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Changing lives
with every breath

Advanced PAP Therapy: Advanced Algorithms

Gary Hamilton, BS, RRT
Clinical Specialist
ResMed Corp

Declarations/ Conflicts of Interest

- Am presently employed by ResMed Corp
- Presently own stock in ResMed Corp

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Course Objectives

By the end of this session, you should be able to:

- Know when a CPAP may not be the device of choice
- Recognize different uses of Bilevel and the different disease states it is applicable to
- Know when servo ventilation is a viable option
  - What diagnoses are appropriate
  - How the device actually improves the patient
- Know when Volume Assured Pressure Support (VAPs) therapy is appropriate

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CPAP Intolerance

Why patients fail CPAP:

- CPAP is uncomfortable
- Patient may feel CPAP is uncomfortable at higher pressures despite pressure relief features
- COPD patients have trapped air/pressure in their lungs, which may increase their work of breathing
- Patient may need higher levels of ventilatory support that CPAP cannot provide

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Not Just an Airway Problem

• OSA	• Airway problem
• COPD	• Ventilation problem
• Neuromuscular	• Ventilation problem
• Cheyne-Stokes	• Ventilation problem
• TECSA	• Airway and Ventilation problem

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Qualification Criteria

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Medicare Policy for Treatment of OSA

(CMS Revision Effective Date: 7/1/2016)

CPAP Qualifications (E0601)

Patient must meet **all** the following criteria to qualify for an E0601 device **(CPAP)**

- ☐ Patient has had a **face-to-face clinical evaluation** by treating physician prior to sleep test. See back for additional information.[1]
- ☐ Patient has had a **Medicare-covered sleep test** that meets either of the following criteria:[2]
  - a. AHI/RDI[3] is ≥ 15 events per hour with a minimum of 30 events; **or**,
  - b. AHI/RDI is ≥ 5 and ≤ 14 events per hour with a minimum of 10 events and documentation of excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, hypertension, ischemic heart disease or history of stroke. See back for additional information.
- ☐ Diagnosed with obstructive sleep apnea (OSA) (ICD-9 code 372.23 or ICD-10 code G47.33)
- ☐ **Patient and/or caregiver has received instruction** from the supplier of the CPAP device and accessories in the proper use and care of the equipment.

Bilevel Qualifications (E0470)

(Follow for CPAP to bilevel conversion)

Patient must meet **all** the following criteria to qualify for an E0470 device **(bilevel without a backup rate)**

- ☐ Patient is **qualified for E0601 (CPAP)**
- ☐ **Treating physician documented that both of the following issues were addressed** prior to changing a patient from an E0601 to an E0470 device due to ineffective therapy:
  - a. An appropriate interface has been properly fitted and the beneficiary is using it without difficulty. The properly fitted interface will be used with the E0470 device; **and**
  - b. The current pressure setting of the E0601 prevents the beneficiary from tolerating the therapy, and lower pressure settings of the E0601 were tried but failed to:
    1. Adequately control the symptoms of OSA; **or**
    2. Improve sleep quality; **or**
    3. Reduce the AHI/RDI to acceptable levels.

☐ Yes ☐ No **Has CPAP been used < 3 months?** (i.e. CPAP was tried and found ineffective during the initial 3-month home trial)

If "No," a new initial face-to-face clinical evaluation is required, but not a new sleep test. A new 3-month trial would begin for use of the bilevel. See back for additional information.

If "Yes," the patient is qualified for an E0470 device (bilevel without a backup rate, such as the AirCurve™ 10 VAutol. See back for additional information.

Documentation for Continued Coverage[4]

(For continuing to bill months 4–13)

- ☐ Between the 31st and 91st day, treating physician has a face-to-face clinical re-evaluation with patient documenting that symptoms of OSA improved.
- ☐ Objective evidence of adherence to use of the positive airway pressure (PAP) device reviewed by treating physician. (Adherence is defined as use of PAP ≥ 4 hours per night on 70% of nights during a consecutive 30-day period anytime during the first 3 months of initial usage.)

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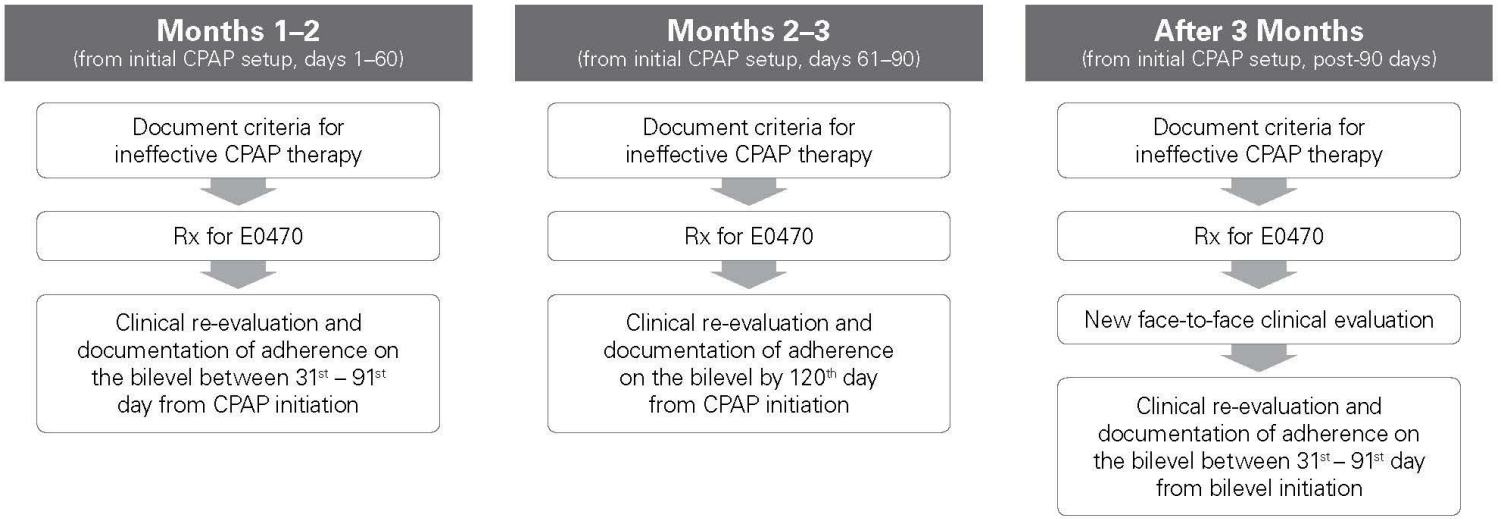
Qualification Criteria

Bilevel Conversion Pathways



1 **Face-to-face clinical evaluation** may include sleep history and symptoms of OSA, Epworth Sleepiness Scale and physical exam documenting body mass index, neck circumference and a focused cardiopulmonary and upper airway evaluation. Some of these elements, in addition to other details, must be documented in patient charts. Each element would not have to be addressed in every evaluation.

2 **Medicare-covered sleep tests** include Type I, Type II, Type III and Type IV (must monitor and record a minimum of three (3) channels). All sleep tests must be interpreted by a physician who holds either: current certification in sleep medicine by the American Board of Sleep Medicine (ABSM); or, current subspecialty certification in sleep medicine by a member board of the American Board of Medical Specialties (ABMS); or, completed residency or fellowship training by an ABMS member board and has completed all the requirements for subspecialty certification in sleep medicine except the examination itself and only until the time of reporting of the first examination for which the physician is eligible; or, active staff membership of a sleep center or laboratory accredited by the American Academy of Sleep Medicine (AASM), Accreditation Commission for Health Care (ACHC) or The Joint Commission (TJC, formerly the Joint Commission on Accreditation of Healthcare Organizations – JCAHO).

3 **AHI** is defined as the average number of episodes of apnea and hypopnea per hour of sleep.
RDI is defined as the average number of apneas plus hypopneas per hour of recording.

4 **If the patient fails the 12-week trial:**
Beneficiaries requalify for a positive airway pressure device with both:

- Face-to-face clinical re-evaluation by treating physician to determine etiology of failure to respond to positive airway pressure therapy; and
- Repeat sleep test in a facility-based setting (Type 1 study).

This information is provided as of the date listed and all coding and reimbursement information is subject to change without notice. It is the provider's responsibility to verify coding and coverage with payors directly. For a full description of the policy go to www.cms.hhs.gov. To contact the ResMed reimbursement hotline, dial 1-800-424-0737

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RAD Guidelines

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Respiratory Assist Device (RAD) Qualifying Guidelines

CMS revision effective date: January 2017

I. Restrictive Thoracic Disorders

Documentation of neuromuscular disease or severe thoracic cage abnormality in the patient's medical record

→

Perform one of the following:

- **ABGs** (done while awake and on prescribed FiO_2) $PaCO_2 \geq 45$ mm Hg or
- **Sleep oximetry**
  Oxygen saturation ≤ 88% for ≥ 5 minutes, minimum 2 hours of recording time (on patient's prescribed FiO_2) or
- **For neuromuscular disease only:**
  Either FVC < 50% of predicted or MIP < 60 cm H_2O

→

COPD does not contribute significantly to pulmonary limitation

→

(E0470) or (E0471)
Based on the treating physician's judgment

II. COPD

ABGs (done while awake and on prescribed FiO_2) $PaCO_2 \geq 52$ mm Hg

→

Sleep oximetry
Oxygen saturation ≤ 88% for ≥ a cumulative 5 minutes, minimum 2 hours nocturnal recording time (on 2 L/min O_2 or patient's prescribed FiO_2, whichever is higher)

→

OSA and CPAP treatment has been considered and ruled out (formal sleep testing is not required if medical record demonstrates sleep apnea is not predominate cause of awake hypercapnia or nocturnal arterial oxygen desaturation)

→

(E0470)

For COPD patients to qualify for a RAD with backup rate (E0471):

Situation 1 After period of initial use of an E0470; **ABG** (done while awake and on prescribed FiO_2) shows $PaCO_2$ worsens ≥ 7 mm Hg compared to original ABG result; **facility-based PSG** demonstrates oxygen saturation ≤ 88% for ≥ a cumulative 5 minutes, minimum 2 hours nocturnal recording time while on an E0470 and not caused by obstructive upper airway events (ie, AHI < 5).

Situation 2 No sooner than 61 days after initial issue of E0470; **ABG** (done while awake and on prescribed FiO_2) shows $PaCO_2$ ≥ 52 mm Hg; **Sleep oximetry** on an E0470 demonstrates oxygen saturation ≤ 88% for ≥ a cumulative 5 minutes, minimum 2 hours nocturnal recording time (on 2 L/min O_2 or patient's prescribed FiO_2, whichever is higher).

Respiratory Assist Device (RAD) Documentation Requirements for Continued Coverage Beyond First 3 Months

Patients on an E0470 or E0471 device must be reevaluated no sooner than 61 days after initiating therapy.

Required Documentation

- Progress of relevant symptoms
- Signed and dated statement by treating physician declaring patient using average 4 hours per 24-hour period and patient benefiting from use

ResMed E0470 and E0471 Devices

E0470–Bilevel without a backup rate:

- AirCurve™ 10 VAuto
- AirCurve™ 10 S
- VPAP™ COPD

E0471–Bilevel with a backup rate:

- AirCurve 10 ST
- AirCurve 10 ASV
- VPAP ST-A
- Stellar™*

* For invasive use, code E0472

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RAD Guidelines

III. Central Sleep Apnea or Complex Sleep Apnea

Complete facility-based attended PSG documents the following → **Diagnosis of central sleep apnea or complex sleep apnea** (see definition below) → Improvement of sleep-associated hypoventilation with the use of an E0470 or E0471 device on settings that will be prescribed for initial use at home (on patient's prescribed FiO2). → **(E0470) or (E0471)** Based on the treating physician's judgment

IV. Hypoventilation

ABGs (done while awake and on prescribed FiO_2) $PaCO_2$ ≥ 45 mm Hg → **Spirometry** FEV1/FVC ≥ 70%
Refer to SEVERE COPD category for information about device coverage for patients with FEV1/FVC <70% →
- **ABGs** (done during sleep or immediately upon awakening on prescribed FiO2 show) $PaCO_2$ worsened ≥ 7 mm Hg compared to original ABG or
- **PSG or HST** demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes, minimum 2 hours nocturnal recording time not caused by obstructive upper airway events (ie, AHI < 5)

→ **(E0470)**

Covered E0470 is being used → **Spirometry** FEV1/FVC ≥ 70%
Refer to SEVERE COPD category for information about device coverage for patients with FEV1/FVC <70% →
- **ABGs** (done while awake and on prescribed FiO_2) $PaCO_2$ worsens ≥ 7 mm Hg compared to ABG result used to qualify for E0470 or
- **PSG or HST** demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes, minimum 2 hours nocturnal recording time, and not caused by obstructive upper airway events (ie, AHI < 5 while on E0470)

→ **(E0471)**

A diagnosis of **central sleep apnea (CSA)** requires all of the following:

1. An apnea–hypopnea index ≥ 5; and
2. Sum total of central apneas plus central hypopneas > 50% of the total apneas and hypopneas; and
3. CAHI* ≥ 5 per hour; and
4. Presence of either sleepiness, difficulty initiating or maintaining sleep, frequent awakenings, or non restorative sleep, awakening short of breath, snoring, or witnessed apneas; and
5. No evidence of daytime or nocturnal hypoventilation

Complex sleep apnea (CompSA) is a form of central apnea identified by all of the following:

1. PSG demonstrates the persistence or emergence of central apneas or central hypopneas upon exposure to CPAP or an E0470 device when titrated to the point where obstructive events have been effectively treated (AHI < 5 per hour); and
2. After resolution of the obstructive events, the sum total of central apneas plus central hypopneas is > 50% of the total apneas plus hypopneas; and
3. After resolution of the obstructive events, CAHI** ≥ 5 per hour

Note: Not all types of HST are appropriate for the evaluation of CSA or CompSA as necessary parameters are not monitored.
*For CSA diagnosis, central apnea–central hypopnea index (CAHI) is defined as the average number of episodes of central apnea and central hypopnea per hour of sleep without the use of a PAP device.
**For CompSA, the CAHI is determined during the use of a PAP device after obstructive events have disappeared.

Ventilator with Non-Invasive Interfaces: Please reference ResMed's Ventilator Reimbursement Fast Facts: PN 1017230.

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ResMed reimbursement hotline, dial **1-800-424-0737**.

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How Does Bilevel Work?

- Prevents nocturnal hypoventilation and hypoxia
  - Cardiovascular consequences
- Improves ventilation (gas exchange)
  - Reduces nocturnal CO_2 levels

Comfort & Compliance

- Decreases daytime sleepiness by correcting sleep architecture
  - Reduces arousals due to SDB and associated sleep fragmentation

*. Antonescu-Turcu A & Parthasarathy S. *Respir Care* 2010

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EPAP, IPAP and PS

IPAP

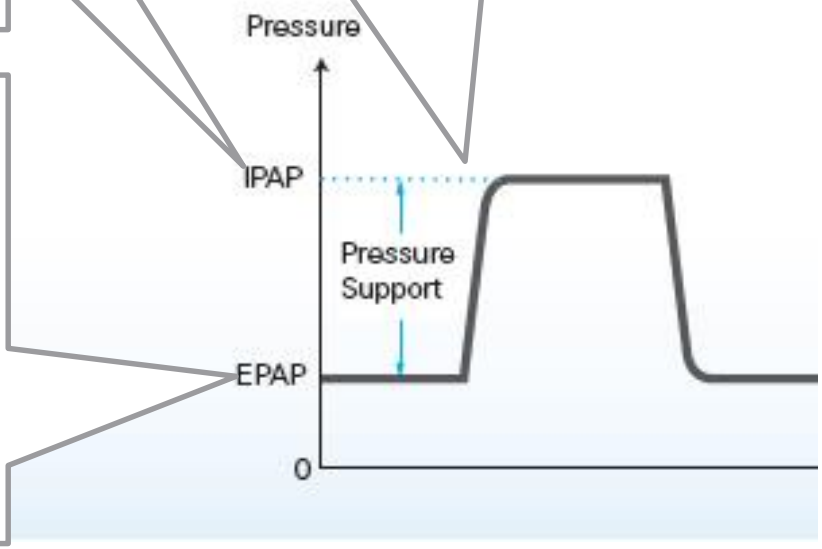
- Achieve adequate tidal volume
- Get the respiratory rate (RR) below 25 bpm
- Decrease the work of breathing
- Reduce $PaCO_2$
- IPAP = EPAP + PS

EPAP

- Overcome obstructive apneas and hypopneas
- Improve oxygenation

Pressure Support (PS)

- PS = IPAP - EPAP
- The greater the PS the greater the ventilatory support
- Care must be taken not to over-ventilate



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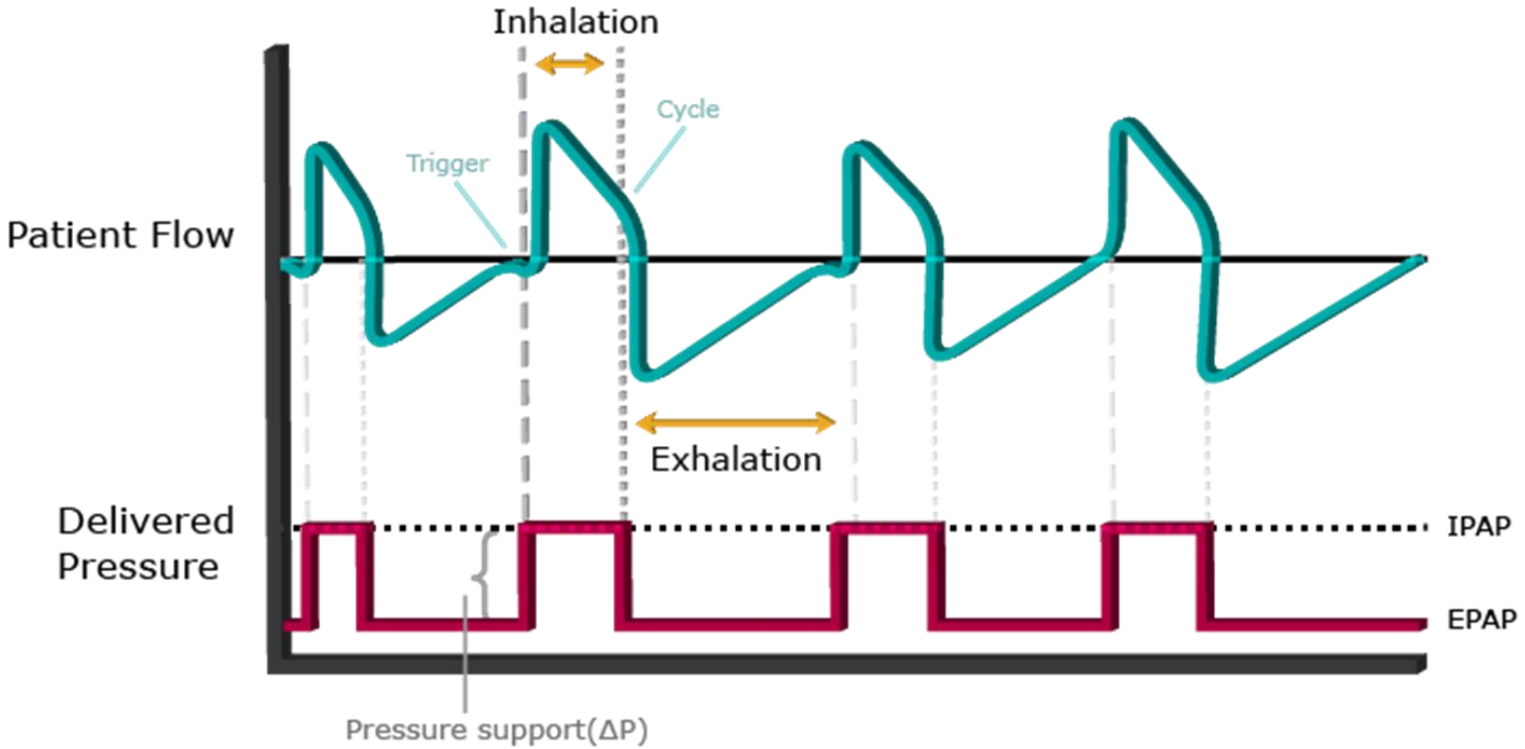
Bilevel Therapy

Bilevel positive airway pressure, commonly referred to by the trademarked names BiPAP, is a form of NIV (Non invasive Ventilation) that uses a time-cycled or flow-cycled change between two different applied levels of positive airway pressure (IPAP and EPAP)*



* Kushida CA et al. *J Clin Sleep Med* 2008

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Consider Using Bilevel When…

- Patient is not tolerating **high pressure** settings[1]
- Events persist at 15 cm H_2O[2]
- Patient complains of **not being able to exhale** despite expiratory pressure relief (EPR™) feature[1]
- Patient has history of **ventilatory insufficiency** such as chronic obstructive pulmonary disease (COPD), restrictive lung disease, or obesity hypoventilation syndrome (OHS)[1]
- Must be a 4 cm H_2O difference between IPAP and EPAP to be considered bilevel therapy[2]

1. Gay P et al. *Sleep* 2006
2. Kushida CA et al. *J Clin Sleep Med* 2008

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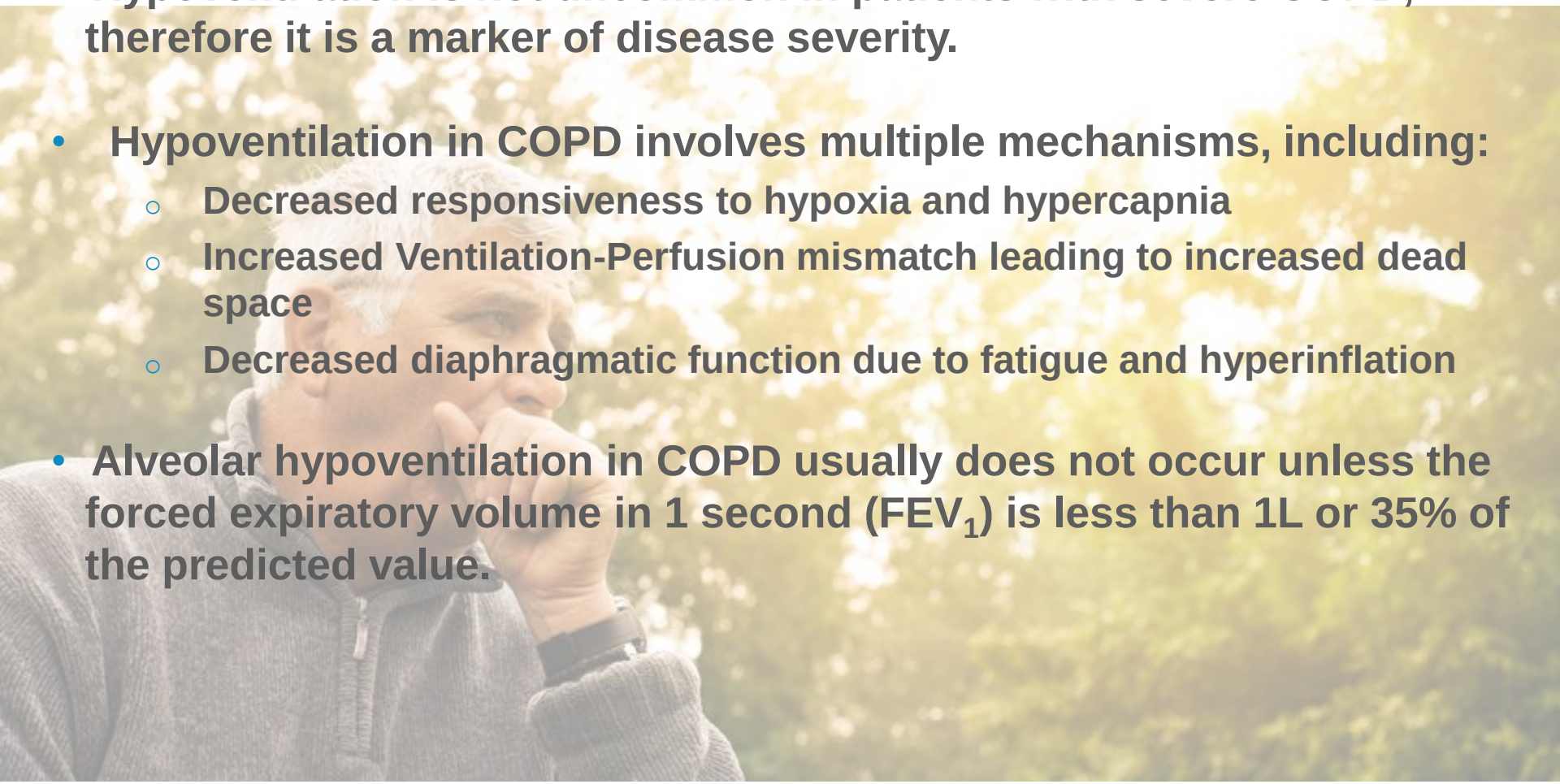
Hypoventilation in COPD Patients

Hypoventilation & COPD



- **Hypoventilation is not uncommon in patients with severe COPD, therefore it is a marker of disease severity.**
- **Hypoventilation in COPD involves multiple mechanisms, including:**
  - **Decreased responsiveness to hypoxia and hypercapnia**
  - **Increased Ventilation-Perfusion mismatch leading to increased dead space**
  - **Decreased diaphragmatic function due to fatigue and hyperinflation**
- **Alveolar hypoventilation in COPD usually does not occur unless the forced expiratory volume in 1 second (FEV_1) is less than 1L or 35% of the predicted value.**

Gold Report 2017

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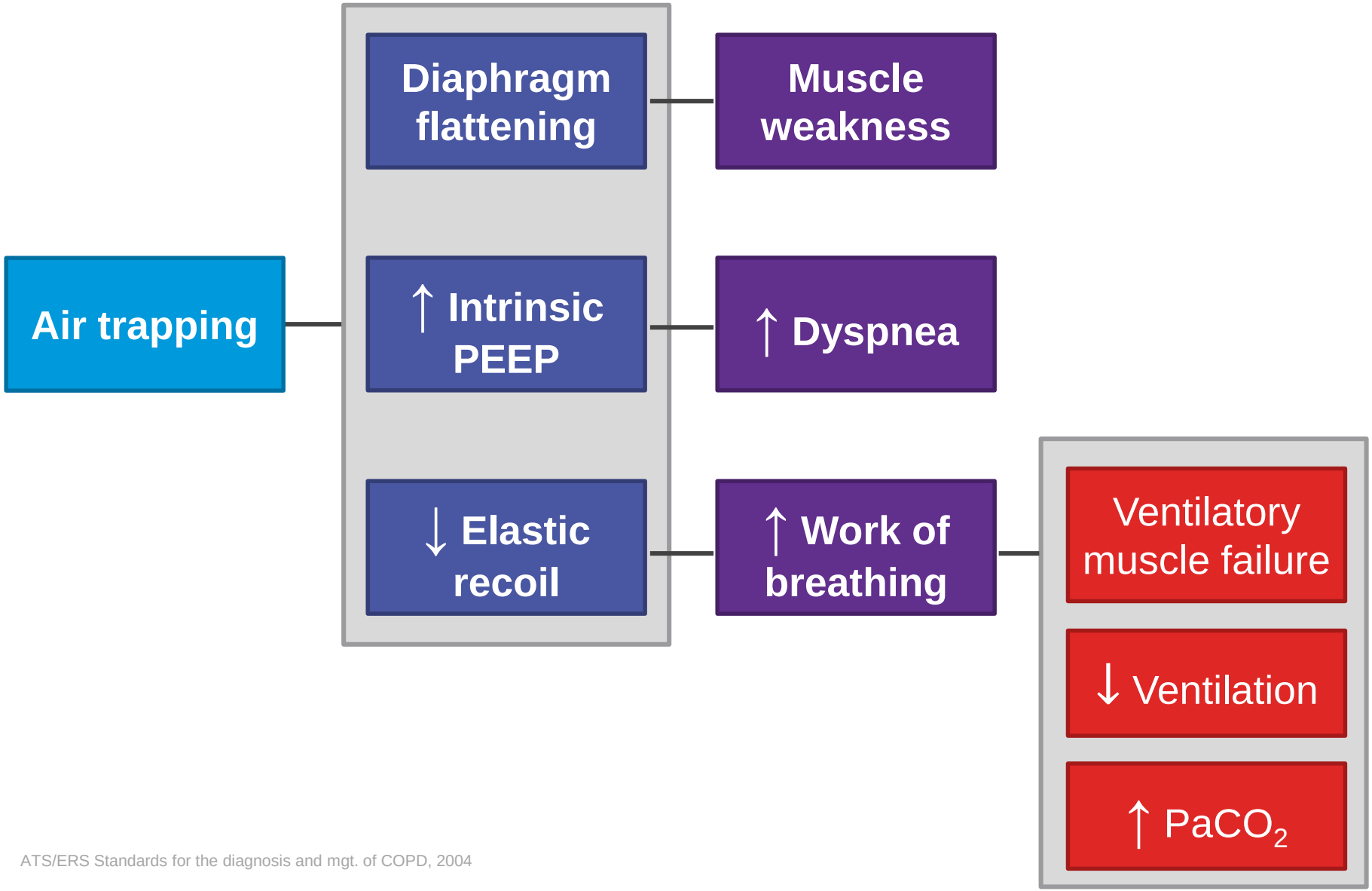
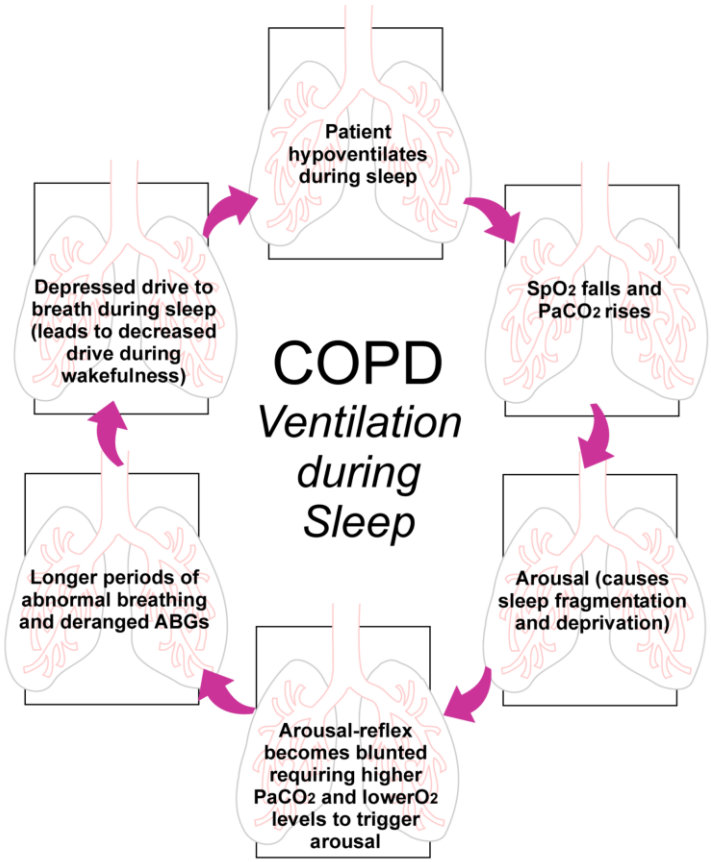
Pathophysiology of COPD



ATS/ERS Standards for the diagnosis and mgt. of COPD, 2004

Effects of Nocturnal Ventilation in COPD

- Typical sleep-related desaturations
  - Due to nocturnal hypoventilation or central apneas
  - Not associated with obstructive apneas
- Greater decrease in alveolar ventilation leading to poor gas exchange and hypoventilation (patients with impaired lung function)
- Worsening daytime blood gases



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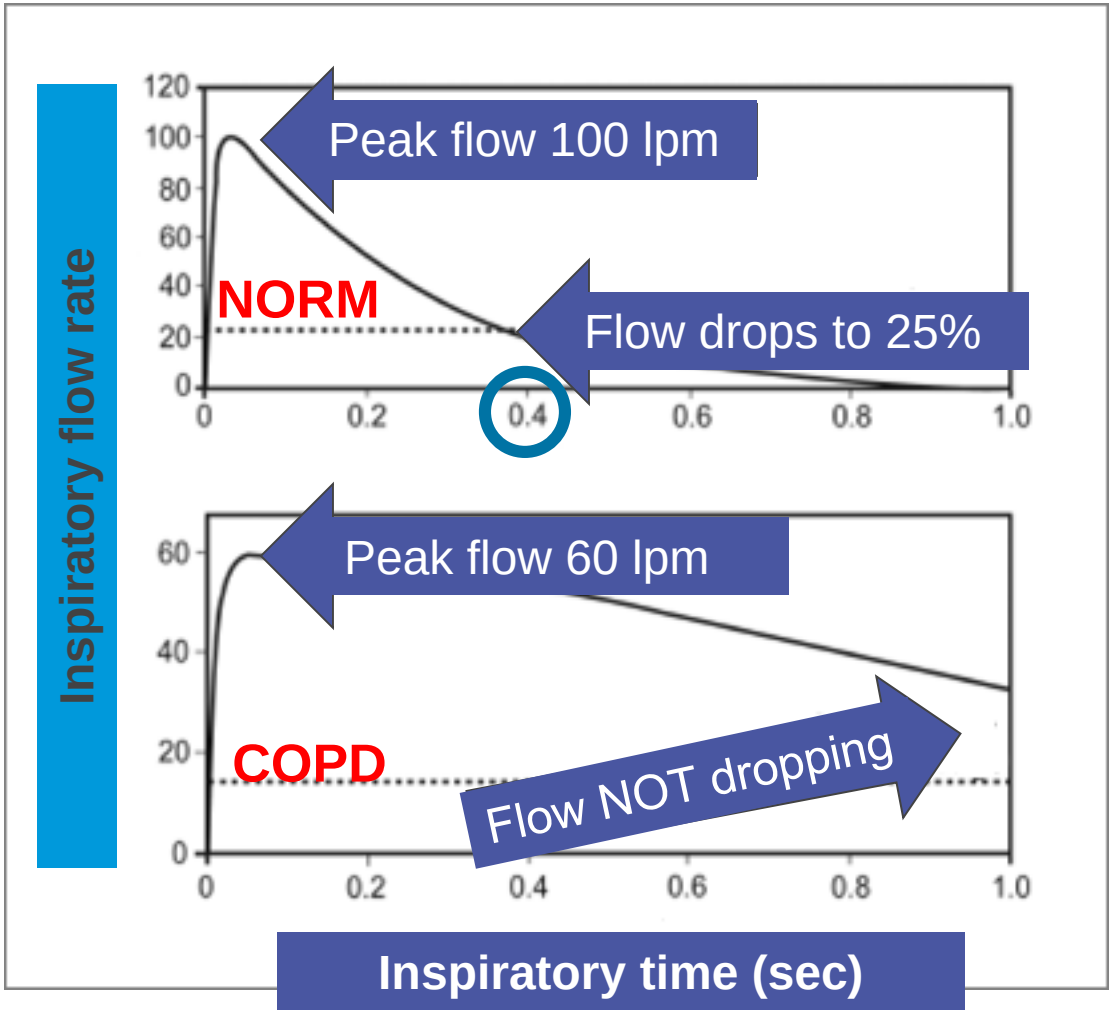
Cycling is Not “One Size Fits All”

“It is paramount to match the appropriate flow-cycling criterion with the specific underlying pathophysiology. Patients with obstructive disease require different cycling criteria than those with acute lung injury or other forms of lung impairment.”



Gentile MA. *Respir Care* 2011

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Hypoventilation in Neuromuscular Disease (NMD) Patients

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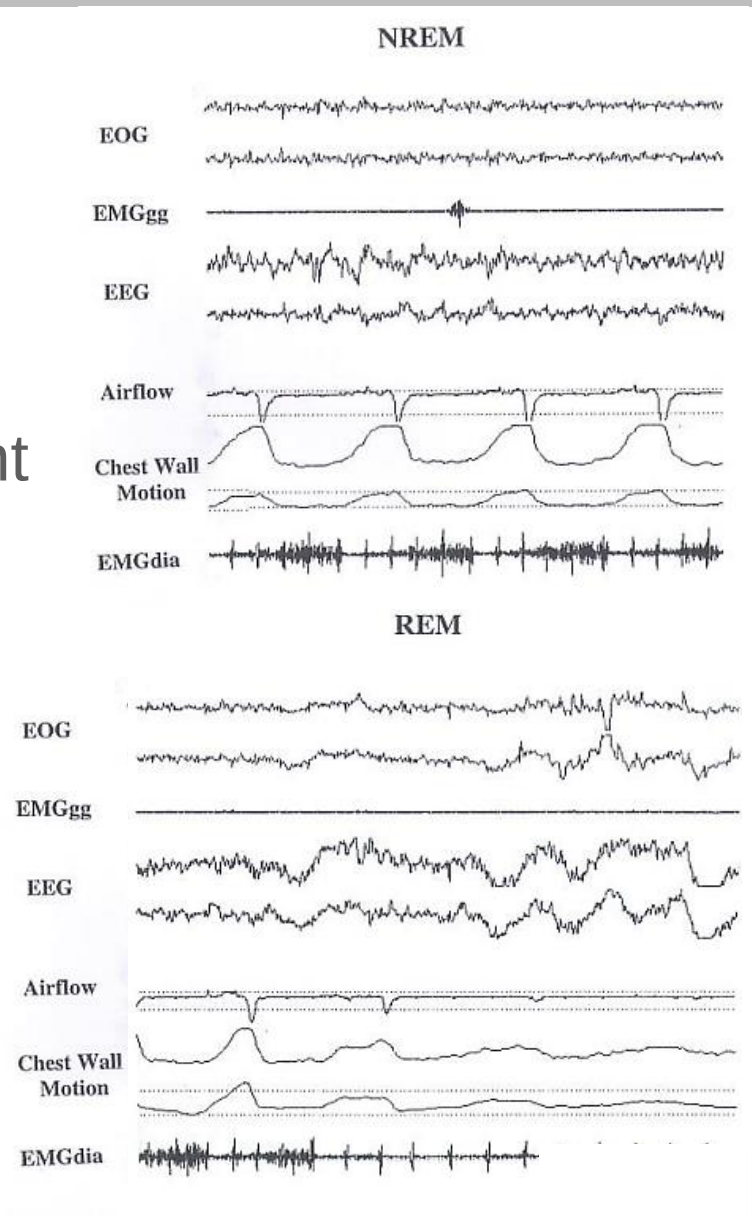
Nocturnal Ventilation in NMD

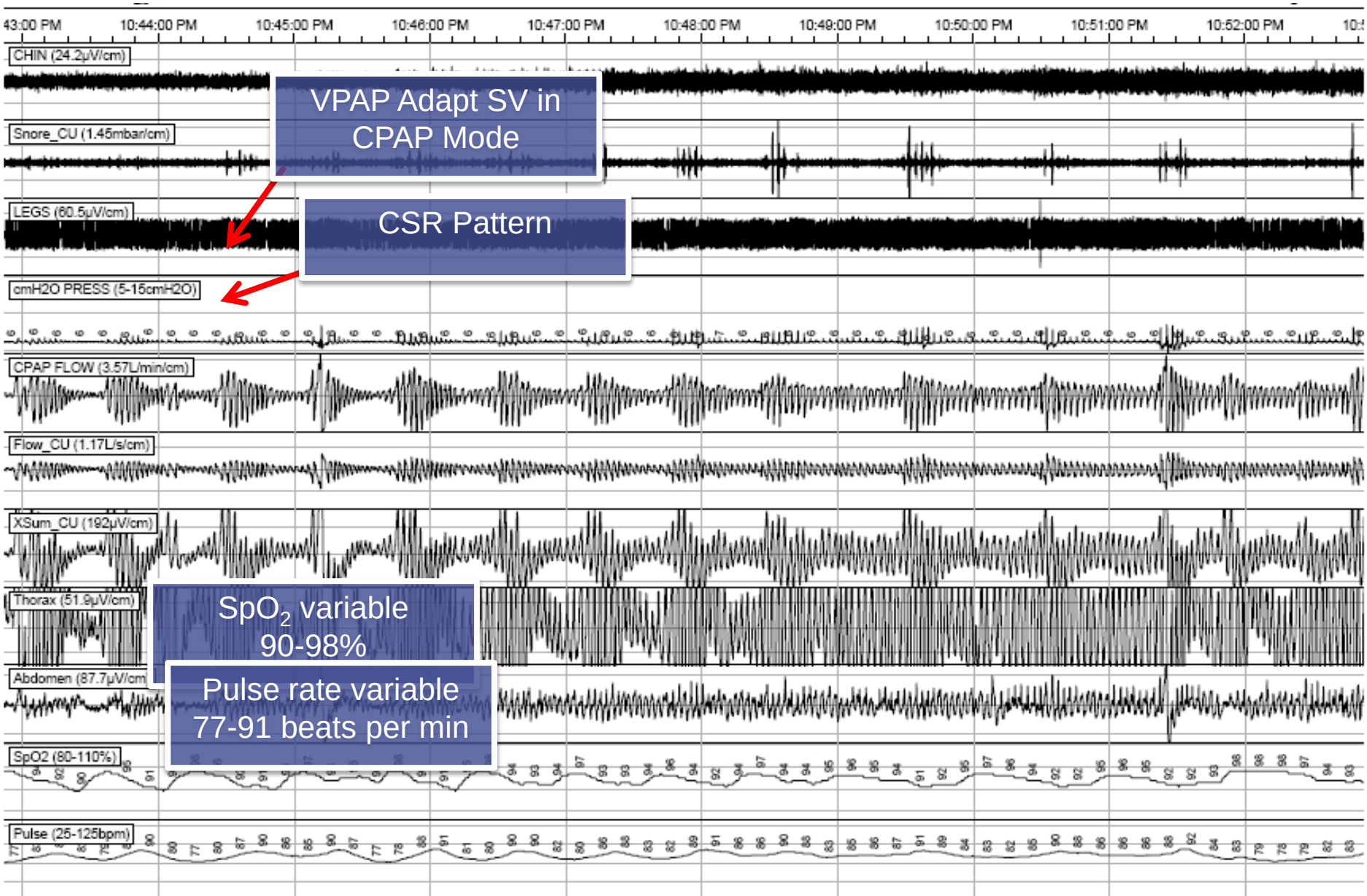
- Patient presents with both nocturnal hypoventilation and central apneas
  - Especially during REM sleep

- Significant diaphragmatic impairment or severe global respiratory muscle weakness
  - Accessory muscles ‘recruited’ during NREM
  - Muscles may not be recruited during REM sleep, resulting in falls in SpO_2 and/or sleep fragmentation



Graph courtesy of Amanda Piper

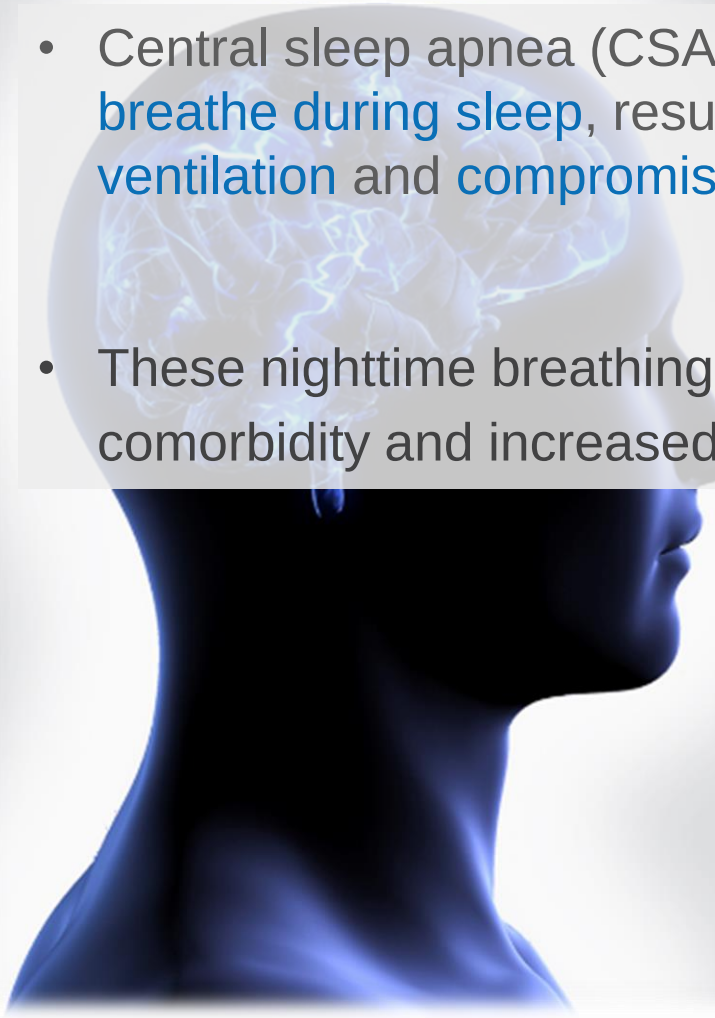
Central Sleep Apnea and ventilation



Central Sleep Apnea

- Central sleep apnea (CSA) is characterized by a lack of drive to breathe during sleep, resulting in repetitive periods of insufficient ventilation and compromised gas exchange

- These nighttime breathing disturbances can lead to important comorbidity and increased risk of adverse cardiovascular outcomes.



- CSA is considered to be the primary diagnosis when ≥ 50% of apneas are central in origin

- Unstable ventilatory control during sleep is the hallmark of CSA.

- International Classification of Sleep Disorders – ICSD3. AASM 2014
- Eckert DJ et al. *Chest* 2007

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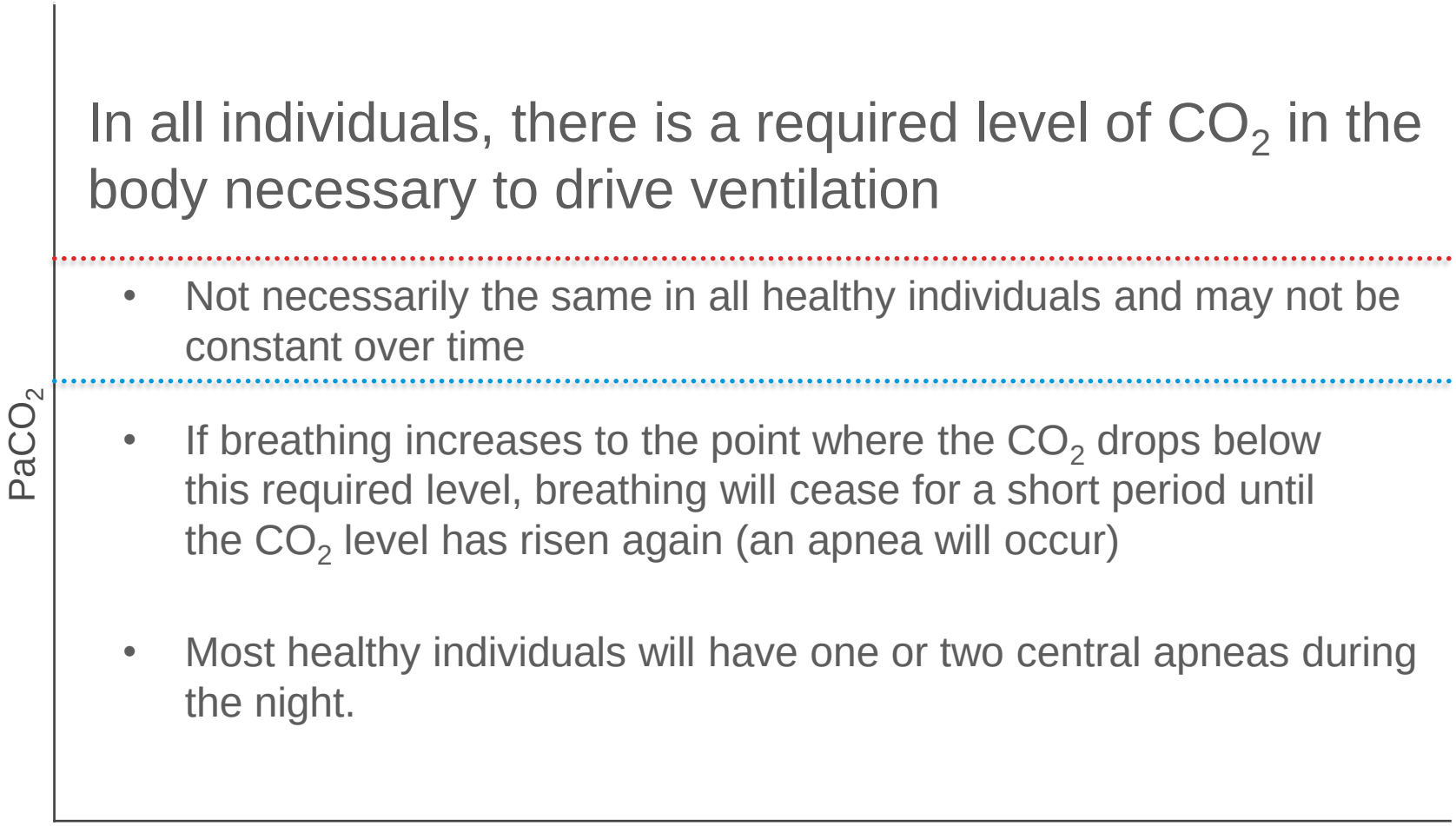
The Apneic Threshold



In all individuals, there is a required level of CO_2 in the body necessary to drive ventilation

- Not necessarily the same in all healthy individuals and may not be constant over time

- If breathing increases to the point where the CO_2 drops below this required level, breathing will cease for a short period until the CO_2 level has risen again (an apnea will occur)

- Most healthy individuals will have one or two central apneas during the night.

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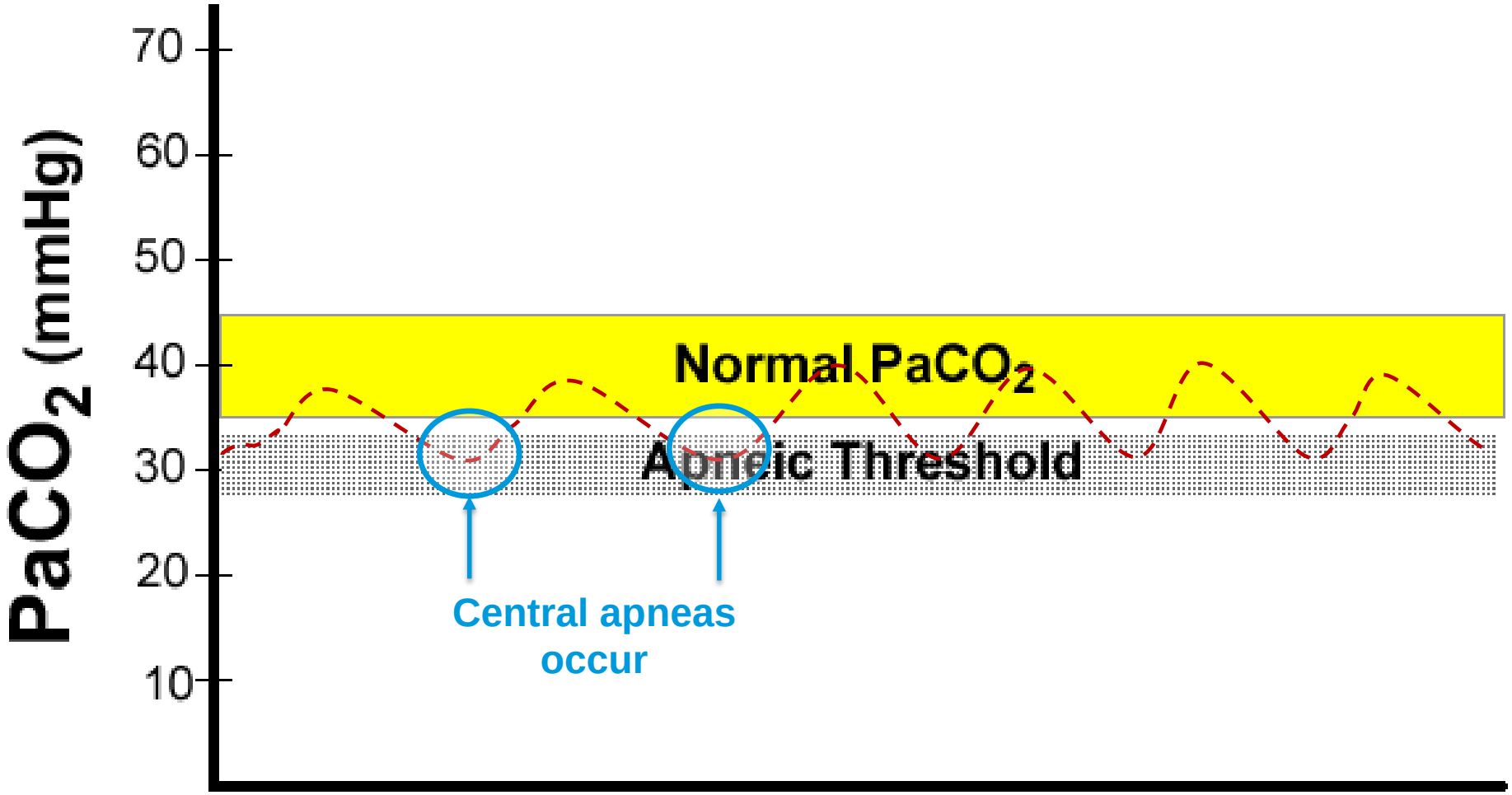
The Apneic Threshold



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Pathophysiology of CSA

- Unstable Ventilatory Control

CSA syndromes are classified in two groups according to the wakefulness CO_2 levels (arterial PCO_2).

1. **Normocapnic spontaneous central sleep apnoea/hypopnoea.**
   - Normal or low arterial PCO_2 when awake and an over response to hypercapnia when asleep
   - Cheyne-Stokes breathing, Idiopathic Central Sleep Apnea and Complex Sleep Apnea

ASV Stabilize ventilation

2. **Hypercapnic central sleep apnoea and hypopnoea.**
   - Abnormal central pattern generator output (“won’t breathe”)
   - Impairment of respiratory motor output (“can’t breathe”)
   - Associated with hypoventilation

Bilevel modes that enhance ventilation

Eckert DJ et al. *Chest* 2007

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Prevalence of CSA

- Prevalence of CSA vary greatly between the various forms
  - Eg: Most healthy individuals will have periodic breathing on high altitude[1]
    - Idiopathic CSA is relatively uncommon (5% of patients referred to a sleep lab)[2]
    - Treatment-emergent CSA is in approximately (3-10%) of obstructive sleep apnea titration studies[3]

- High prevalence of CSA existing in patient sub-groups
  - **6.5%** SDB patients have **complex sleep apnea[3]**
  - **24%** opiate patients exhibit central sleep apnea[4]
  - **31%** patients with **HFpEF have central sleep apnea[5]**

- More prevalent in older individuals than in the middle aged population[6].

- CSR-CSA is also more common in men and extremely rare in pre-menopausal women. Overall prevalence in women is 0.3% compared to 7.8% in men[6].

1. White DP et al. J Appl Physiol 1987
2. Malhotra A et al. Clinical Sleep Disorders. LWW 2004
3. Javaheri S et al. *J Clin Sleep Med* 2009
4. Correa D et al. *Anesth Analg* 2015
5. MacDonald M et al. *J Clin Sleep Med* 2008
6. Bixler EO et al. *Am J Respir Crit Care Med* 2001

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Who Are the Right Patients for ASV Therapy?

ASV Indication For Use

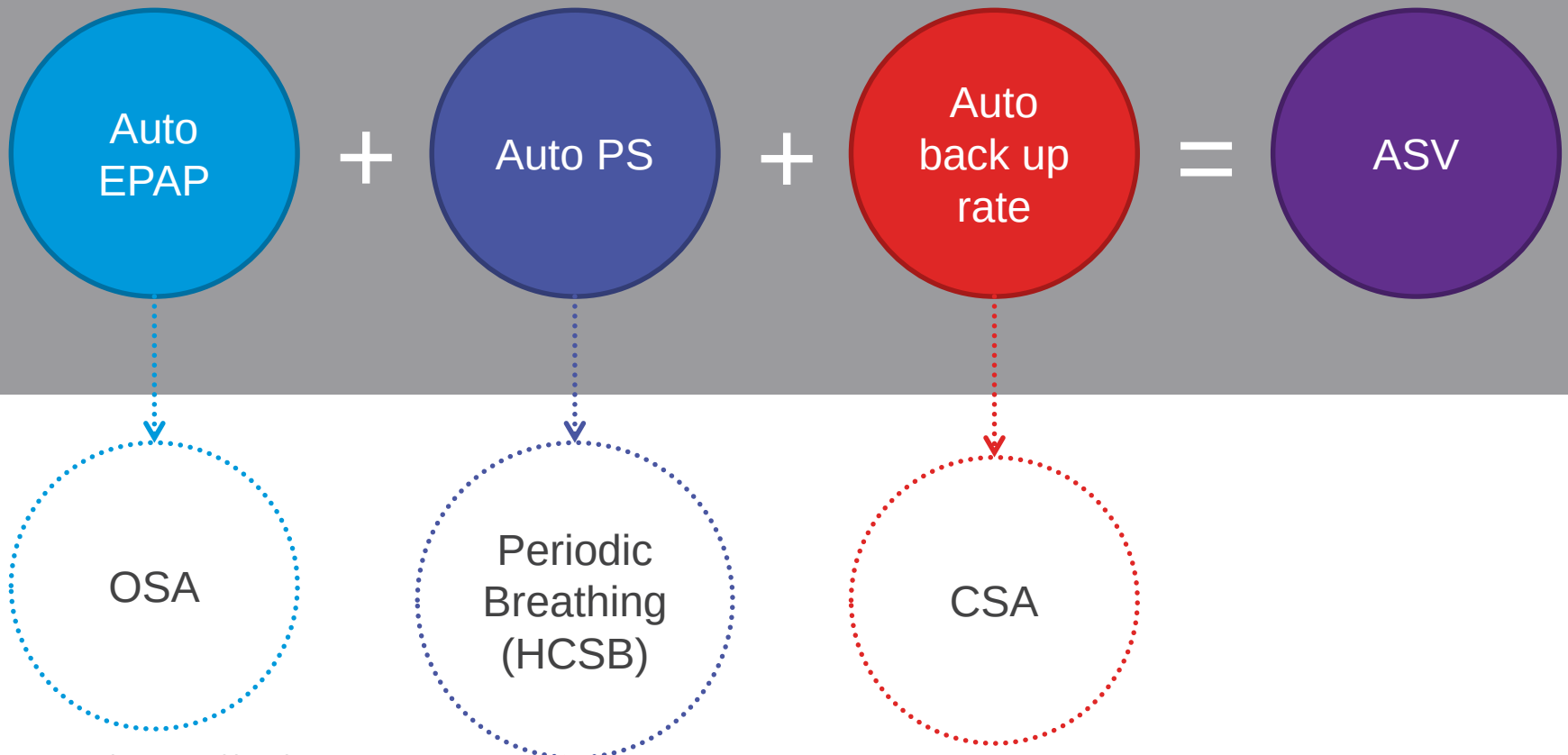
- The ASV device is indicated for the treatment of patients weighing more than 66 lb (30 kg) with obstructive sleep apnea (OSA), central and/or mixed apneas, or periodic breathing. It is intended for home and hospital use.

ASV Contraindication

- ASV therapy is contraindicated in patients with chronic, symptomatic heart failure (NYHA 2-4) with reduced left ventricular ejection fraction (LVEF ≤ 45%) and moderate to severe predominant central sleep apnea.

ASV Algorithm in Summary

Components of ASV Devices



EPAP: expiratory positive airway pressure
HCSB: Hunter Cheyne-Stokes breathing
PS: pressure support.

Modified from Javaheri S et al. *Chest* 2014

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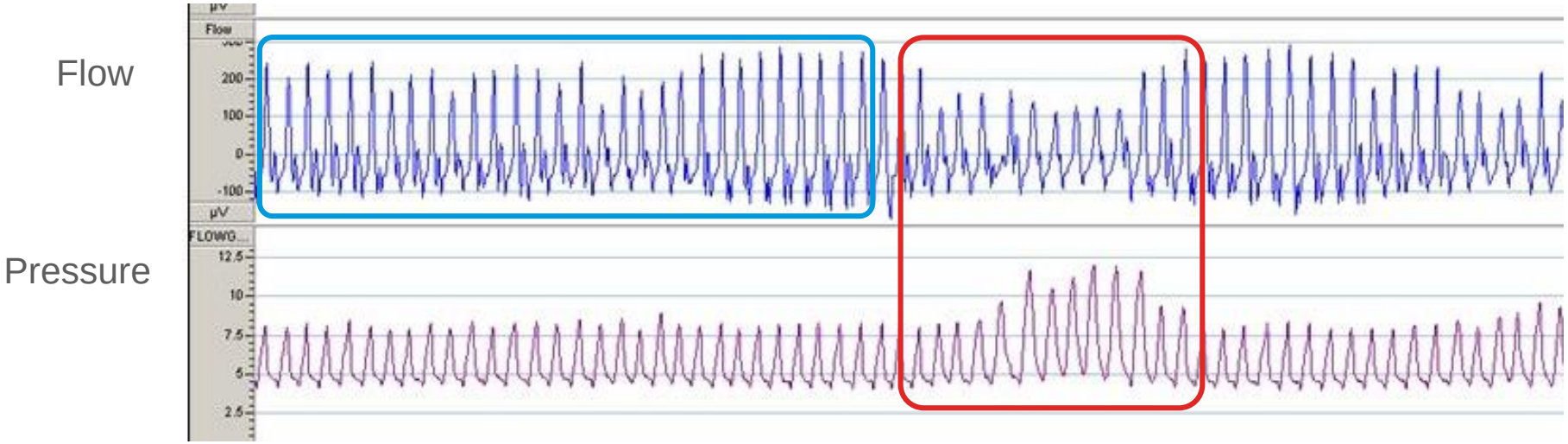
1. ASV Creates a Target Ventilation

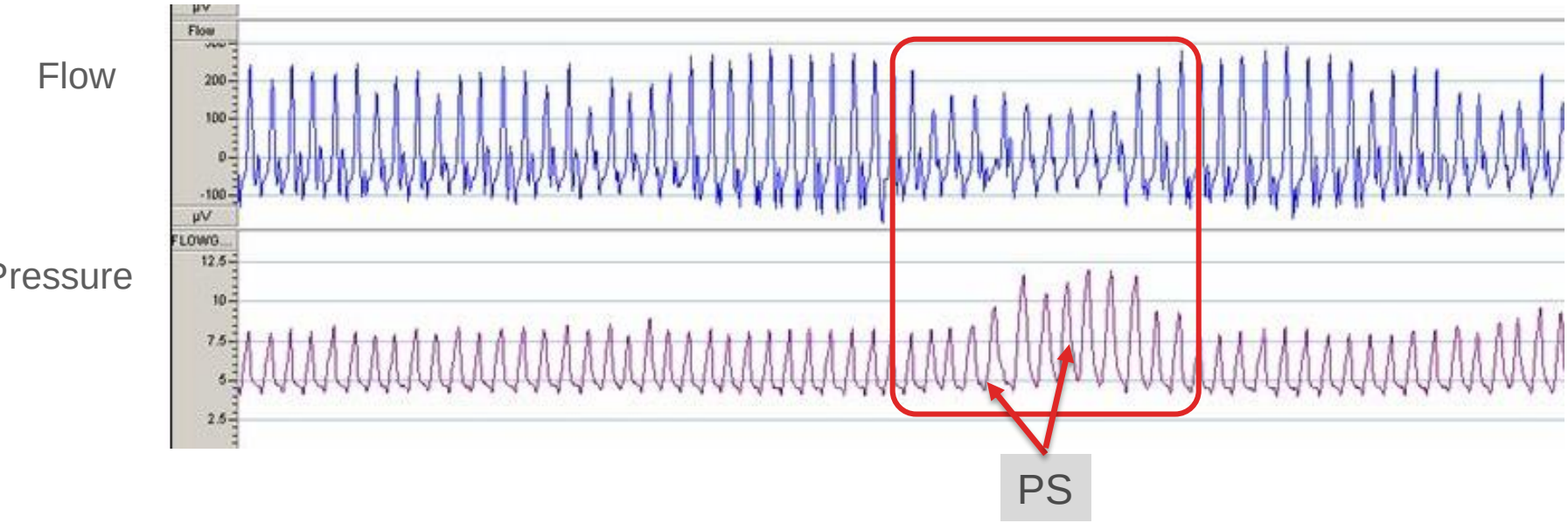
- Target MV is set to 90% of the patient's recent 3 minute average
- Target MV is continually adjusted to reflect changes in patient's own MV during the night and through various sleep stages.

3-minute moving window



2. ASV Responds Quickly – Stabilizing Ventilation

- Prevents under and over ventilation by dynamically increasing (for hypopneas) or decreasing (for hyperpneas) inspiratory pressure support (PS)



2. ASV Responds Quickly – Stabilizing Ventilation

If the upper airway is collapsed, no matter how advanced your algorithm is, it

CANNOT STABILIZE VENTILATION

AirCurve 10 ASV : 2 options	
ASV mode	**ASVAuto mode**
Manually set EPAP to protect airway against collapse	Use an Auto-adjusting EPAP that is responsive to Obstructive Apnea predictors (Flow Limitation and Snore)

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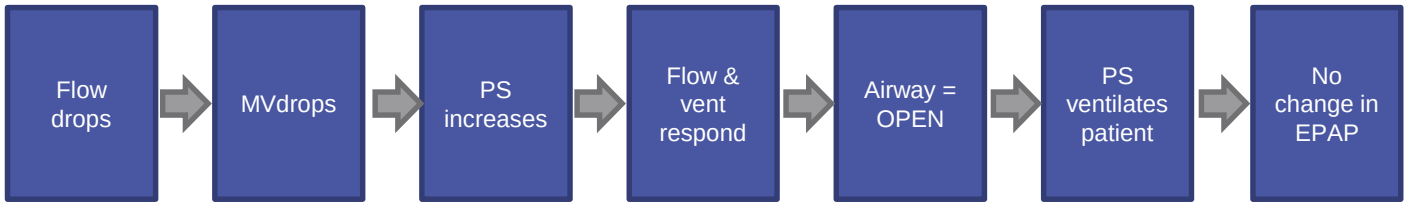
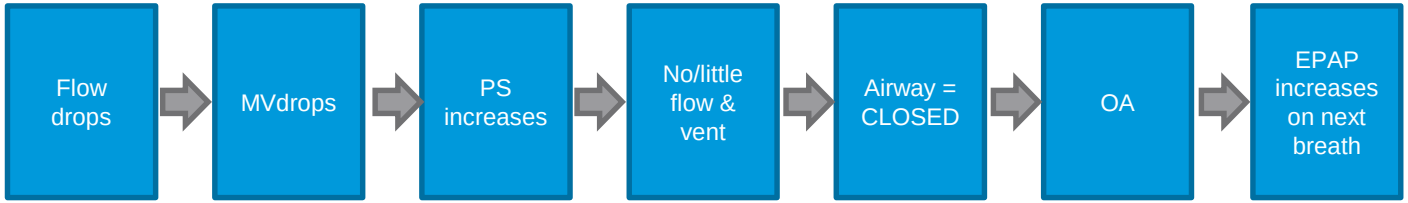
ASVAuto Response to Events

Scenario 1: central apnea



Scenario 2: obstructive apnea



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Scenario 1: Central Apnea

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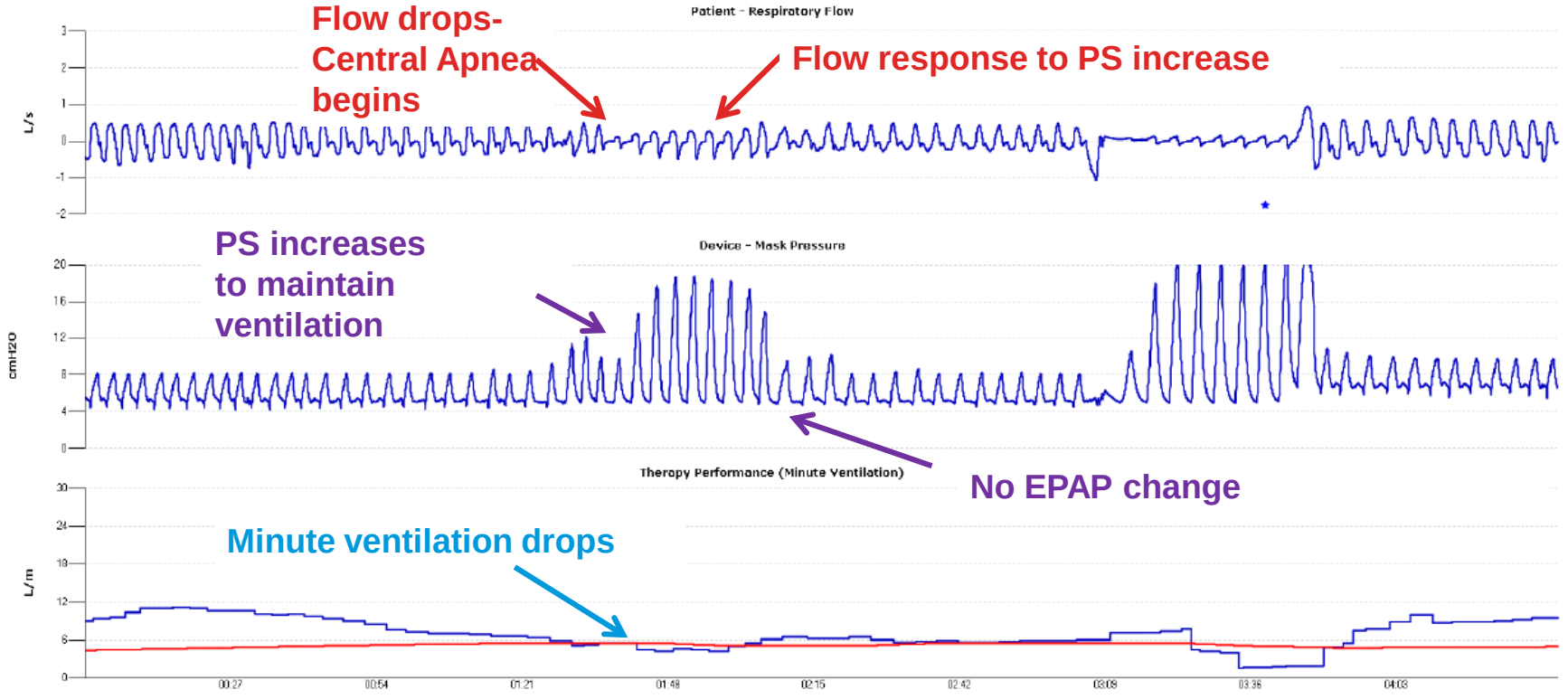
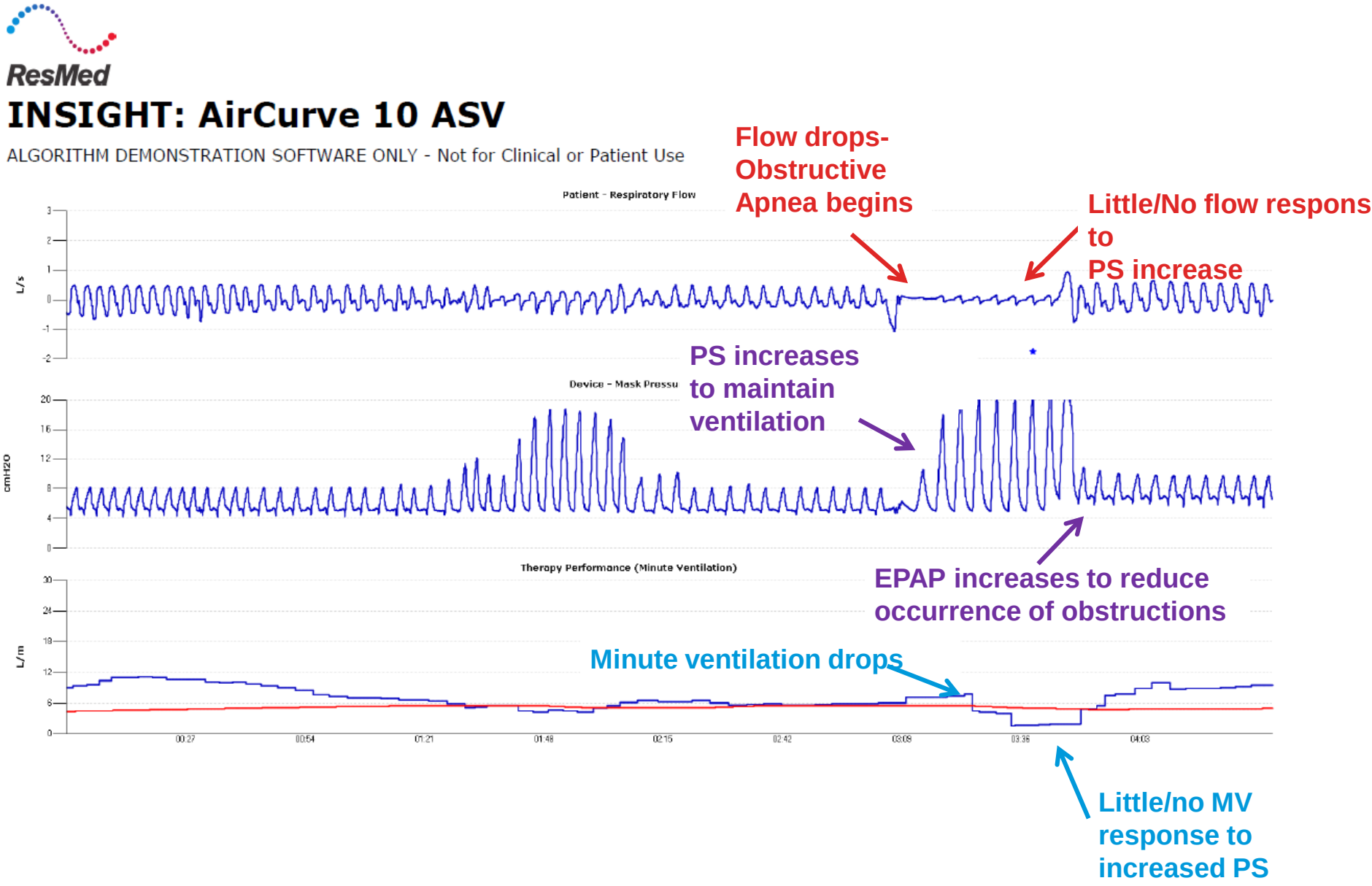
INSIGHT: AirCurve 10 ASV

ALGORITHM DEMONSTRATION SOFTWARE ONLY - Not for Clinical or Patient Use



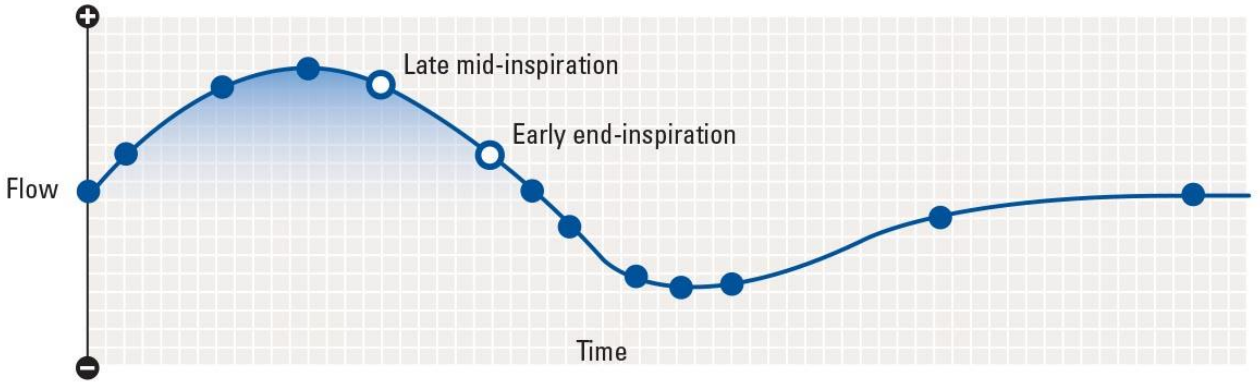
Scenario 2: Obstructive Apnea



3. ASV Predicts Patient's Needs

- Algorithm tracks 13 points in the breath cycle, continually and accurately mapping respiratory rate and MV.
- Predicts when to insert PS and EPAP

Tracking changes in patient's respiratory rate and airflow



- Easy-Breathe replicates natural wave shape of normal breathing

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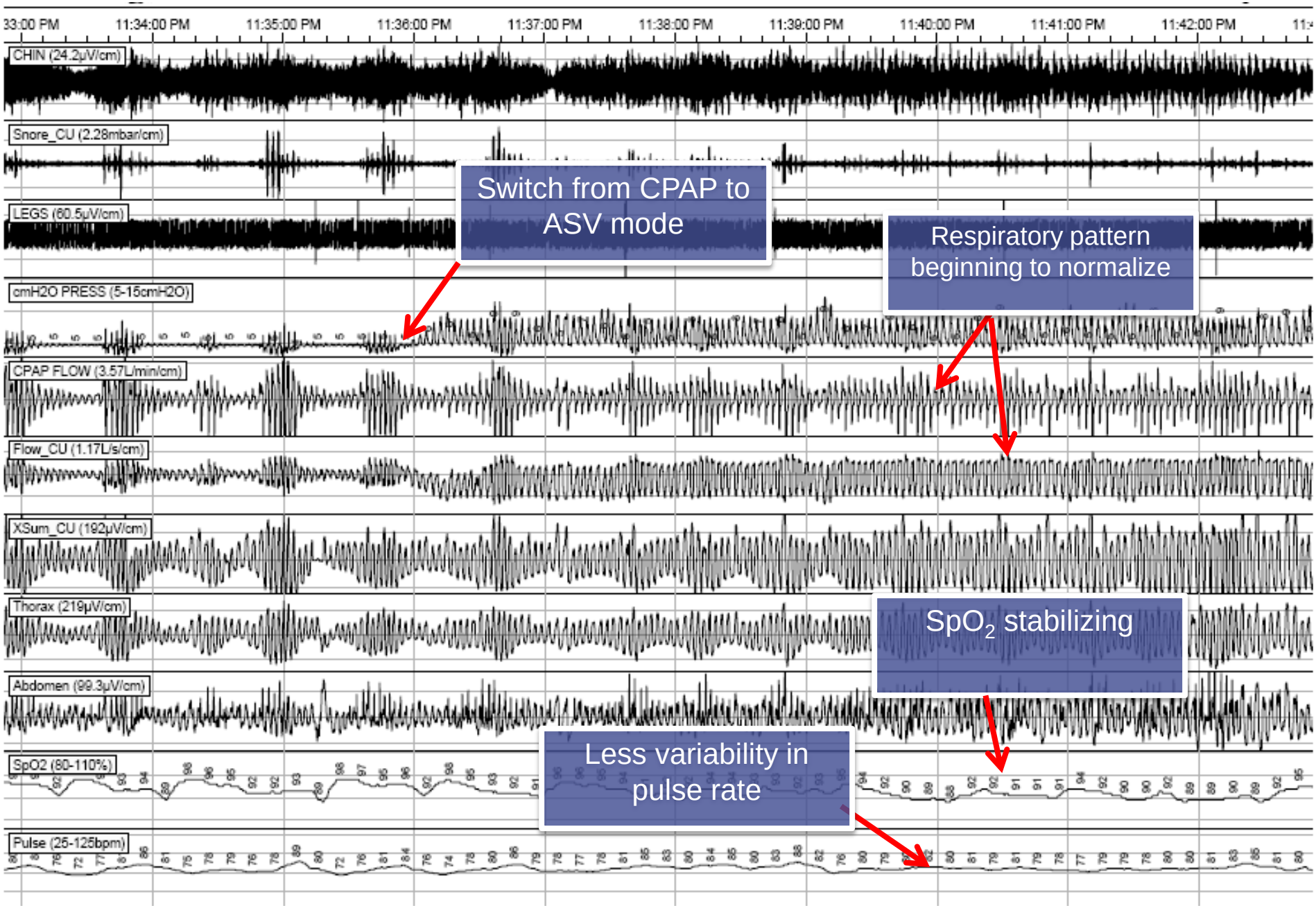
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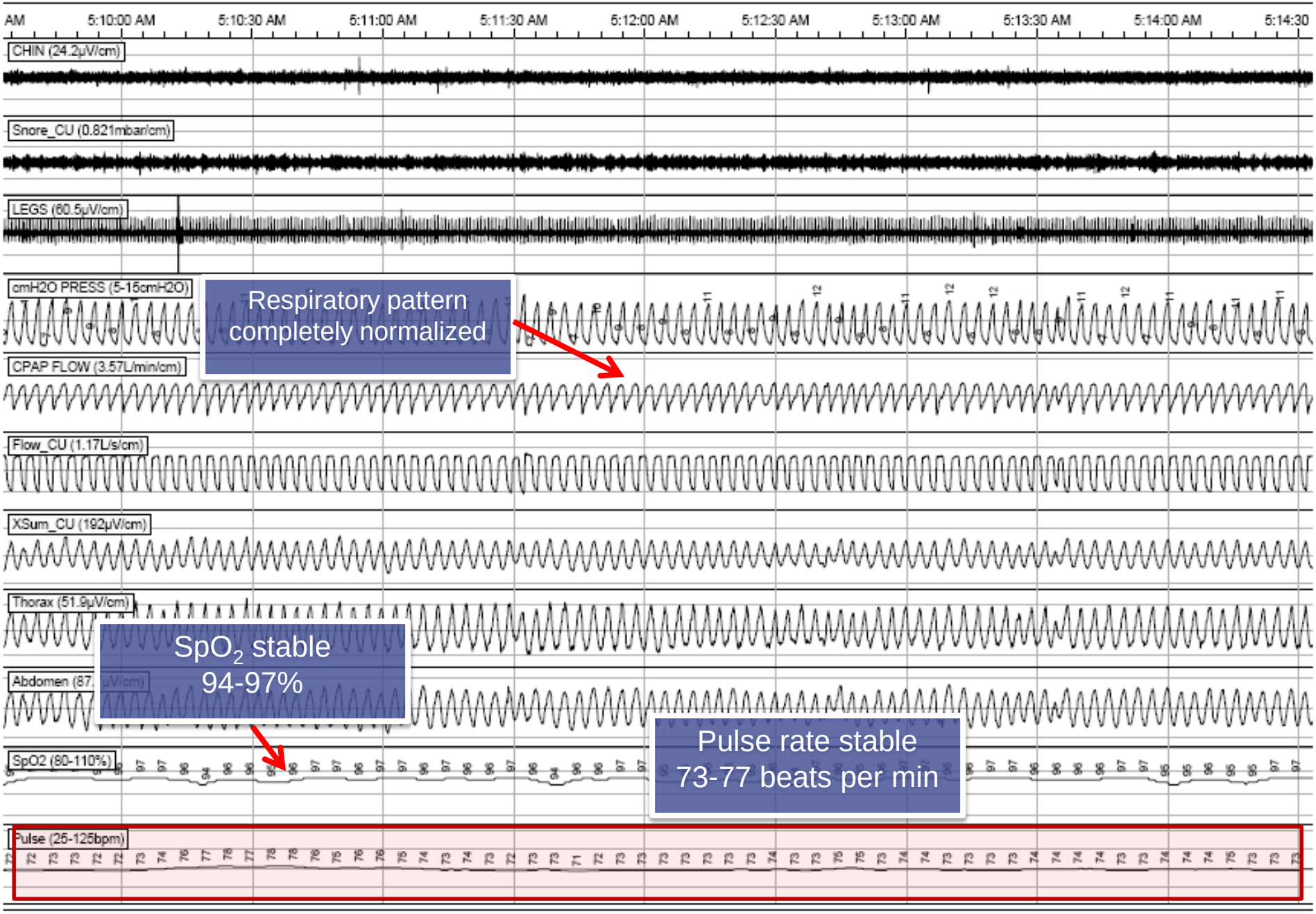
11:35:00 PM
11:36:00 PM
11:37:00 PM
11:38:00 PM
11:39:00 PM
11:40:00 PM
11:41:00 PM
11:42:00 PM
CHIN (24.2µV/cm)
Snore_CU (2.28mbar/cm)
LEGS (60.5µV/cm)
cmH2O PRESS (5-15cmH2O)
CPAP FLOW (3.57L/min/cm)
Flow_CU (1.17L/s/cm)
XSum_CU (192µV/cm)
Thorax (219µV/cm)
Abdomen (99.3µV/cm)
SpO2 (80-110%)
Pulse (25-125bpm)
Switch from CPAP to ASV mode
Respiratory pattern beginning to normalize
SpO2 stabilizing
Less variability in pulse rate


AM
5:10:00 AM
5:10:30 AM
5:11:00 AM
5:11:30 AM
5:12:00 AM
5:12:30 AM
5:13:00 AM
5:13:30 AM
5:14:00 AM
5:14:30
CHIN (24.2µV/cm)
Snore_CU (0.821mbar/cm)
LEGS (60.5µV/cm)
cmH2O PRESS (5-15cmH2O)
Respiratory pattern completely normalized
CPAP FLOW (3.57L/min/cm)
Flow_CU (1.17L/s/cm)
XSum_CU (192µV/cm)
Thorax (51.9µV/cm)
SpO2 stable 94-97%
Abdomen (87.
SpO2 (80-110%)
Pulse rate stable 73-77 beats per min
Pulse (25-125bpm)

VAPS Therapy

The term “VAPS,” Volume Assured Pressure Support, refers to hybrid modes of ventilation that aim to provide a minimum level of ventilation by automatically varying the level of pressure support provided by the ventilator.

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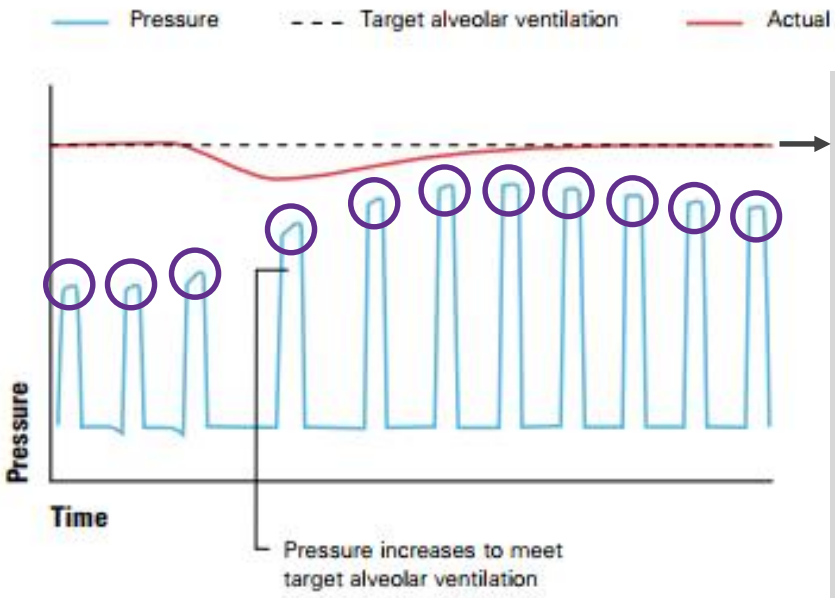
Volume Assured Therapy

The aim of VAPS mode is to adapt the delivered **IPAP** to changes in lung mechanics to assure a defined pre-set tidal volume (VT) delivery by automatically adjusting pressure support to achieve optimal ventilator support.



More stable ventilation is achieved while:

- improving patient comfort
- reducing work of breathing
- optimizing patient-ventilator interaction
- providing adequate levels of treatment pressure

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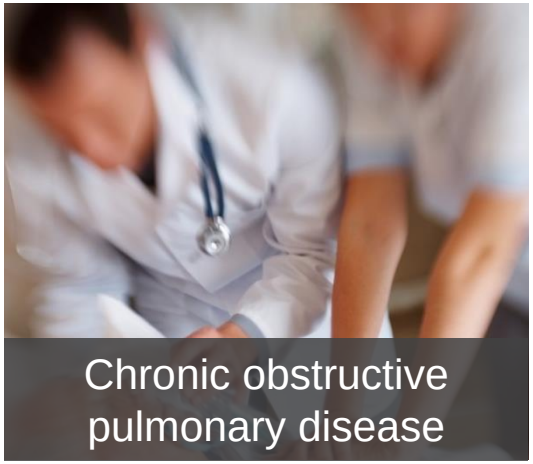
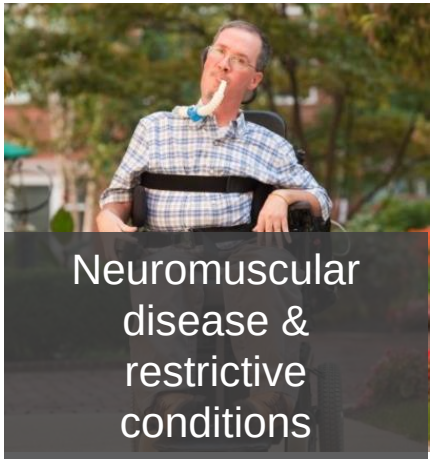
Who is VAPS Suitable For?

Continuous or intermittent ventilatory support for patients weighing more than 66 pounds (30 kg) who require mechanical ventilation





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AVAPS and iVAPS

- Philips- Average Volume Assured Pressure Support
  - Looks at tidal volume
  - Automatic back up rate
  - Automatic Epap in Ventilator (Trilogy)

- ResMed- Intelligent Volume Assured Pressure Support
  - Looks at minute ventilation
  - Automatic back up rate
  - Automatic Epap in Ventilator (Astral)

ResMed

Why Go VAPS?

- Bilevels/pressure support very comfortable for patients
  - Flow based- to start the breath and to end the breath
  - Patients are in control of their breathing
- Negative- they can’t guarantee volumes- just pressure
- Using a Vaps mode
  - Still comfortable for patient
  - Yet when patient’s lung compliance is challenged
    - positional
    - sleep stage
  - Volume will still be delivered

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Review

- CPAP may not be the device of choice for specific patients
- Diagnoses will be a big determinant of what PAP machine will be appropriate for the patient
- Goals of therapy will tell you what machine you should use
  - Stabilize airway
  - Ventilate the patient
  - Stabilize the patient's ventilation
  - Ventilate and guarantee the delivered volumes
- And Remember- consistent monitoring can uncover problems not picked up on- and enable them to be addressed

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Questions?