Non-Invasive Respiratory Volume Monitoring

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Objectives

1. Understand the importance of Minute Ventilation in monitoring non-intubated patients
2. Understand the basic technology and accuracy of a new respiratory volume monitor (*ExSpiron™*)
3. Understand how the *ExSpiron* can be used to provide an early indication of respiratory depression
4. Understand different clinical environments and patient conditions where the utility of the *ExSpiron* has been demonstrated
“EKG for Respiration”

Cardiac

- Diagnostics
- Monitoring
- Telemetry
- Home care
- Advanced therapeutics
- Closed loop (pacemakers, defibrillators, etc.)

Respiratory?

- X Real-time diagnostics
- X Telemetry
- X Advanced warning
- X Therapeutic monitoring

Cardiac Standard of Care advanced because of Ability to Monitor Real-Time Parameters and Follow Interventions
Respiratory Volume Monitoring

- Fundamental unit of breathing (MV = TV x RR)
- Non-invasive, real-time, continuous, shows trends
- Displays 30 second averages updated every 5 sec
- Communicate quantitative information, not subjective
- Very few false alarms; Remote monitoring capability
**ExSpiron** Electrode Padset

- Printed circuit
- Single integrated connector
- Adjusts for patient size
- Facilitates uniform placement
- 24 hour wear time
- Radiolucent
Trace
• Normal ventilation
• Hypoventilation
• Respiratory pauses
• Hyperventilation

Trend
• Quantitative measurements of MV, TV, RR
• Changes after medication or therapy

History
• Values stored for charting / transfer to EHR / QI
• Printed/saved report (PDF, Excel)
More Air = More Impedance  (Less Current)

Less Air = Less Impedance  (More Current)
Theory of Operation: Ohm’s Law

Detailed Technical Description
Starting with Ohm’s Law (Equation 1):

\[ Z = \frac{V}{I}, \]

where \( Z \)= Impedance, \( V \)= Voltage, and \( I \)= Current, the ExSpiron uses a constant current source \((I = \text{constant})\) so the Impedance \((Z)\) is proportional to the Voltage \((V)\):

\[ V \propto Z \quad (2). \]

The ExSpiron measures the Voltage \((V)\) across the electrodes over time and it is well known and documented in the literature that when measuring the voltage drop across a pair of electrodes placed across the chest that the change in Impedance is proportional to the Volume of inspiration:

\[ \Delta V \propto \Delta Z \propto \text{Volume of Inspiration}(TV) \quad (3) \]
Theory of Operation: $\Delta Z / \Delta t$

Typical Impedance Curve Collected When Breathing
(Time (t) vs. Impedance (Z))

Above is a typical impedance curve collected by the ExSpiron. Each breath is identified with its respective change in impedance $Z$. 

Confidential
Theory of Operation: MV from series of breaths

\[ TV_1 = k \times Z_1^{(4)}, \]

Depicts the equation for calculating the tidal volume for breath one.

\[ MV = \frac{\Delta Volume}{\Delta Time} \quad (5), \]

Depicts the general equation for Minute Volume

\[ MV = k \times \sum_{n=1}^{N} \left. \frac{\Delta Z_n}{\Delta t_n} \right|_T \quad (6), \]

Depicts equation for calculating the Minute Volume for a series of N breaths, where \( k \) is the patient specific calibration constant and \( N \) is the number of breaths over time period \( T \)
Clinically Relevant Accuracy: 90% vs gold standard

The ExSpiron™ is FDA cleared as a non-invasive system that graphically displays lung volumes against time and reports an approximate value of:
- Tidal Volume
- Respiratory Rate
- Minute Ventilation

Evaluation of a Novel Noninvasive Respiration Monitor Providing Continuous Measurement of Minute Ventilation in Ambulatory Subjects in a Variety of Clinical Scenarios

Christopher Voscopoulos, MD,* Jordan Brayanov, PhD,† Diane Ladd, DNP,‡ Michael Lalli, BSE,† Alexander Panasyuk, PhD,† and Jenny Freeman, MD†

~90% accuracy for MV & TV

>98% accuracy for RR

Not “fooled” by obstructed breaths
Ventilation Management Problem

**Intubated / Controlled**
- ICU / OR

- ✓ Control ventilation
- ✓ Continuous ventilation monitoring
- ✓ Safe sedation / pain management
- ✓ Ventilation OK even with relative overdose

**Non-intubated / Unknown**
- ICU / Proc Sed / PACU / Floor

- ✗ Unknown air exchange
- ✗ Limits control of sedation / pain mgt
- ✗ Subjective patient assessment and ventilation ability
- ✗ Unknown response to therapy
MV changes provide **Earliest Warning**

Modified from *Lynn and Curry, Patient Safety in Surgery, 2011*
Respiratory Failure: **More than Hypoxia**

- **Respiratory Arrest**
- **Organ Failure**
- **Heart Attack**
- **Ischemia**
- **Brain Damage**

**Failure of CO2 Removal**
- \( \uparrow \text{CO2} \downarrow \text{pH} \)

**Failure of Oxygenation**

**Failure of Lung Expansion**

**Atelectasis**
- **Pneumonia**
- **Fever**
• Non-invasive Minute Ventilation
• Tidal Volume
• Respiratory Rate
• Nurse Call signals the clinician

Other measurements show **NO** early sign of respiratory depression

- MV 30%
- O₂ Sat: 98%
- EtCO₂: N/A
- RR: 10
Evaluation of respiratory volume monitoring (RVM) to detect respiratory compromise in advance of pulse oximetry and help minimize false desaturation alarms

Samuel M. Galvagno, Jr, DO, PhD, Peggy G. Duke, MD, Daniel S. Eversole, PhD, and Edward E. George, MD, PhD. Waltham, Massachusetts

<table>
<thead>
<tr>
<th></th>
<th>No Pt [%]</th>
<th>LMV in PACU [#/hr]</th>
<th>Recorded SpO2 Alarms (1-min)</th>
<th>Opioids</th>
<th>PACU LOS [hr]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Transient False True RN Records</td>
<td>No. Pt [%]</td>
<td>Dosage [µg/kg/hr]</td>
</tr>
<tr>
<td>With Low MV:</td>
<td>198 [76%]</td>
<td>2.3 ±0.1</td>
<td>58 10 7 1</td>
<td>133 [67%]</td>
<td>40 ±3</td>
</tr>
<tr>
<td>No Low MV:</td>
<td>61 [24%]</td>
<td>0</td>
<td>29 9 0 1</td>
<td>33 [53%]</td>
<td>33 ±4</td>
</tr>
<tr>
<td>Total:</td>
<td>259 [100%]</td>
<td>1.8 ±0.1</td>
<td>87 19 7 2</td>
<td>166 [64%]</td>
<td>39 ±2</td>
</tr>
</tbody>
</table>

- 106/113 recorded SpO2 alarms were false alarms (94%)
- Real SpO2 alarms were immediately preceded by low MV by 12.8 min, with earlier low MV starting 71 mins earlier
• 51 patients
• 9,575 respiratory epochs
• Very weak correlation MV vs RR (r=0.05)
• RR alarm at 6 breaths/min would miss > 82% of Low MV episodes
• RR alone has only 18.2% sensitivity – for predicting Low MV

**MV indicates respiratory performance; RR not an adequate proxy.**

Changes in ventilation were reflected by the RVM in 37.7s, while ETCO₂ often failed to reach a new asymptote before 2.5mins.

Large changes in MV (7.0 L/min to 2.0 L/min) resulted in small changes in ETCO₂ via nasal cannula (33.7 mmHg to 36.8 mmHg)
ExSpiron utility in multiple environments

- Critical Care
- Post-Anesthesia Care Unit
- OR / Monitored Anesthesia Care
- Transport
- Procedural Sedation
- General Hospital Floor
- Surgery Centers and Remote Sites
Sleep apnea criteria scores (SACS) was calculated for 56 PACU patients by Flemon’s Criteria.

Although 9/13 High SACS patients also had an OSA diagnosis, High SACS patients experienced less Low Minute Ventilation events than Low SACS patients (3.5 ± 0.4 vs 2.3 ± 0.5 events/hr).

High SACS patients also spent less time with Low Minute Ventilation than Low SACS patients (14.5 ± 2.2 vs 6.3 ± 2.2 min/hr).
• 102 PACU patients, 48hr observational study
• 10.8% of patients had repetitive Low Minute Ventilation events, indicative of opioid-induced respiratory depression
• Usage of the RVM in practice could identify these high-risk patients, enabling prevention of respiratory depression
• Monitored 35 general surgery patients in the PACU and General Hospital Floor

• Surprisingly, higher STOP-Bang score patients had less frequent and short Low Minute Ventilation events

• Low Minute Ventilation was characterized by reduced tidal volumes

• Postoperative patient monitoring of MV could help identify at-risk patients unnoticed by other risk factors

ASA 2016
**Respiratory Volume Monitoring Could Improve Safety in Procedural Sedation**

Donald Mathews MD¹, Michael Oberding MD¹, Eric Simmons MD¹, Karl Kristiansen MD¹, Stephen O’Donnell MD¹, Kevin Abnet MD¹

¹: Department of Anesthesiology, University of Vermont College of Medicine, Burlington, Vermont

**SAMBA 2016**

- **Comparison of 25 Colonoscopy patients to 48 Upper Endoscopy patients, with RVM used for care in some Endoscopy patients**

- Colonoscopy patients spent the most time with Low Minute Ventilation

- Anesthesiologist engagement with the RVM resulted in 60% less average time with Low MV compared to control
Monitored 6 ICU patients for up to 24 hours after extubation

Following extubation, average MV fell by 11%, recovering back to 100% the following hour

Rapid shallow breathing index decreased following extubation, driven by changes in tidal volume rather than respiratory rate
Redefining Respiratory Management

- Nurse Call
- Central Monitoring
- Non-Invasive Ventilation
- Transport
- High Flow Therapy
- PCA
- Multimodal Therapeutics (pain, pulmonary)
- Transition from Invasive Ventilation
- EMR