Gas Modules and Anesthesia Monitors – Proper testing requirements

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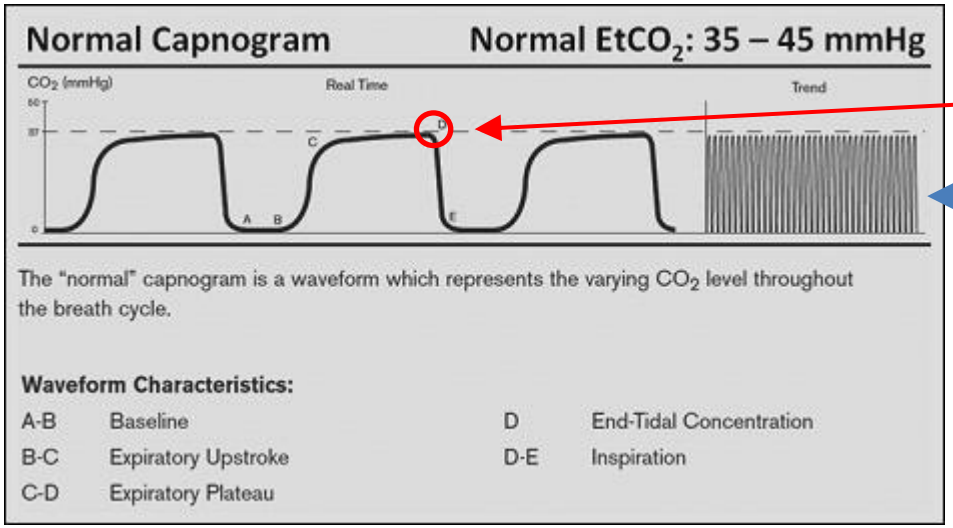
Goals for today

- Capnometry 101 – what is it and its increasing importance
- Gas Monitor 101 – types and locations
- Failure Modes – how do gas monitors fail and how do these failures affect performance
- Common testing method
- Case for proper testing

Capnography 101 – what is it?

- Defined as the monitoring of exhaled carbon dioxide through the respiratory system.
  - Capnometry – End tidal CO2 (EtCO2) number only - 32 mmHg
  - Capnography – CO2 waveform with volumetric information



EtCO2

Capnogram

- Not the same thing as pulse ox – which measures how much oxygen is in your blood

Humans and Gas Engines Analogy

Component	Humans	Gas Engine
Fuel	Glucose	Gasoline
Oxidizer	Oxygen	Oxygen
Chemical process	Citric Acid Cycle	Combustion
Give off (Respiration)	Carbon Dioxide (CO2)	Carbon Monoxide

- Pulse Ox only shows you how much oxygen is in the blood, not how well it is being used.
- CO2 provides instant assessment of respiratory health by direct measurement of waste (exhaust) gasses.
- Capnography is the best way to assess respiratory health.

Capnometry 101 – why is it important

– To the trained medical professionals, specific issues can be identified and corrected

Normal Waveform

Apnea

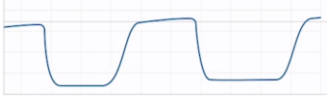
Hypoventilation

Hyperventilation

Partial Airway Obstruction

Return of Spontaneous Circulation

Rebreathing of CO2



Asthma, Emphysema or COPD

Cardiac Arrest with CPR

Confirmation of airway placement

Quality of CPR

Sedation quality

Ventilator settings

Growing use of capnometry

- Because of its clinical value, clinicians are embracing capnometry
- Large number of changes in standard of care and association guidelines the last two decades

Some of the latest regulatory changes

- 2003/1999 – AAAAPSF (American Association for Accreditation of Ambulatory Plastic Surgery Facilities, Inc.) – Anesthesia monitoring
- 2004 - AAMS (Association of Air Medical Services) – capnography onboard
- 2006 - AAP (American Academy of Pediatrics) – Tube placement and PICU bedside
- 2006 - American Academy of Pediatrics, American Academy of Pediatric Dentistry – sedated patients
- 2007/2003 – AARC (American Association for Respiratory Care)- Monitoring for mechanical support
- 2007 – American Academy of Sleep Medicine
- 2009/2005/2001 ACEP (American College of Emergency Physicians)
- 2010 – AHA (American Heart Association)
- 2009/2007 – APSF (Anesthesia Patient Safety Foundation)
- 2009, 2005, 2004, 2002 – ASA (American Society of Anesthesiologists)
- 2009 – American Gastroenterological Association
- 2008/2003 – ASGE (American Society for Gastrointestinal Endoscopy)
- 2008 – CSA (California Society of Anesthesiologists)
- 2009/2005 – ENA (Emergency Nurses Association)
- 2010 – FDA (Food and Drug Administration)
- 2007 – (ISMP (Institute for Safe Medication Practices)
- Many more state and local government and licensing bodies

Major guidelines changes

- 2004 – Joint Commission recommends capnometry for patients self-administering analgesia (infusion pumps)
- 2010/2015 - American Heart Association (AHA) modified guidelines to use continuous capnometry during CPR and ECC events (defibrillators)
- 2011 - American Association for Respiratory Care (AARC) recommended
  - Continuous capnometry during ventilation (vents and patient monitors)
  - Waveform capnography for determining correct tube placement
  - Continuous capnometry during transport of mechanically ventilated patients
  - Capnometry to guide ventilator management
  - Capnography to identify abnormalities of exhaled air flow
  - Capnography during CPR
- 2011/2016 - American Society of Anesthesiologists (ASA) amended its Standards to require EtCO2 monitoring during both moderate and deep sedation
- 2019 - Enhanced Recovery After Surgery Society (ERAS) use of capnography in post op for patients who received analgesia.
- 2020 - Society of Pediatric Sedation (SPS) use of capnometry when sedating children.

How does this affect Clinical Engineering?

- Gas monitors must work properly under an increasing range of conditions
- Large increase in the number of devices has resulted in a larger PM burden
- Device PMs must be adequate yet efficient

Gas Monitor 101 - Capnometers

- Measure CO2 concentration in patient breath
- May or may not provide a capnograph
- Commonly called end tidal modules, gas modules or CO2 modules
- Standalone or modules

Capnostream 35

GE e-sCXX and E-CXX

Philips LoFlo


Masimo ISA

Philips 3015A/B

Gas Monitor 101 – Anesthesia gas monitors

- Measure CO2, O2, N2O & anesthetic agent – waveform for each gas
- Not to be confused with gas vaporizers

GE E-CAIOV

GF-210R

GE SAM

Mindray AG 5

Philips M1019A

Sample Type - Two Types

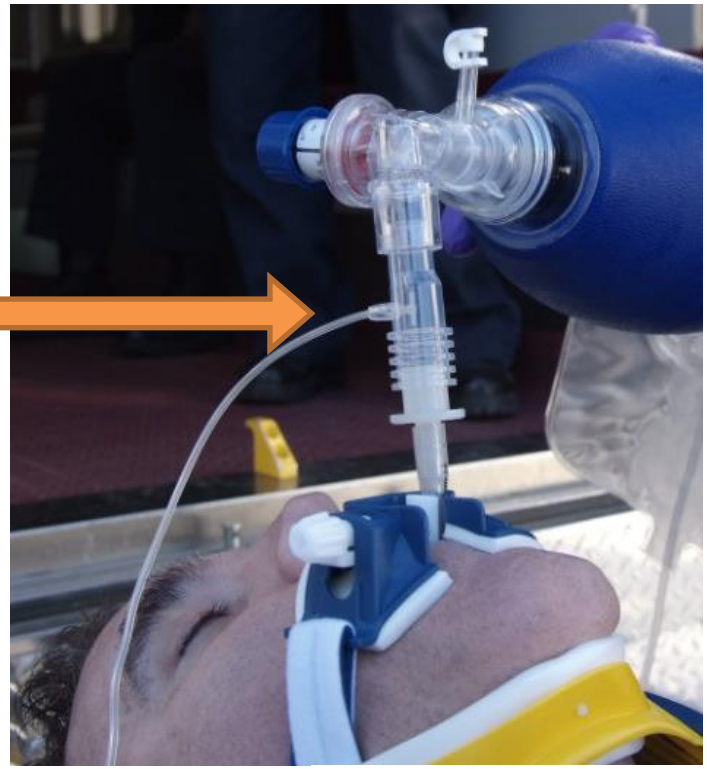
- On air way
- Side stream

Sample Type - Mainstream (On airway)

- Located inline on the main breathing circuit
- Direct reading
- Only works with intubated patients
- Sensor only
- Requires calibration only

Sample Type – Side Stream

- Small sample pulled from the patient using a built-in pump
- 3 to 5 second delay
- Most common: 80%+ of all capnometers in hospitals
- Intubated and non-intubated patients
- Complex device with pumps, gas sensors, water traps and other tech built into them
- PM is more complicated



Where are gas monitors found?

Gas monitors are found everywhere

- Stand alone (less common today)
- Gas modules – plug into multi-parameter monitors
- Attached to Infusion pumps
- Defibrillators
- Anesthesia machines

Found in the:

- OR, ER, ambulance, post op recovery, ICU, NICU, surgical centers, dentist offices, etc.

Are often sent to depots or the OEM for unnecessary repair

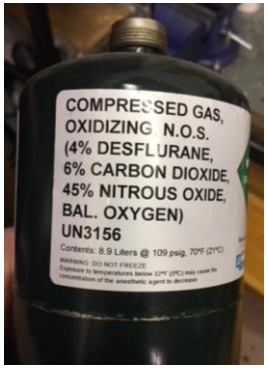
GE e-sCXX and E-CXX

Alaris

Zoll Defibrillator

Calibration Gas 101

- Why do we use calibration gas?
  - Most accurate way to calibrate any sensor
- Two main types of gas
  - Metabolic CO2 gases
    - Typically 5%/10% CO2 mixed with various amounts of Oxygen, Nitrogen or regular air
    - Used for CO2 monitors
  - Anesthetic gases
    - Metabolic + Anesthetic gases like Desflurane and Nitrous Oxide (N2O)
    - Used in anesthesia multi-gas monitors
- Come in a wide variety of shapes, sizes and pressures/volumes



Failure Modes

- What are some ways that gas monitors can fail?
  - Out of calibration
  - Poor sampling
  - Leaks – connections, hoses
  - Mechanical problems
    - Fans
    - Buttons
    - Displays
    - Connectors

Failure Modes - Hidden

- Failures under pressure (ventilated patients) – less obvious leaks that only show up with higher airway pressures
- Poor response time – especially true with higher breath rates of infants

Poor Sampling

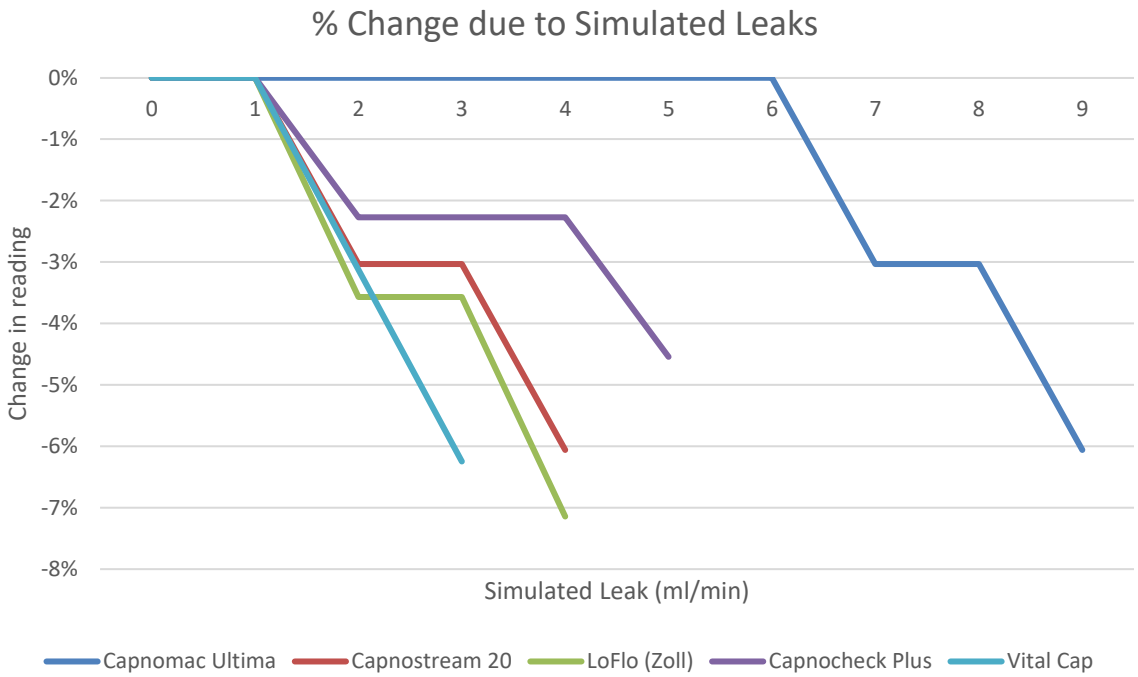
- Pump is weak or defective
- Filters are plugged
- Internal lines are plugged or full of debris

Lead to

- Delayed response
- Incorrect readings

Leaks

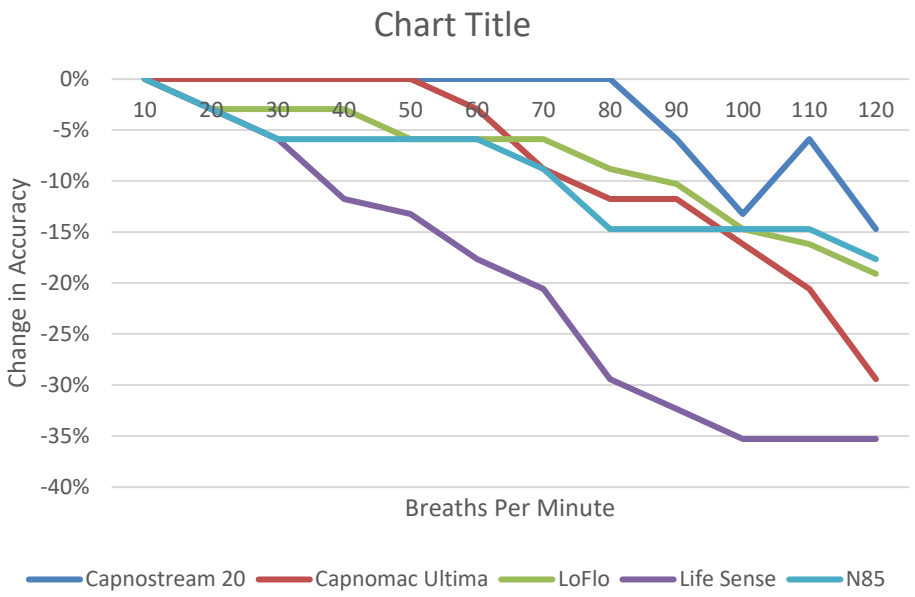
- Upstream (low pressure) leaks can dilute the sample causing low readings



- Can be exacerbated with mechanically ventilated patients

Respiratory Rate and its Effect on Accuracy

- Not all gas monitors perform well at higher respiratory rates



Barometric Pressure Calibration

- Gas monitors use barometric pressure to provide partial pressure gas readings.
- Barometers in gas monitors are calibrated and verified
- Clinical engineers also use barometric pressure to convent gas vol% to partial pressures during gas calibration
- Clinical engineers incorrectly use barometric pressures from weather websites
  - Barometric pressure from weather websites are “corrected” to sea level
  - Most biomeds don’t realize this
  - Weather pressures will be higher than the actual pressure
  - The correction factor is roughly 26 mmHg per 1000ft of elevation
- Using weather barometric pressures result in incorrect calibrations, which lead to incorrect CO2 readings

- Example
  - At 1000 ft, weather reported barometric pressure will be off by 26 mmHg. This results in the EtCO2 readings being off by 1.3 mmHg or around 4%
  - At 4000 ft of elevation, readings will be off by 5.2 mmHg (16%)

Best Practice: Use an absolute barometric pressure gauge on site

Failure Mode – Out of Calibration

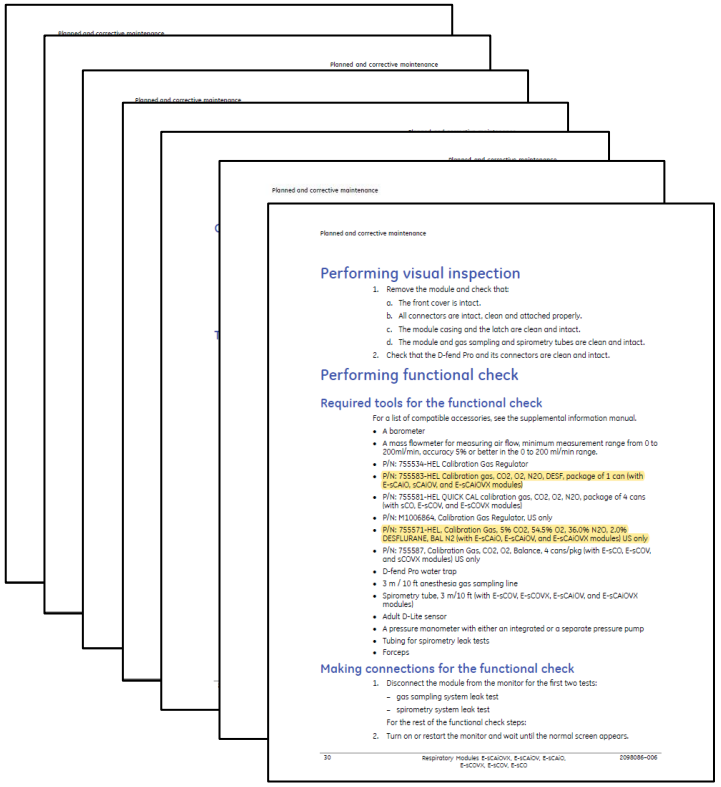
- Wrong calibration gas
- Insufficient warm up time
- Incorrect barometric pressure

More Significant Than Most Think

- Gas modules provide medical staff vital detailed information
- Seemingly small issues can impact performance more than expected

Ideal Testing Methods – OEM Service Manuals

- OEM service manuals define proper testing for devices
- Proper testing
  - Takes time
  - Requires a variety of equipment.



Planned and corrective maintenance

Performing visual inspection

1. Remove the module and check that:
   a. The front cover is intact.
   b. All connectors are intact, clean and attached properly.
   c. The module casing and the latch are clean and intact.
   d. The module and gas sampling and spirometry tubes are clean and intact.
2. Check that the D-fend Pro and its connectors are clean and intact.

Performing functional check

Required tools for the functional check

For a list of compatible accessories, see the supplemental information manual.

- A barometer
- A mass flowmeter for measuring air flow, minimum measurement range from 0 to 200ml/min, accuracy 5% or better in the 0 to 200 ml/min range.
- P/N: 755534-HEL Calibration Gas Regulator
- P/N: 755583-HEL Calibration gas, CO2, O2, N2O, DESF, package of 1 can (with E-sCAiO, sCAiOV, and E-sCAiOVX modules)
- P/N: 755581-HEL QUICK CAL calibration gas, CO2, O2, N2O, package of 4 cans (with sCO, E-sCOV, and E-sCOVX modules)
- P/N: M1006864, Calibration Gas Regulator, US only
- P/N: 755571-HEL, Calibration Gas, 5% CO2, 54.5% O2, 36.0% N2O, 2.0% DESFLURANE, BAL N2 (with E-sCAiO, E-sCAiOV, and E-sCAiOVX modules) US only
- P/N: 755587, Calibration Gas, CO2, O2, Balance, 4 cans/pkg (with E-sCO, E-sCOV, and sCOVX modules) US only
- D-fend Pro water trap
- 3 m / 10 ft anesthesia gas sampling line
- Spirometry tube, 3 m/10 ft (with E-sCOV, E-sCOVX, E-sCAiOV, and E-sCAiOVX modules)
- Adult D-Lite sensor
- A pressure manometer with either an integrated or a separate pressure pump
- Tubing for spirometry leak tests
- Forceps

Making connections for the functional check

1. Disconnect the module from the monitor for the first two tests:
   - gas sampling system leak test
   - spirometry system leak test

   For the rest of the functional check steps:
2. Turn on or restart the monitor and wait until the normal screen appears.

30 Respiratory Modules E-sCAiOVX, E-sCAiOV, E-sCAiO, E-sCOVX, E-sCOV, E-sCO 2098086-006

Testing Methods - Reality

- Many shops only calibrate CO2 with calibration gas.
- Skip most or all of the other tests because of
  - Complexity
  - Time
  - Volume of testing
  - Perceived lack of criticality for CO2 monitors

Issues with current testing methods

- Gas usage
- Skipping flow and leak tests
- Inadequate testing – open to liability
- Adjusted barometric pressure
- Uses a lot of gas, bags and tubing, etc.
- Large volume to test
- “Only a capnometer”

Best practice testing methods

- Full leak check
- Pump flow check
- Absolute barometric pressure gauge
- Calibration after sufficient warm up time
- Patient Simulation
- Mechanical inspection
- Full documentation