RESPIRATORY MOTION INC.

INSPIRED INNOVATION

Non-Invasive Respiratory Volume Monitoring

Jenny E. Freeman, M. D.

STA 2017, January 14

San Diego, CA

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

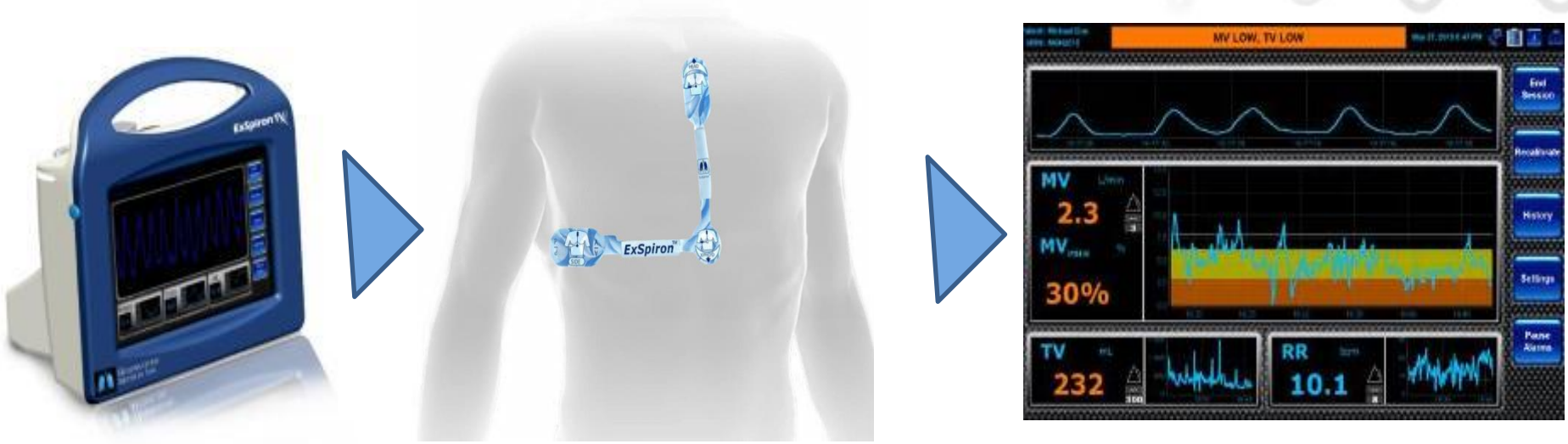
- ✓ Diagnostics
- ✓ Monitoring
- ✓ Telemetry
- ✓ Home care
- ✓ Advanced therapeutics
- ✓ Closed loop
  (pacemakers, defibrillators, etc.)

Respiratory ?

- ✗ Real-time diagnostics
- ✗ Telemetry
- ✗ Advanced warning
- ✗ 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


ExSpiron 1x
1.7
253
6.7
Respiratory Motion Inc.
ExSpiron
CE
LATEX FREE

Trace

- Normal ventilation
- Hypoventilation
- Respiratory pauses
- Hyperventilation

Trend

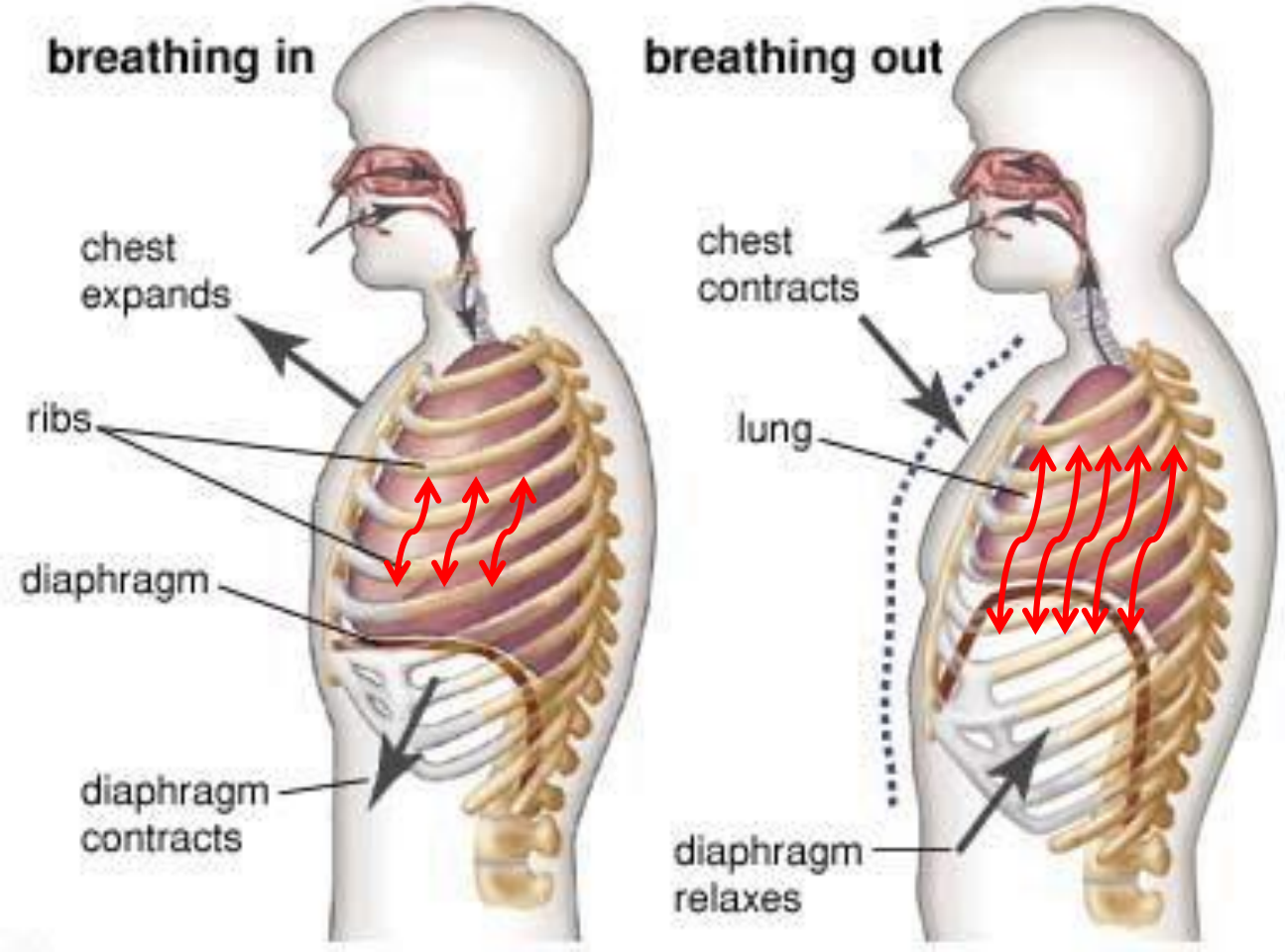
- Quantitative measurements of MV, TV, RR
- Changes after medication or therapy

History

- Values stored for charting / transfer to EHR / QI
- Printed/saved report (PDF, Excel)

Thoracic Impedance

= Low Voltage Electrical Current



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 $\left(I = constant\right)$ so the Impedance (*Z*) is proportional to the Voltage (*V*):

$$V \propto Z \text{ (2).}$$

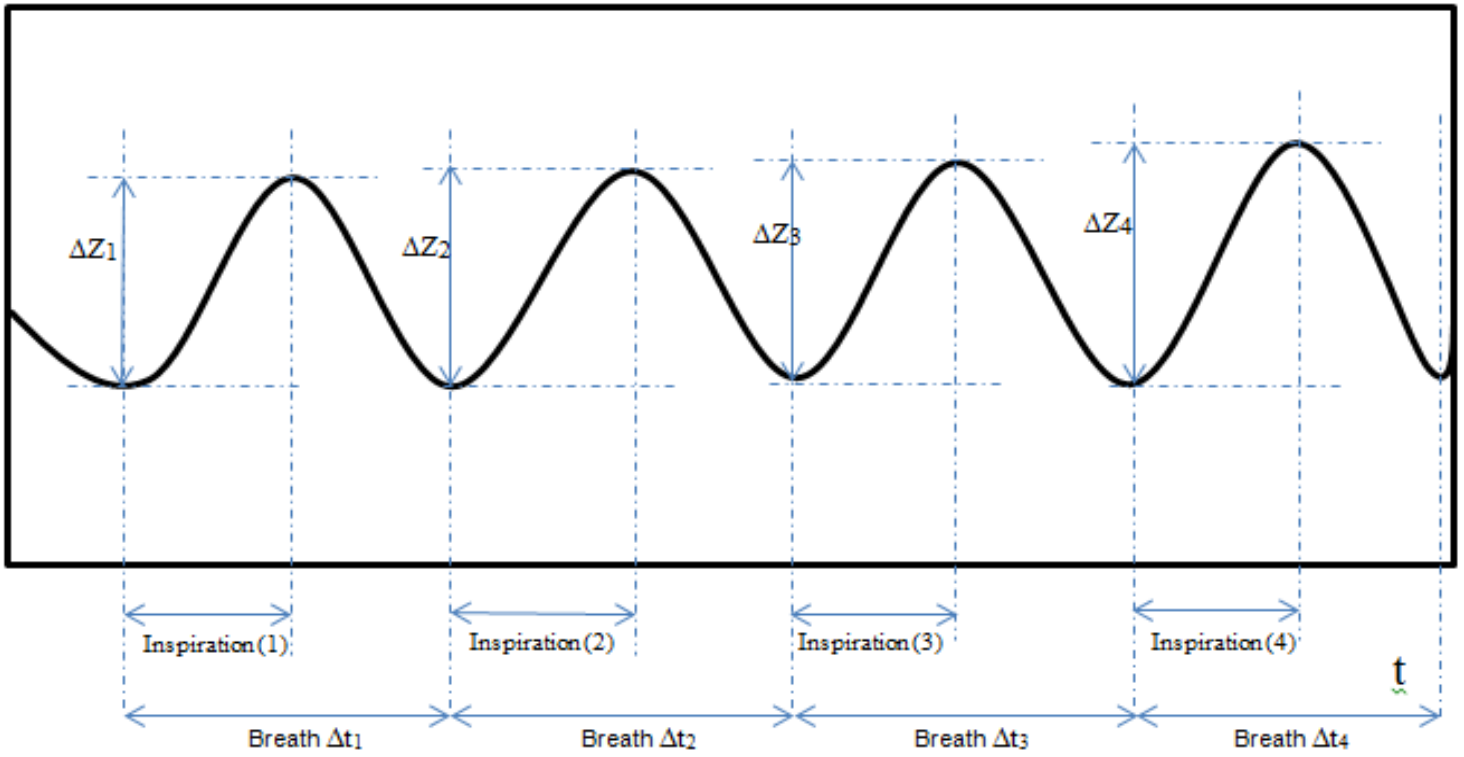
The ExSpiron measures the Voltage (V) across the electrodes over time and it is well known and documented in the literature that when measuring the voltage drop across a pair of electrodes placed across the chest that the change in Impedance is proportional to the Volume of inspiration:

$$\Delta V \propto \Delta Z \propto Volume of\ Inspiration(TV) \text{ (3)}$$

Theory of Operation: ΔZ / Δt

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.

Theory of Operation: MV from series of breaths

$$TV_1 = k \times Z_1 \quad (4),$$

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

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

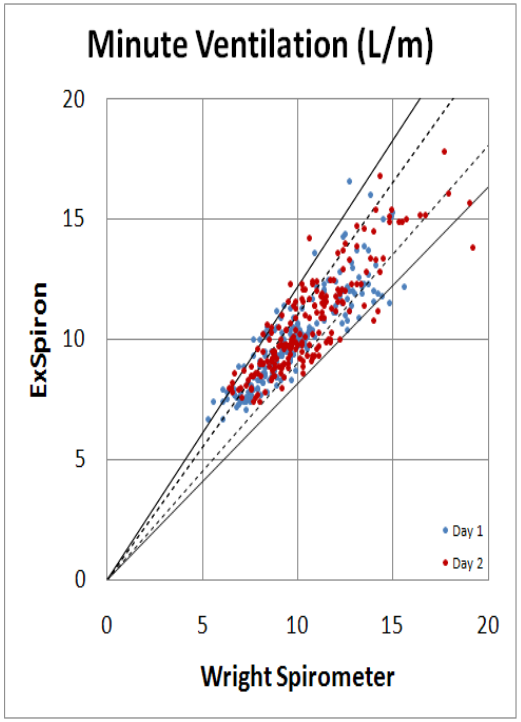
Depicts the general equation for Minute Volume

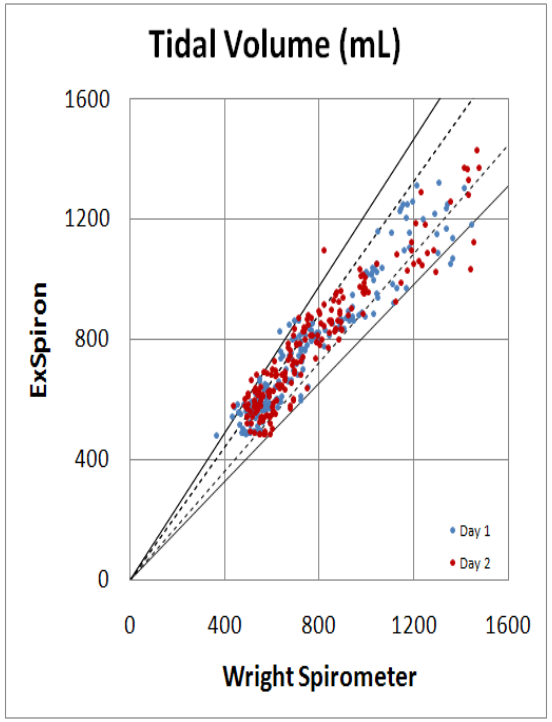
$$MV = k \times \sum_{n=1}^{N} \frac{\Delta Z_n}{\Delta t_n}\Bigg|_T \quad (6),$$

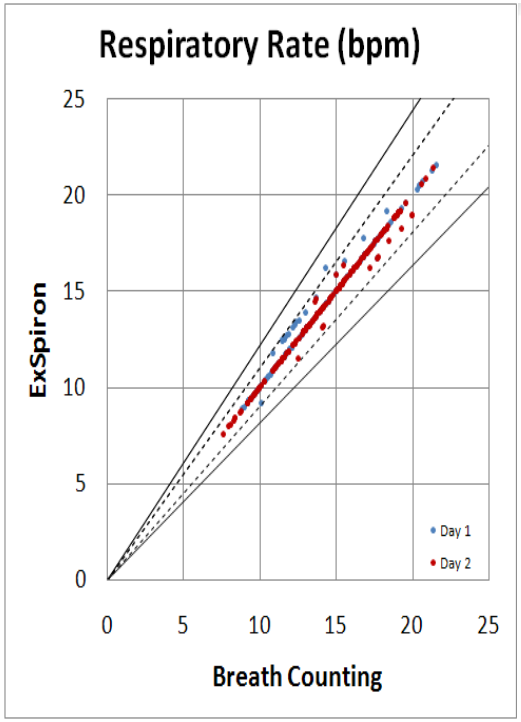
Depicts equation for calculating the Minute Volume for a series of N breaths,

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

Percent Error on Day 1 and Day 2

	Minute Ventilation	Tidal Volume	Respiratory Rate
Bias	**-2.1**	**-1.9**	**-0.2**
Precision	**10.5**	**10.3**	**2.0**
Accuracy	**10.7**	**10.4**	**2.0**

Voscopoulos C, MacNabb M, Brayanov J, Qin L, Freeman J, Mullen G, Ladd D, George E. The evaluation of a non-invasive respiratory volume monitor in surgical patients undergoing elective surgery with general anesthesia. J Clin Monit Comput 2015; 29(2):223-30

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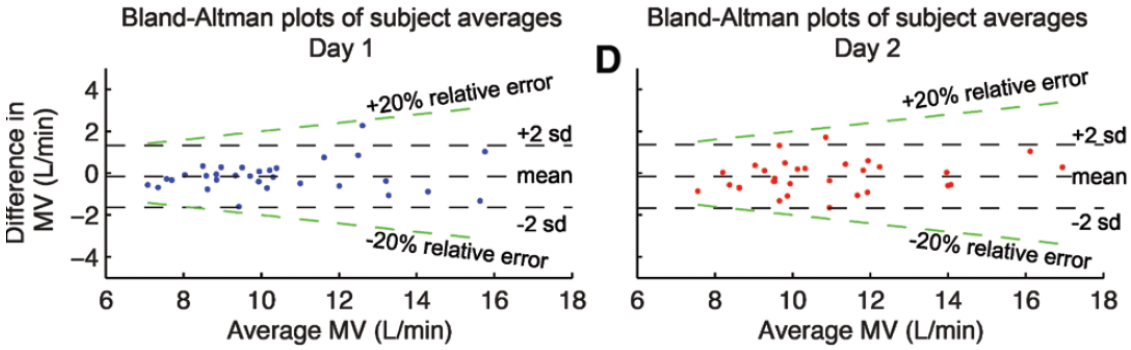
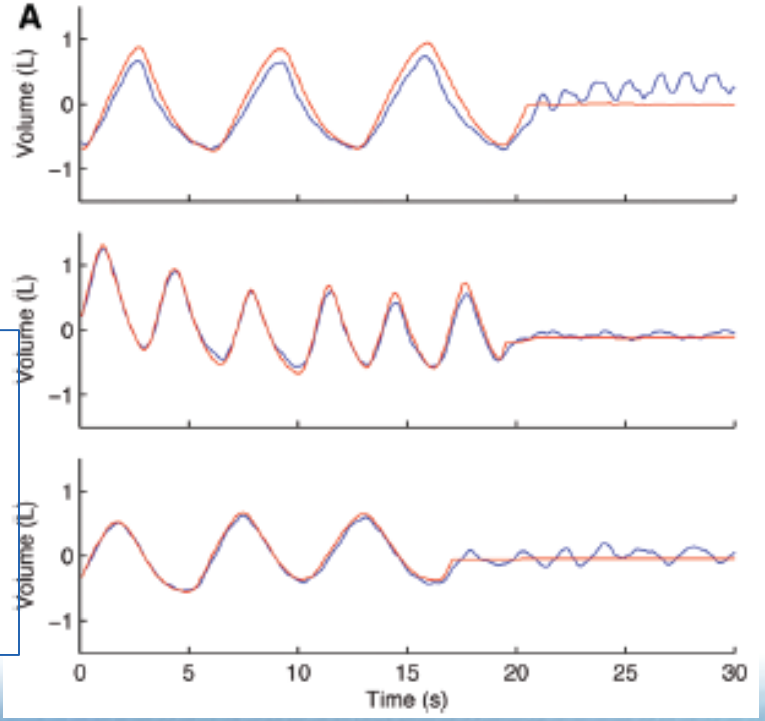
July 2013 • Volume 117 • Number 1 www.anesthesia-analgesia.org

SPECIAL ARTICLE

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

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Ventilation Management Problem

Intubated / Controlled

ICU / OR

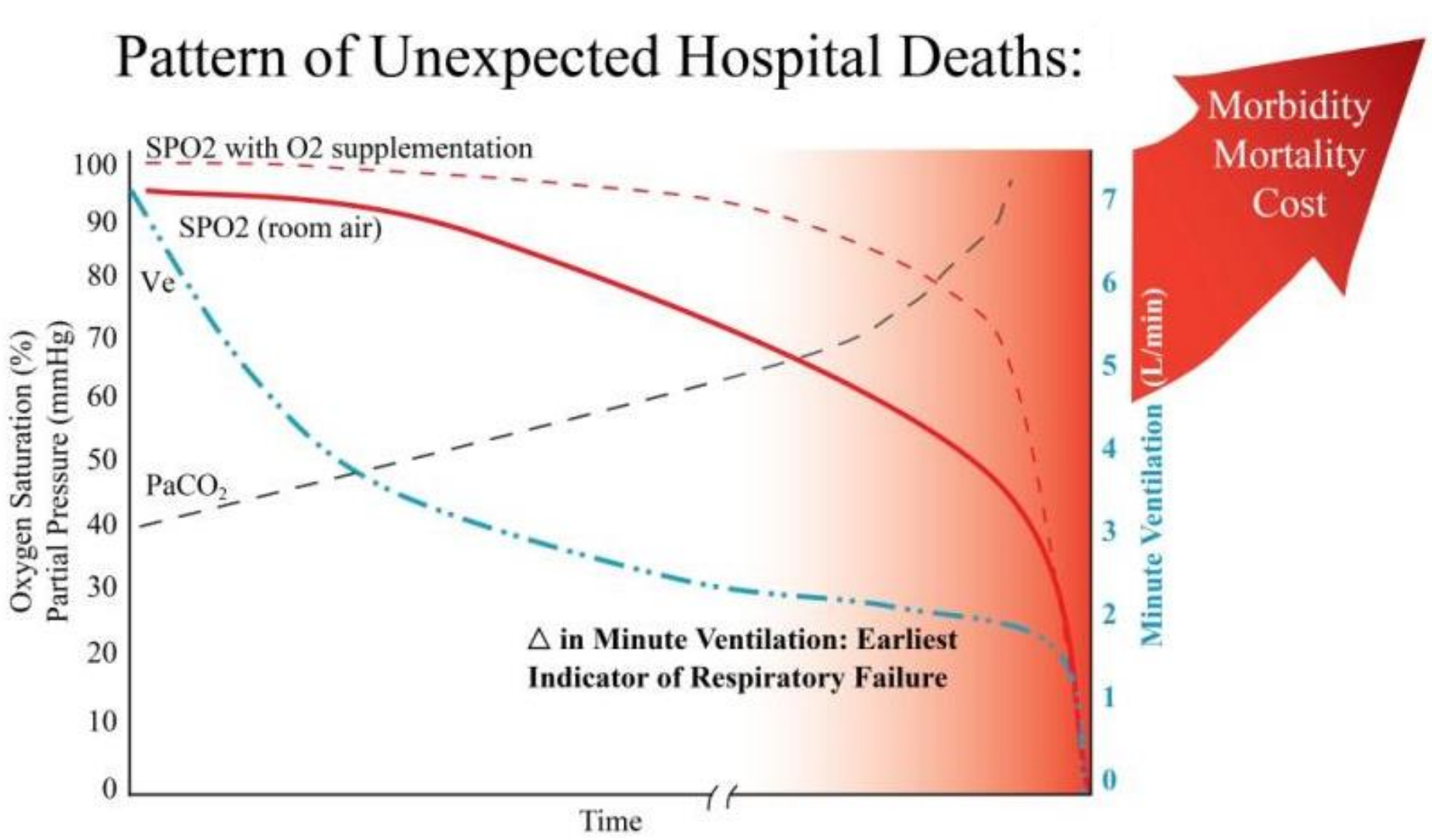
- ✓ Control ventilation
- ✓ Continuous ventilation monitoring
- ✓ Safe sedation / pain management
- ✓ Ventilation OK even with relative overdose

Non-intubated / Unknown

ICU / Proc Sed / PACU / Floor

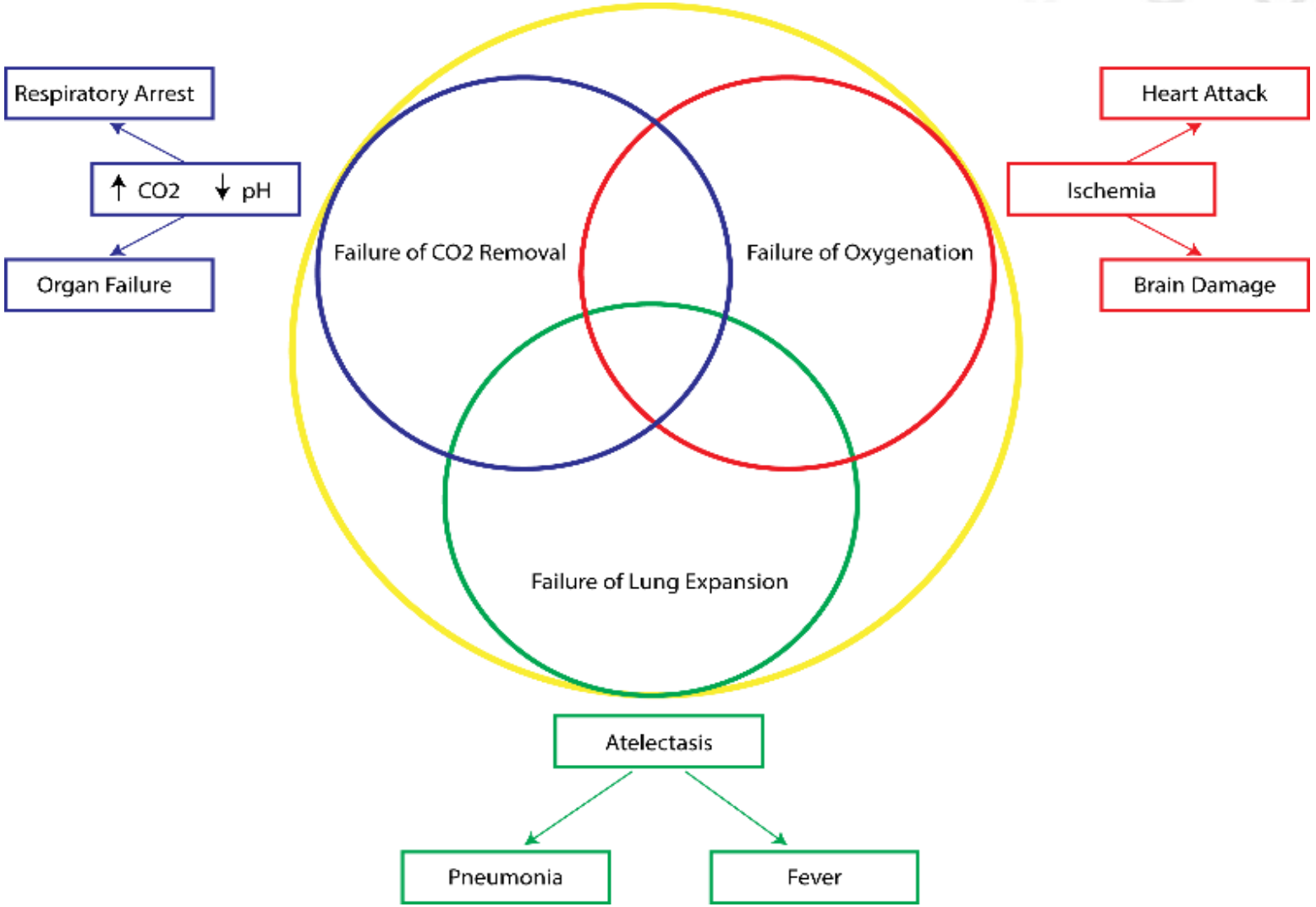
- ✗ Unknown air exchange
- ✗ Limits control of sedation / pain mgt
- ✗ Subjective patient assessment and ventilation ability
- ✗ Unknown response to therapy

MV changes provide **Earliest Warning**

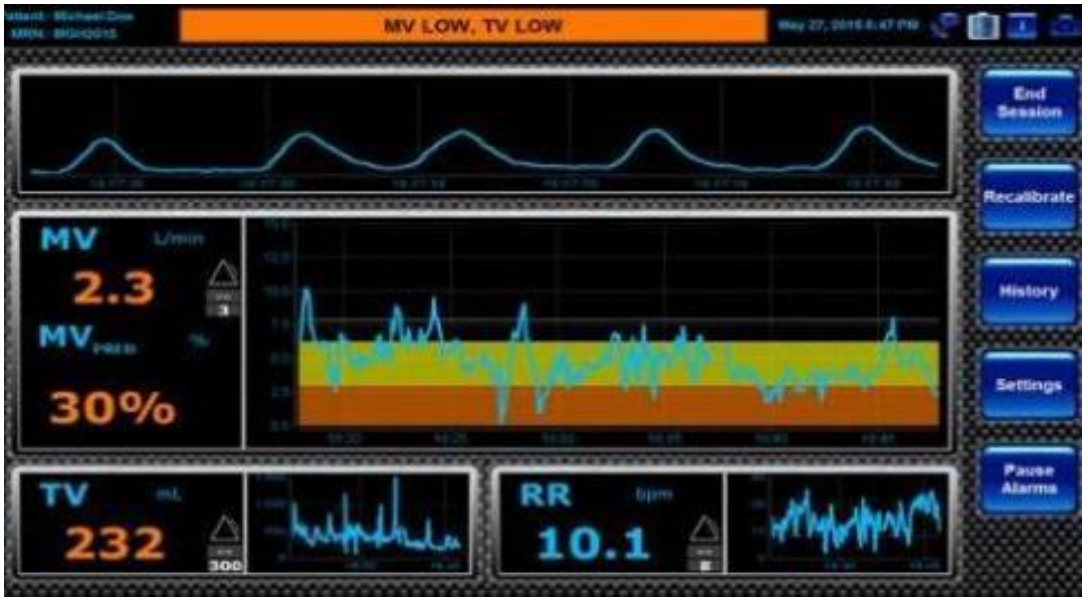


Modified from *Lynn and Curry, Patient Safety in Surgery, 2011*

Respiratory Failure: More than Hypoxia



- Non-invasive Minute Ventilation
- Tidal Volume
- Respiratory Rate
- Nurse Call signals the clinician



MV 30%

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

Normal!

O_2 Sat: 98%

$EtCO_2$: N/A

RR: 10

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Journal of Trauma and Acute Care Surgery:
November 2016 - Volume 81 - Issue 5 - p S162–S170

ORIGINAL ARTICLE

Evaluation of respiratory volume monitoring (RVM) to detect respiratory compromise in advance of pulse oximetry and help minimize false desaturation alarms

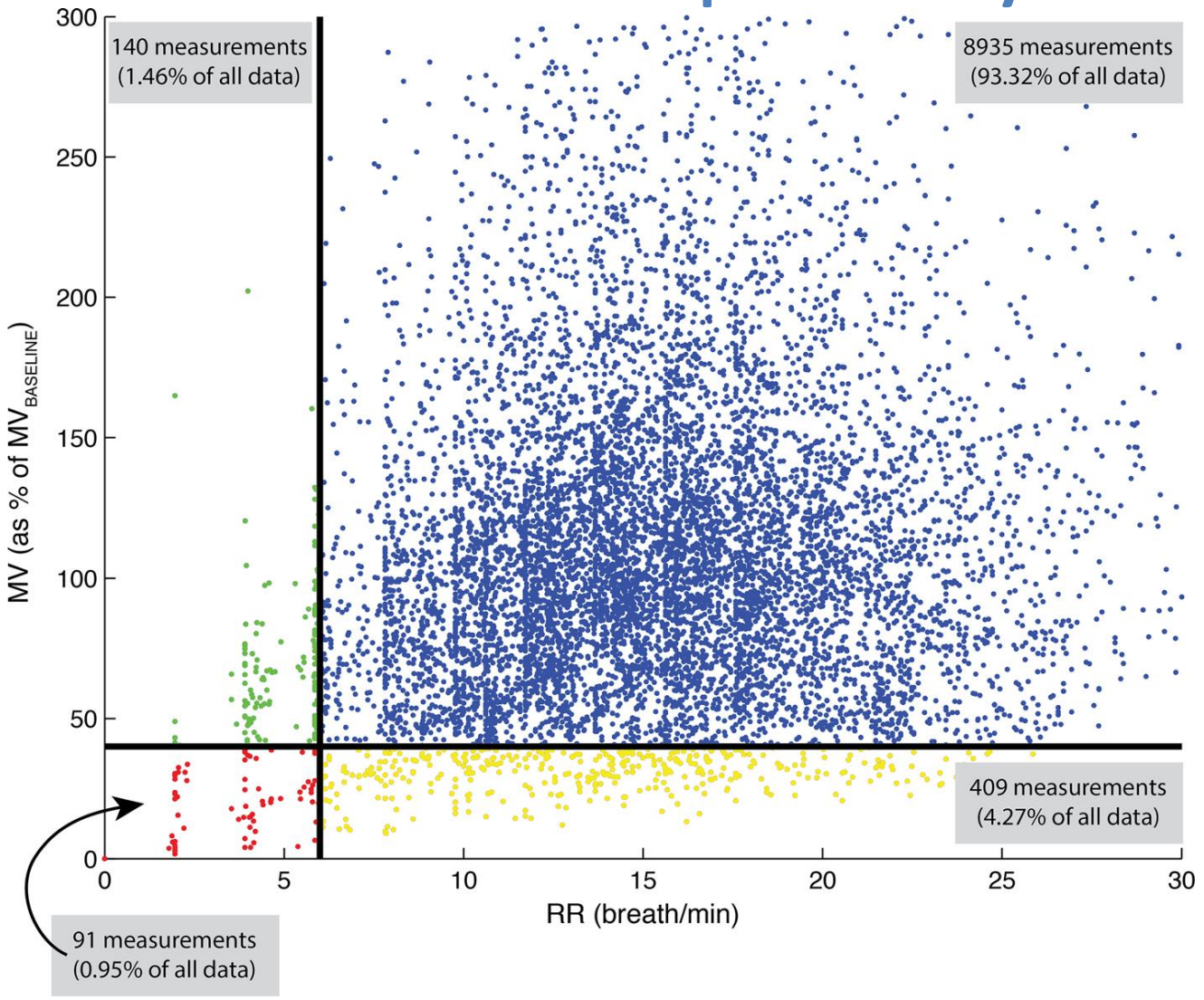
Samuel M. Galvagno, Jr, DO, PhD, Peggy G. Duke, MD, Daniel S. Eversole, PhD, *and* **Edward E. George, MD, PhD**, *Waltham, Massachusetts*

	No Pt [%]	LMV in PACU	Recorded SpO_2 Alarms: Transient (1-min)	Hypoxemic events (≥2min)			Opioids: No. Pt [%]	Dosage	Frequency	PACU LOS
		[#/hr]		False	True	RN Records		[μg/kg/hr]	[Doses/hr]	[hr]
With Low MV:	198 [76%]	2.3 ±0.1	58	10	7	1	133 [67%]	40 ±3	2.0 ±0.1	2.8 ±0.1
No Low MV:	61 [24%]	0	29	9	0	1	33 [53%]	33 ±4	2.3 ±0.2	2.4 ±0.1
Total:	259 [100%]	1.8 ±0.1	87	19	7	2	166 [64%]	39 ±2	2.1 ±0.1	2.7 ±0.1

- ***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***

Minute Ventilation vs Respiratory Rate

- 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



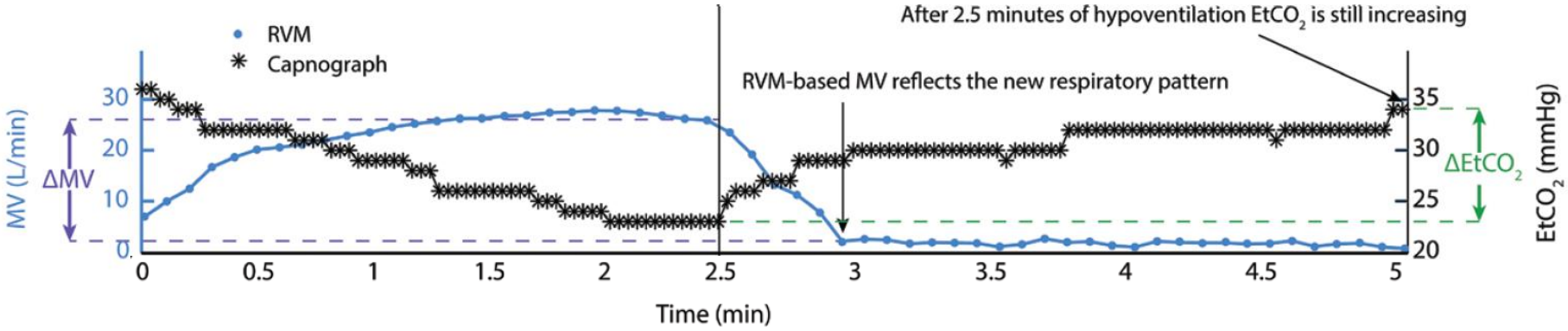
MV indicates respiratory performance; RR not an adequate proxy.

Holley K, MacNabb M, Georgiadis P, Minasyan H, Shukla A, Mathews D. Monitoring minute ventilation versus respiratory rate to measure the adequacy of ventilation in patients undergoing upper endoscopic procedures. J Clin Monitor Comp 2015

Anesthesia & Analgesia:
January 2017 - Volume 124 - Issue 1 - p 120–126

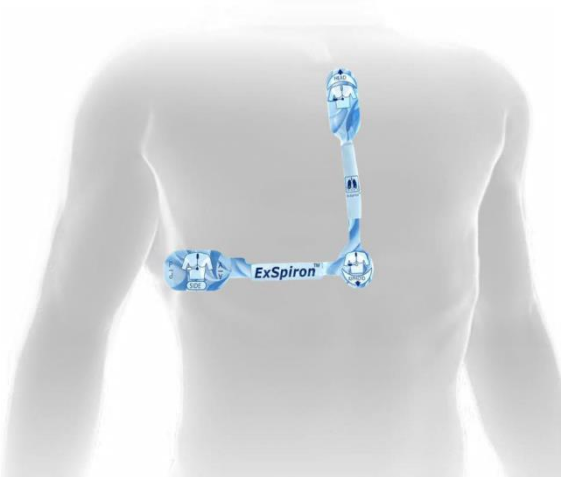
A Comparison of Measurements of Change in Respiratory Status in Spontaneously Breathing Volunteers by the ExSpiron Noninvasive Respiratory Volume Monitor Versus the Capnostream Capnometer

Williams, George W. II MD; George, Christy A. MD; Harvey, Brian C. PhD; Freeman, Jenny E. MD



- ***Changes in ventilation were reflected by the RVM in 37.7s, while $ETCO_2$ 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 $ETCO_2$ via nasal cannula (33.7 mmHg to 36.8 mmHg)***

ExSpiron utility in multiple environments

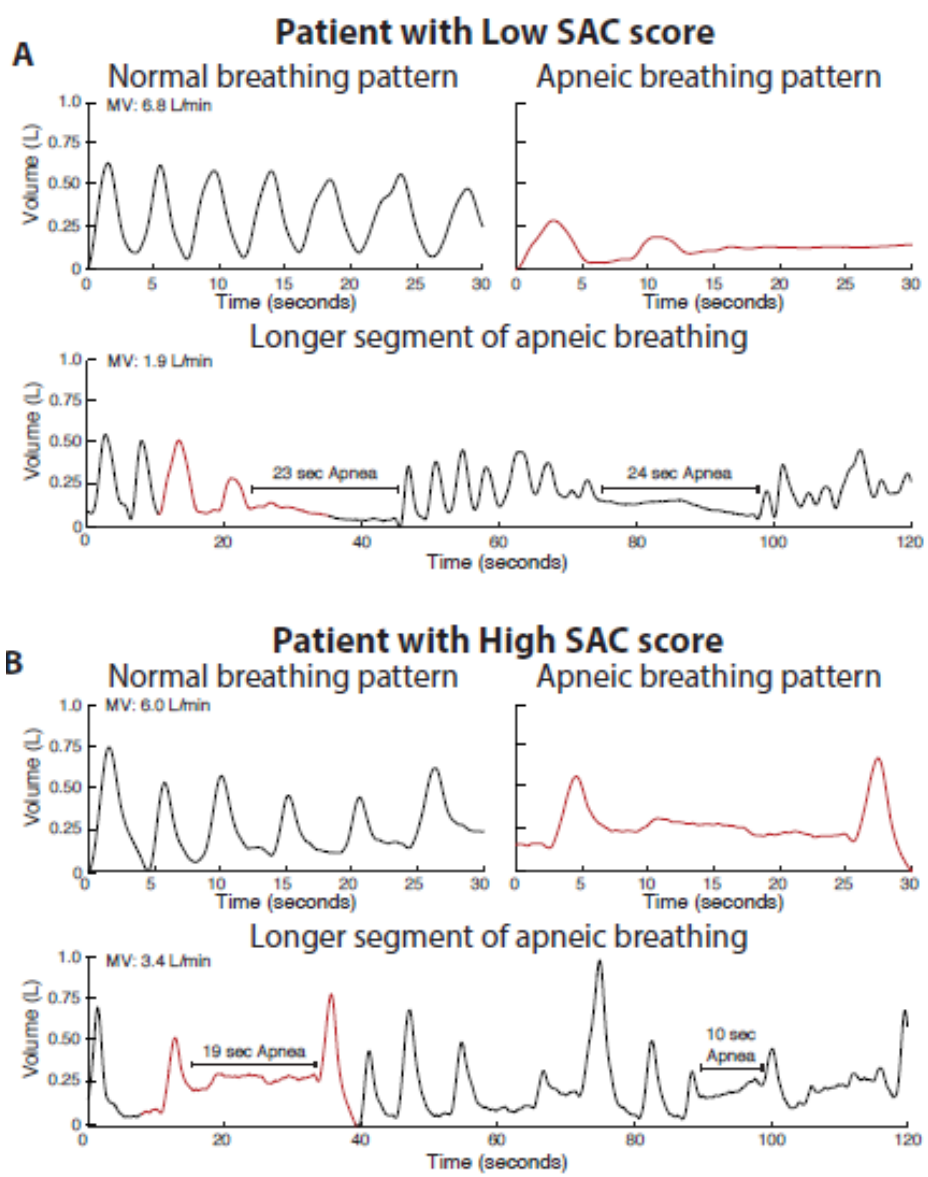


- Critical Care
- Post-Anesthesia Care Unit
- OR / Monitored Anesthesia Care
- Transport
- Procedural Sedation
- General Hospital Floor
- Surgery Centers and Remote Sites

MAYO CLINIC

Using Non-Invasive Respiratory Volume Monitoring in the Post-Anesthesia Care Unit to Monitor Post-Operative Respiratory Depression in Patients Identified as At-Risk for Obstructive Sleep Apnea Utilizing the Flemon's Criteria

Martin YN, M.D., Ph.D.[1], Cavalcante A, M.D.[1], Eversole D, Ph.D.[2], Sprung J, M.D.[1], Freeman J, M.D.[2], Weingarten T, M.D.[1]
[1]Department of Anesthesiology, Mayo Clinic, Rochester, MN, [2]Respiratory Motion, Inc., Waltham, MA



IARS 2016

- ***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).***

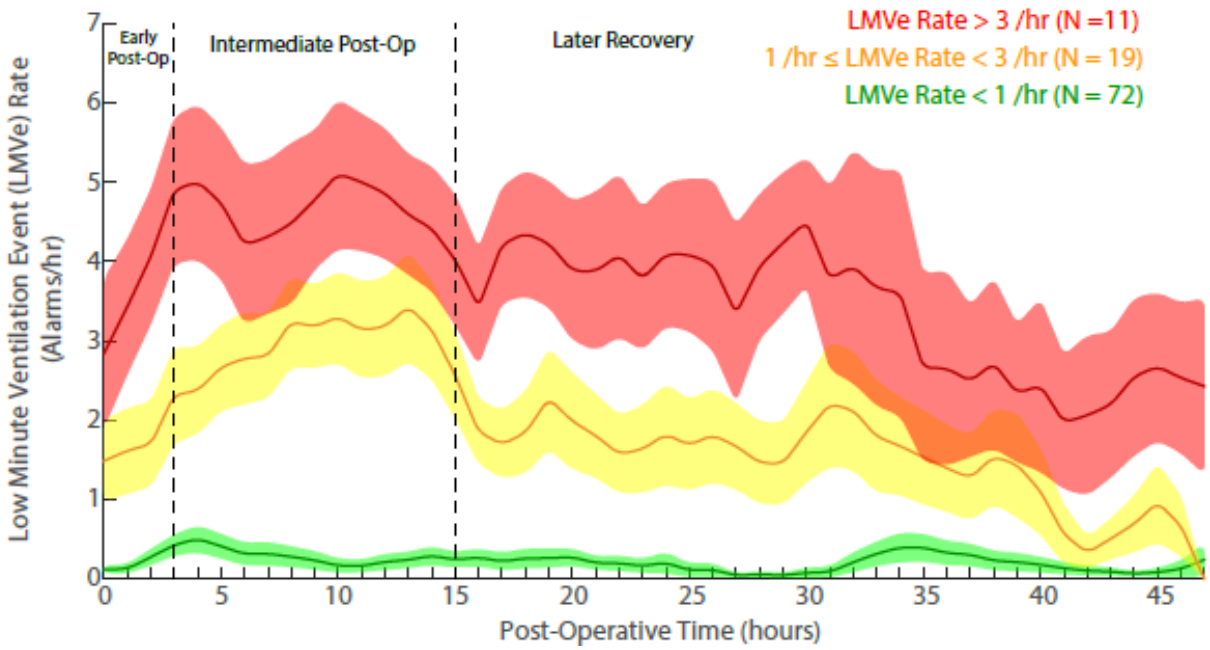
FREQUENCY OF LOW MINUTE VENTILATION EVENTS AS INDICATION OF POST-OPERATIVE RESPIRATORY DEPRESSION

Wael Saasouh[1], Brian Harvey[2], Alparslan Turan[1]
[1]Outcomes Research, Anesthesiology Institute, Cleveland Clinic Foundation, Cleveland, OH [2]Respiratory Motion, Inc., Waltham, MA

Cleveland Clinic

- ***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***

ASA 2016



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Non-Invasive Assessment of Low Minute Ventilation in the Post-Anesthesia Care Unit and General Hospital Floor

Iwona Bonney[1], Jordan Brayanov[2], Tiffany Otero[1], Sophie Dean[1], Farhad Zahedi[1], Roman Schumann[1]

[1]Anesthesiology, Tufts Medical Center, Boston, MA, [2]Respiratory Motion, Inc., Waltham, MA

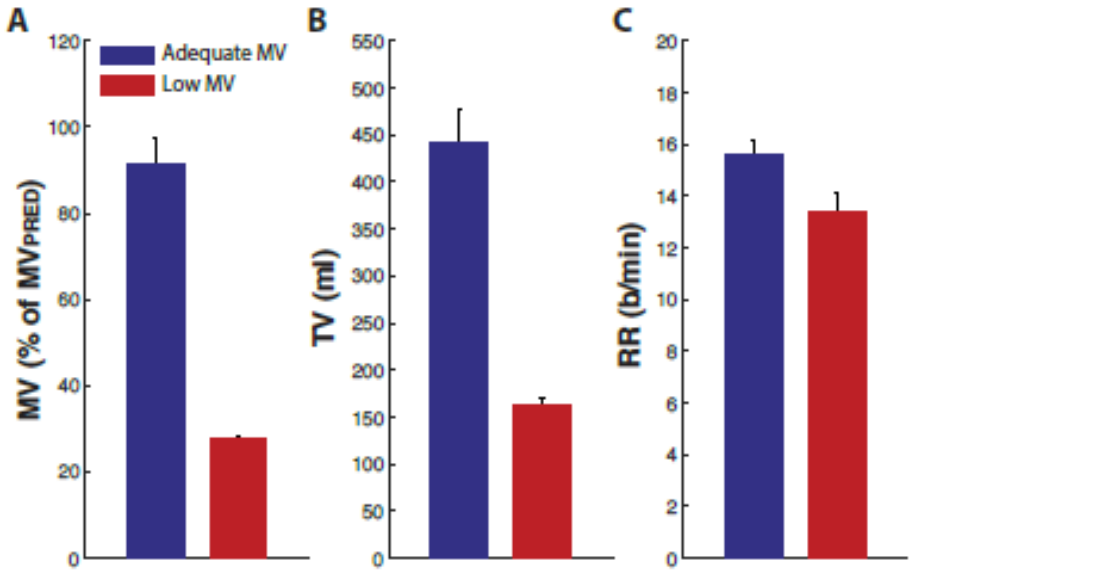
Tufts Medical Center

ASA 2016

- ***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***

Group	Low SB	High SB	P-value
OSA Risk	Low	Moderate/Severe	
Number of Patients	24	11	
STOP-BANG (SD)	2.2 (1.5)	5.4 (0.7)	< 0.0001
Height, cm (SD)	163 (10)	166 (9)	0.43
Weight, kg (SD)	80 (16)	106 (26)	0.0006
BMI, kg/m^2 (SD)	30.0 (6.1)	38.5 (9.0)	0.002
Length of Monitoring, hr, (SD)	18.9 (2.4)	17.1 (2.4)	0.045
Average Percent MV_{PRED} (SEM)	87.1 (6.7)	94.3 (14.5)	0.61
Mean Time Between LMVe, hr*	1.1	2.6	< 0.0001
Mean LMVe Duration (min)*	3.1	2.9	0.37

Changes in RVM measurements during "Low MV" episodes



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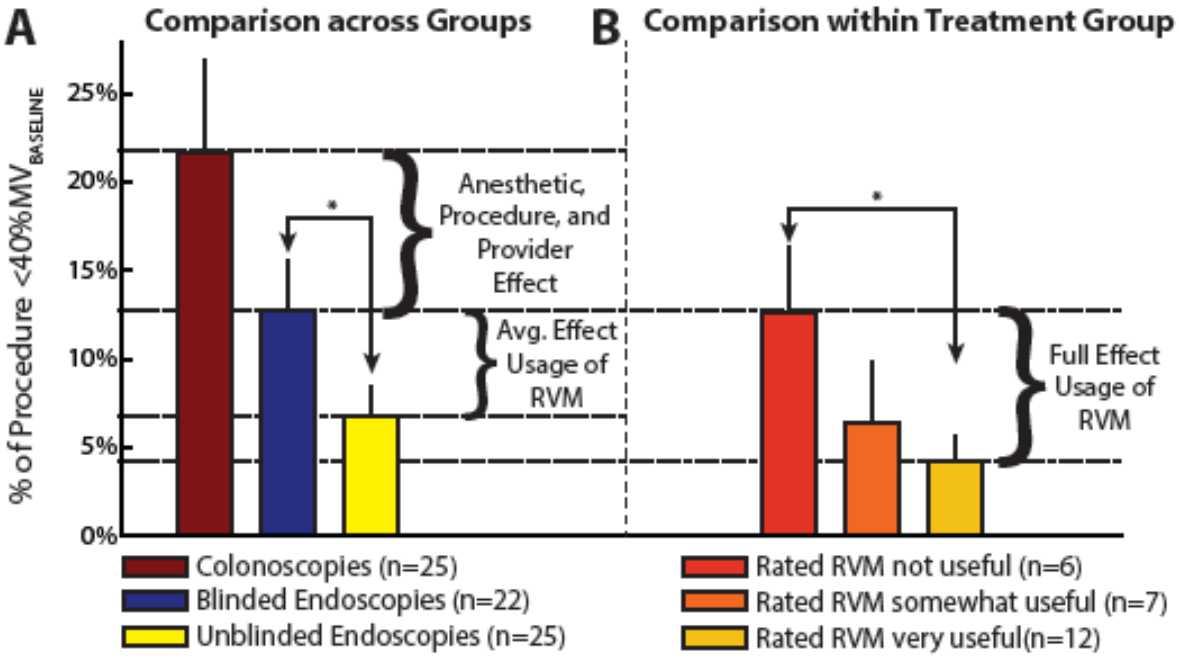
Respiratory Volume Monitoring Could Improve Safety in Procedural Sedation

Donald Mathews MD[1], Michael Oberding MD[1], Eric Simmons MD[1], Karl Kristiansen MD[1], Stephen O'Donnell MD[1], Kevin Abnet MD[1]

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

The University of Vermont College of Medicine

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***

Measurement of RSBI in Non-Intubated Patients Using Respiratory Volume Monitoring

Juan Ripoll, MD[1], Sarah Robison MD[1], Jordan Brayanov PhD[2], Jenny Freeman MD[2], Jose Diaz-Gomez MD[1], John Moss MD[1]

[1]Mayo Clinic, Jacksonville, FL, [2]Respiratory Motion, Inc., Waltham, MA

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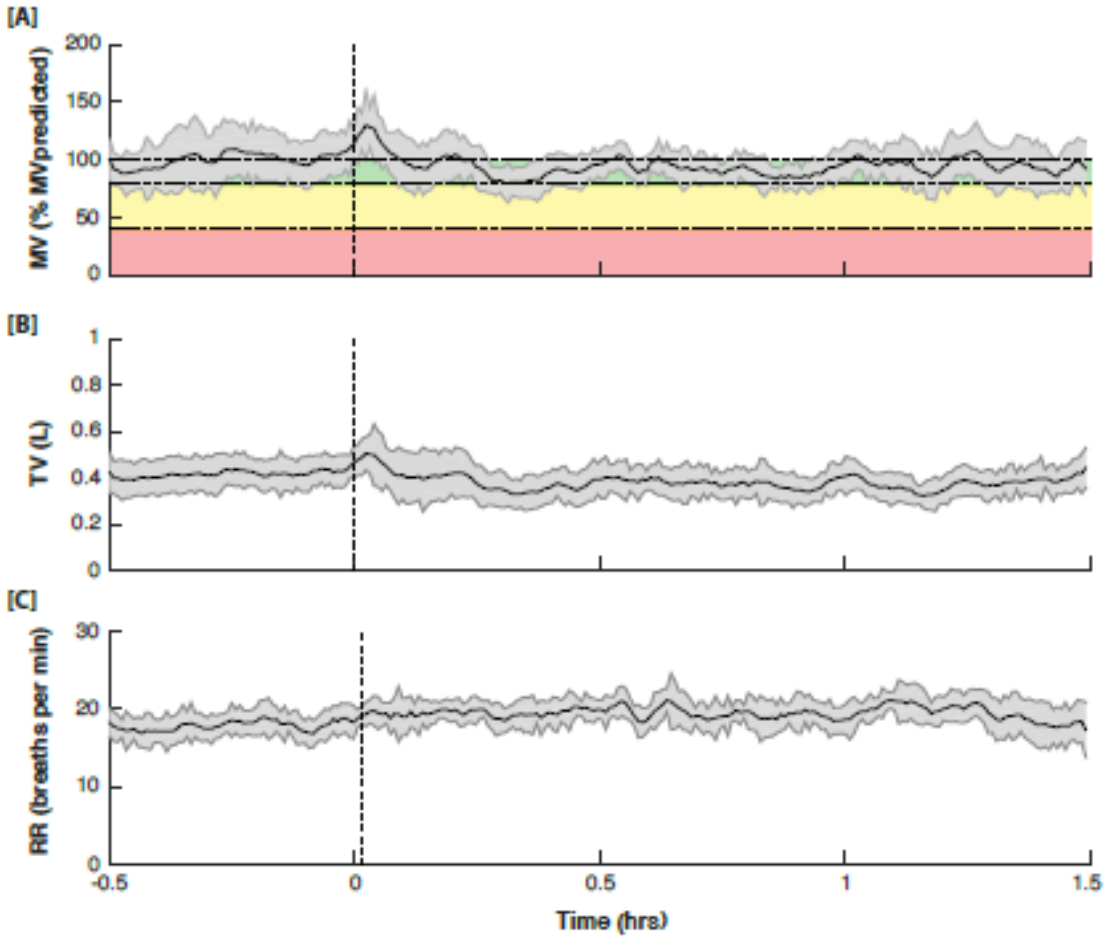
MHSRS 2016



- *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*

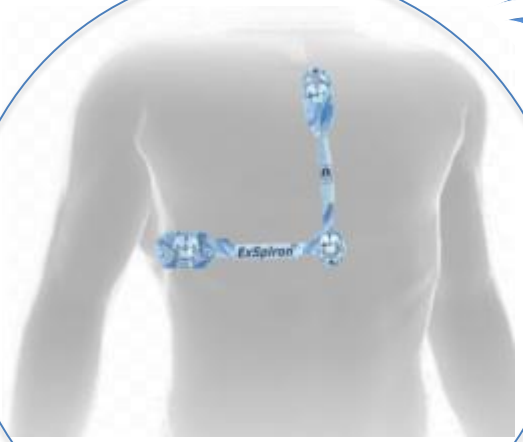
Redefining Respiratory Management

Nurse Call

Central Monitoring

EMR

Non-Invasive Ventilation



Transport

High Flow Therapy

PCA

Multimodal Therapeutics (pain, pulmonary)

Transition from Invasive Ventilation

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