patient brought to OR for orthopedic surgery. Within minutes following induction, high airway pressures and desaturation occurred, followed by hypotension and cardiac arrest.

Resuscitation was unsuccessful.

Investigation found that failure of the expiratory valve led to tension pneumothorax.

Failure to test anesthesia machine prior to surgery and to properly monitor patient during surgery. *Med Malpractice Verdict Settlements*, 18:4, 2002.

You *may* get away with it...



■ GE HEALTHCARE ADU ANESTHESIA MACHINE

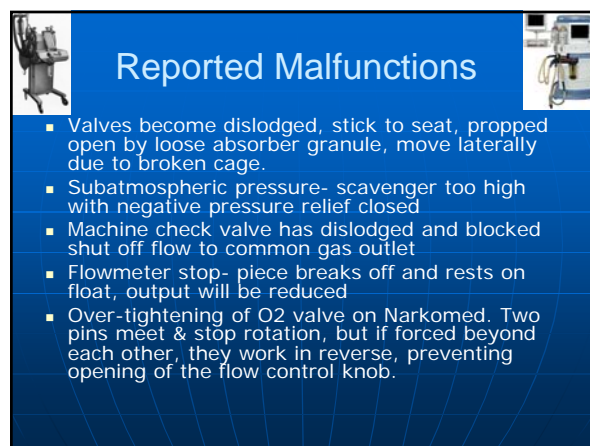
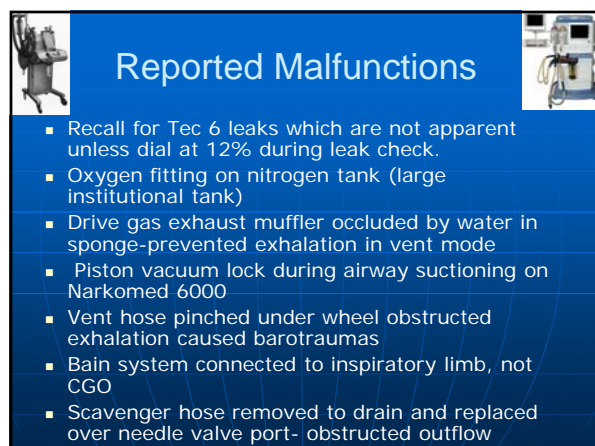
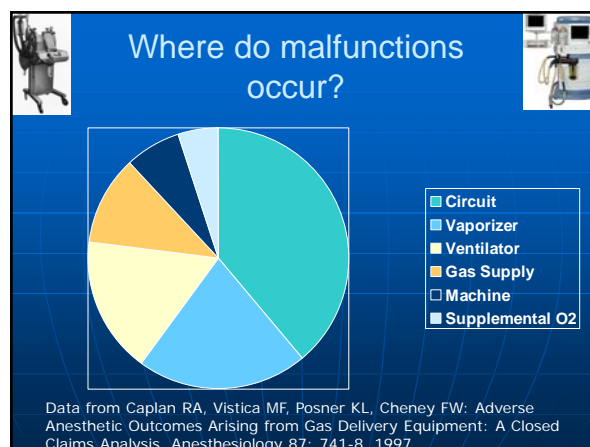
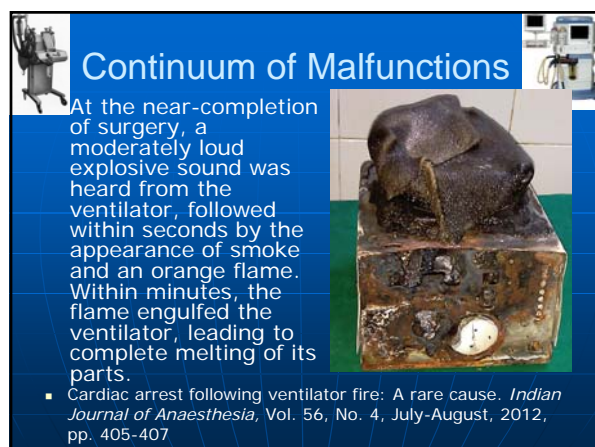
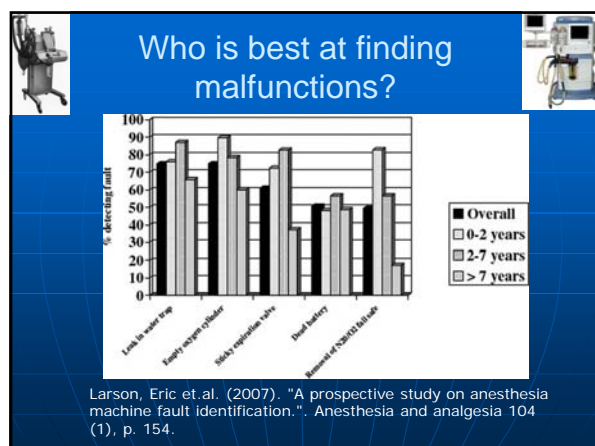
■ **Event Date** 06/02/2008

■ **Event Description** Customer reported that, prior to the case, the anesthesiologist inadvertently misconnected the anesthesia machine's hoses. Subsequently, clinician reportedly induced and intubated the pt. Pt's SpO₂ dropped and clinician was unable to ventilate. Patient has been diagnosed with an hypoxic brain injury.

■ FDA Center for Devices and Radiological Health report #9610105-2008-00018

So we just need to do the checkout! (?)

- "During simulation-based board examination most senior anesthesia residents became aware of equipment failures but many failed to correctly diagnosis and manage the failure.

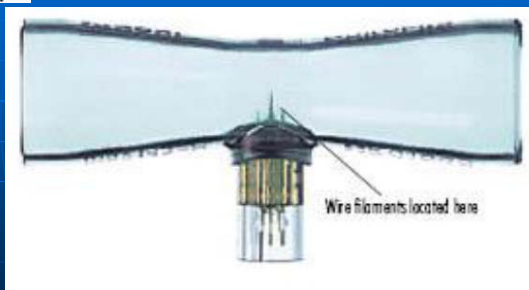


Reported Malfunctions

- Adjustment screw on back of NAD interlock system. If too loose, will allow >1 vaporizer to be on
- Loose locking nuts in bypass mechanism of Isotec 5, which obstructed FGF through vaporizer and effectively shut off O2 flow into CGO
- Modulus II O2 knob coming loose from spindle, but engaging at its distal end the proportioning chain, thus increasing the N2O flow, with only minimal O2 flow
- Narkomed internal short circuit led to fire
- High flow, high concentration Sevo- Soda Lime BURST INTO FLAMES

New solutions and newer problems?

- An anesthesiologist manually initiated calibration of the machine's flow sensor to correct a suspected sensor error. Shortly after, the unit began making "popping" noises, and the breathing system began emitting smoke. Staff found that its Spirolog flow sensor was blackened and partially melted...subsequently found that foreign plastic material, likely a piece of packaging or mold flash from the breathing circuit mask, had entered the sensor and ignited during flow-sensor calibration.
- ECRI Institute. Flammable material introduced into Draeger ventilator and anesthesia unit flow sensors could ignite, posing risks to patients. *Health Devices* 2009 Oct; 38(10): 339-40.



Why do malfunctions arise?

- Improper checkout
- Improper construction
- Improper setup/connections
- Incorrect interpretation of monitors/alarms
- "Helpful" co-workers


MARCUS, R.
Human factors in pediatric anesthesia incidents. *Pediatric Anesthesia* (2006 March) 16 (3), 242-250

Helpful co-workers




Helpful co-workers


- Leak test performed after installing new circuit, and MD went to PACU
- Tech came in and started to change soda lime before being called away
- Absorbent canister was left unlatched
- MD returned with new patient and was unable to ventilate after induction
- To Do or Not to Do a Preinduction Check-Up of the Anesthesia Machine Ianchulev, S. Comunale, M. (2005) *Anesth Analg* 101(3): 774-6




UNEXPECTED GAS CONCENTRATIONS




- Low oxygen:
 - Flowmeters- setting and free movement
 - Oxygen analyzer
 - Contaminated supply?







UNEXPECTED GAS CONCENTRATIONS



- Low oxygen:
 - Flowmeters- setting and free movement
 - Oxygen analyzer
 - Contaminated supply?
 - Supply pressure fluctuation?
 - Dilution?




UNEXPECTED GAS CONCENTRATIONS




And speaking of carbon monoxide...


- Introduced from tissue washout, Hgb catabolism, or formed in dry soda lime.




RESPONSE TO LOW CIRCUIT OXYGEN CONCENTRATION




- Check flowmeter settings and function
- Increase O_2 flow to overcome dilution by other gasses
- Correlate reading with alternate O_2 sensor
- Calibrate or change, if necessary
- Consider changing to cylinder supply (open cylinder(s) and disconnect pipeline)
- If problem is not remedied, consider malfunction in flowmeter or proportioner
- Switch to alternate outlet (auxilliary O_2 flowmeter or free standing tank with resuscitator bag)




UNEXPECTED GAS CONCENTRATIONS




- **Oxygen Concentration Higher Than Expected :**
- Is it a problem?
 - Light anesthesia
 - FIRE




UNEXPECTED GAS CONCENTRATIONS




- Agent lower than expected (can you name 4 causes?)
 - Internal or external causes
 - Dial setting
 - Reservoir level- don't count on it
 - Flowrate vs. dial setting
 - Uptake in circuit
 - Carrier gas
 - Misfilling
 - Leak



RESPONSE TO LOW VAPOR CONCENTRATION




- Check vaporizer setting and reservoir fill level
- Consider reduced output that can occur at high FGF and high dial setting
- Consider effect of carrier gas (N_2O may briefly decrease output)
- Consider possibility of misfilled vaporizer. Can monitor identify mixed agents?
- Consider a leak at vaporizer attachment or drain valve
- Consider uptake of vapor into rubber, plastic, or absorber circuit components



UNEXPECTED GAS CONCENTRATIONS


Output Higher Than Expected




- Agent higher than expected
 - Reverse previous considerations
 - High dial setting
 - Overfilled/tipped
 - Mis-filled
 - Circuit component efflux
 - Oxygen flush "pressurizing effect" or "pumping effect"



High vapor output

PRESSURE AND VOLUME DISCREPENCIES



- Inadequate ventilation with low expired volume or low inspiratory pressure alarm
 - A loss of inspiratory pressure without a loss of circuit volume generally indicates a mechanical malfunction in the machine, as opposed to a system leak.




PRESSURE AND VOLUME DISCREPENCIES




- Inadequate Ventilation
- BACKUP SYSTEM!
 - Leaks (Disconnects are much more prevalent than breaks in the circuit tubing)
 - Disconnects
 - Misfits



PRESSURE AND VOLUME DISCREPENCIES

- Hidden sources of leaks
 - ETT
 - RGM
 - Scavenger
 - OGT
 - Overflow valve





Narkomed 6000







Massive gas leak following misconnection of a Datex-Ohmeda Multi Absorber Disposable canister. BJA 109(1) July, 2012




Drager Fabius and Apollo APL

Groudine, S. Wires Block APL Valve Interfering with Ventilation. *APSF Newsletter* Spring-Summer 2011

Vijayakumar, A & A. 2010. 111 (2): 579.

Robards, C, Corda, D. A Potential Hazard Involving the Gas Sampling ... *Anesthesia & Analgesia*. 111(2):578-579, August 2010.




PRESSURE AND VOLUME DISCREPENCIES





PRESSURE AND VOLUME DISCREPENCIES

- Drager ventilator relief valve




PRESSURE AND VOLUME DISCREPENCIES

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PRESSURE AND VOLUME DISCREPENCIES

- Drager ventilator relief valve



PRESSURE AND VOLUME DISCREPENCIES


- ...the monitor panel displayed the messages "apnea volume" and "minute volume low," yet the low airway pressure alarm was not triggered and other parameters and clinical signs pointed to normal ventilation of the lungs. These conflicting data led to some delay in localizing the leak.
- Chung DC, Ho AM, Tay BA: "Apnea-volume" warning during normal ventilation of the lungs: an unusual leak in the Narkomed 4 Anesthesia System. *Journal of Clinical Anesthesia*. 13(1):40-3, 2001.




PRESSURE AND VOLUME DISCREPENCIES

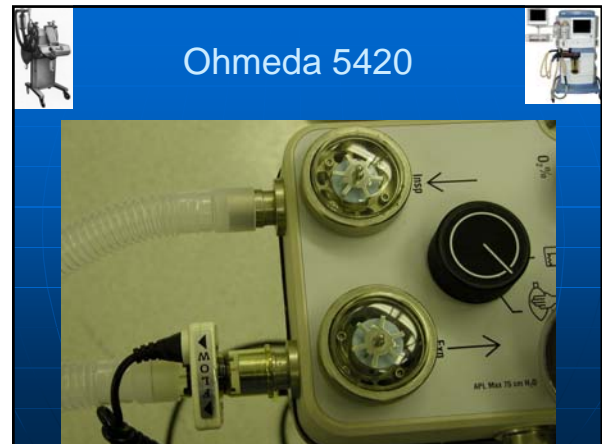
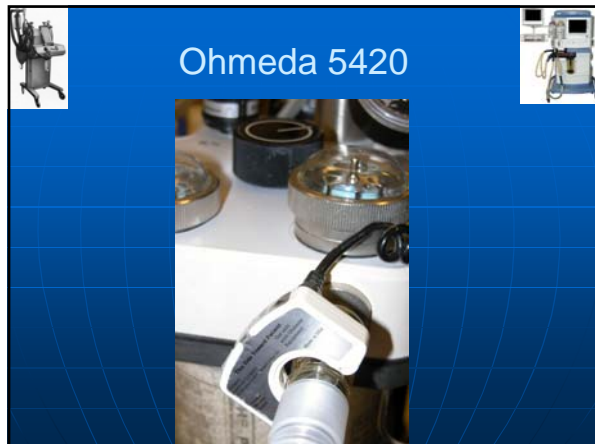
- Low exhaled volume with normal bellows and/or chest movement
 - FGF masks leak
 - Pressure-limiting
 - Pressure sampling tubing kink
 - Spirometer malfunctions
 - Mechanical, optical, pneumatic confounds

"Apnea pressure"



"Apnea pressure" or "Continuing pressure"







RESPONSE TO LOW PRESSURE OR VOLUME ALARM



- Assess indicators of intact respiration (ETCO₂, breath sounds, etc.) and assure adequate respiration by whatever means are available
- Volume Loss: Search for leaks and other volume loss
 - Disconnect
 - Uncuffed ETT
 - Suction tube in trachea
 - Overactive scavenger
 - Gas monitor sampling rate
 - Incompetent ventilator relief valve
 - Rule out ventilator problems by switching to manual ventilation mode
- No Volume Loss Apparent:
 - Check ventilator settings, inspiratory flow rate, and bellows movement
 - Check for high pressure limit set too low
 - Check for low pressure threshold set too high
 - Consider monitoring malfunction or limitation
 - Kinked pressure line, extreme high or low ventilator setting, spirometer misassembly, moisture, or miscalibration
 - Consider a lack of delivered volume due to circuit distensibility or FGF reduction

PRESSURE AND VOLUME DISCREPANCIES

- Fresh gas decoupling
 - Older ventilators do not compensate for contribution of FGF to tidal volume.
 - Overcome with newer machines (Ohmeda 7900, and 7100 (Aestiva), and Dräger 6400, Julian, Divan, Apollo, and Fabius)

■ Fabius simulation

Fresh gas coupling



Calculation of fresh gas flow contribution to tidal volume

$$\frac{I \times FGF \times 1000}{I (I + E)} = \text{contribution of fresh gas flow to tidal volume, in milliliters}$$

where,

I = inspiratory proportion of the respiratory cycle
 E = expiratory proportion of the respiratory cycle
 FGF = fresh gas flow in liters per minute
 f = respiratory rate (breaths per minute)



According to the formula, with a respiratory rate of 10, a fresh gas flow of 5 liters per minute, and an I:E ratio of 1:2,

$$\frac{1 \times 5 \times 1000}{10 (1 + 2)} = 167 \text{ ml/ breath are added by the fresh gas flow.}$$



PRESSURE AND VOLUME DISCREPENCIES


■ Inadequate Ventilation With High Inspiratory Pressures

- Kink, cough, bronchospasm
- Flow obstruction or Inadequate venting
 - Bag/vent switch
 - Water in circuit
 - PEEP valve
 - Kinked hose
 - Rapid rate with high I:E
 - Vent relief valve or exhaust malfunction
 - Scavenger + pressure relief
 - CGO check valve
 - Unidirectional valves






PRESSURE AND VOLUME DISCREPENCIES


- Second case of day. After induction, breathing bag continually grew, and PAP rose to 40. Change to bag mode did not remedy problem. Opening valve/canister drawer relieved pressure. Plastic wrapper was found obstructing main exhaust outlet.
- Cattano, et. al. Obstruction to Dräger Apollo Exhaust Valve. APSF Newsletter Fall, 2013
- Obstruction of exhaust valve not detected by Apollo self-check.
- Joyal JJ, Vannucci A, Kangrga I. High end-expiratory airway pressures caused by internal obstruction of the Dräger Apollo® scavenger system that is not detected by the workstation self-test and visual inspection. Anesthesiology 2012; 116: 1162-4; discussion 1164-6.

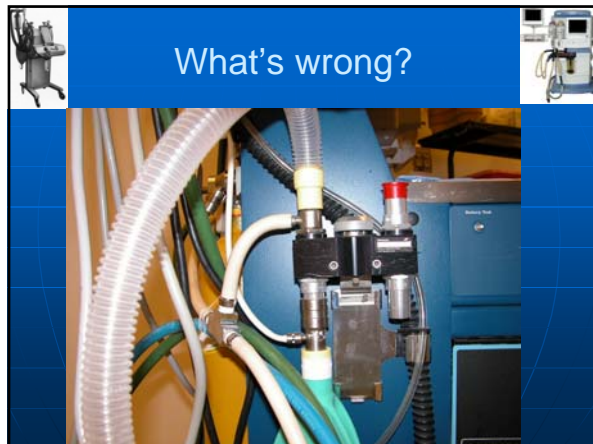



PRESSURE AND VOLUME DISCREPENCIES






PRESSURE AND VOLUME DISCREPENCIES






What's wrong?



PRESSURE AND VOLUME DISCREPENCIES

- Inadequate Ventilation With High Inspiratory Pressures
- Excessive inflow
 - Drive gas contamination
 - High FGF with high I:E
 - Oxygen flush malfunction




RESPONSE TO HIGH CIRCUIT PRESSURE

- Assess physiologic causes
- Bronchospasm, laryngospasm (without ETT), coughing, pneumothorax
- Change to manual ventilation mode
- Assess patency of ETT or circuit
- Assess for mechanical malfunction
- unidirectional valve sticking, misplaced PEEP valve, humidifier obstruction
- Consider outflow obstruction leading to excess volume
- O2 flush valve activated or leaking
- Punctured bellows
- Excessive FGF
- Incomplete circuit obstruction, impeding exhalation
- Extreme ventilator settings (rapid rate, high I:E)
- Ventilator relief valve stuck closed
- Scavenger obstructed



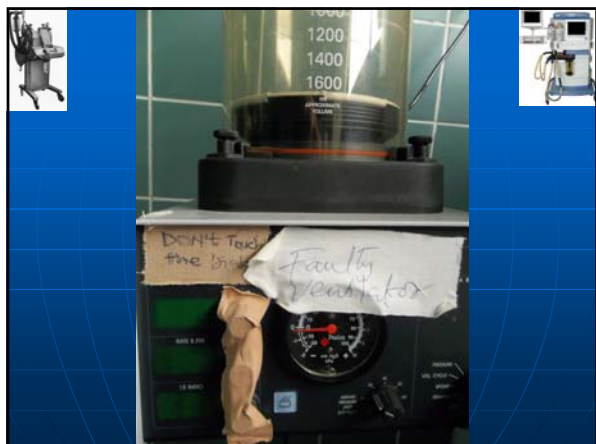
Where to learn more

- Manufacturer and User Facility Device Experience Database "MAUDE"
- <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm>



"My anesthesia machine is a piece of history"





ASA Guidelines for Determining Anesthesia Machine Obsolescence

- No arbitrary age
- Absolute criteria:
 - O₂ ratio device
 - O₂ fail safe
 - O₂ pressure alarm
 - Vaporizer interlock
 - PISS & DISS

ASA Guidelines for Determining Anesthesia Machine Obsolescence

- Absolute criteria:
 - Measured flow vaporizer
 - > 1 flow control knob/carrier gas
 - Vaporizers must increase counter-clockwise
 - Scavenger connections not interchangeable with breathing system
 - Inability to obtain certified service

ASA Guidelines for Determining Anesthesia Machine Obsolescence

- Relative criteria:
 - Inability to isolate the APL valve
 - O₂ knob fluted & protected
 - Single power switch for electrical
 - Anti-disconnect common gas connector
 - Airway pressure alarm
 - Frequent maintenance (lemon)
 - Salient differences from other machines in use
 - Inability to accommodate contemporary vaporizers, gas flows, ventilation, etc.

Benefits of New Generation Machines

- Reduced connections
- Heated components
- Low flow and advanced ventilation modes
- Improvements in APL design
- Eliminated valves from scavengers
- Valve competence checked
- Compliance and compression compensation
- Fresh gas decoupling
- Self check-out... better?
- Checkout becomes transparent, but COMPLEX

The old method of compliance compensation



Dependence on Electricity

- Batteries take on a new level of importance
- All allow manual ventilation via APL
- ADU and Aisys can't deliver agent
- ADU, Avance, Aisys force alternate oxygen source use
- Anestar, 6400, Fabius, Apollo maintain flow

Dependence on Electricity

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A10874 - High Priority Medical Device Alert
Medical Device
Ongoing Action
 Updated: September 10, 2008

Draeger—Apollo, Pallas, and Primus Anesthesia Machines: Faulty Electrical Component May Stop Automatic Ventilation and Cause Other Errors

Product Identifier:

Anesthesia Machines:	Serial Nos.:	Area of Distribution:
(1) ARZC-0142 through ARZC-0153, ARZC-0172 through ARZC-0177, ARZC-0192, ARZC-0193, ARZC-0196 through ARZC-0200, ARZD-0001 through ARZD-0003, ARZD-0010 through ARZD-0044, ARZD-0058 through ARZD-0087, ARZD-0117 through ARZD-0122, ARZD-0125 through ARZD-0136, ARZD-0183 through ARZD-0203, ARZD-0255 through ARZD-0271, ARZE-0001 through ARZE-0005, ARZE-0008 through ARZE-0010, ARZE-0023 through ARZE-0030, ARZE-0050 through ARZE-0065, ARZE-0113, ARZE-0116, ARZE-0173 through ARZE-0176, ARZE-0189 through ARZE-0204, ARZE-0214 through ARZE-0216, ARZF-0011 through ARZF-0031, ARZF-0084, ARZF-0087 through ARZF-0111.	(1) Apollo	(1) Japan, U.S.

Suggested Distribution:

- Anesthesia
- Clinical Biomedical Engineering
- OR/Surgery

UMDNS Terms:

- Anesthesia Units [10134]

Geographic Regions:

- Africa
- Asia
- Australia
- Canada
- Europe
- Japan

Dependence on Electricity

- 34-week primigravida with eclampsia on ventilator.
- 12 hours after intubation, developed desaturation, bradycardia, cardiac arrest.

Krishna Kumar BR, Ravi M, Dinesh K, Nanda A.
 Ventilator malfunction. *J Anaesthesiol Clin Pharmacol* 2011;27:576

What would have aided discovery of vent failure?

More than you wanted to know about every type of anesthesia machine

- <https://www.ecri.org/ES/Documents/Anesthesia%20Units.pdf>

Summary

- Malfunctions span the gamut of severity, and ease of discovery
- Vigilance
- Preparedness
- Clinical Correlation
- Redundancy
- Override Mechanisms