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Changing lives
with every breath

Addressing the Challenges of Assessment and Effective Therapy

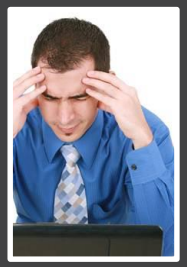
Importance of Sleep

Sleep is important to health because it allows for metabolic restoration of the brain and body. The following occur during sleep:

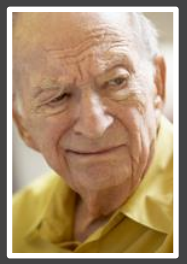
Growth hormone secretion

Alterations in breathing (slow & shallow)

When a person does not get the right amount of sleep, it affects their health in some of the following ways:



Lack of concentration & judgment



Increased irritability & mood problems

Higher risk for anxiety & depression

Douglas Neil. Oxford University Press 2002

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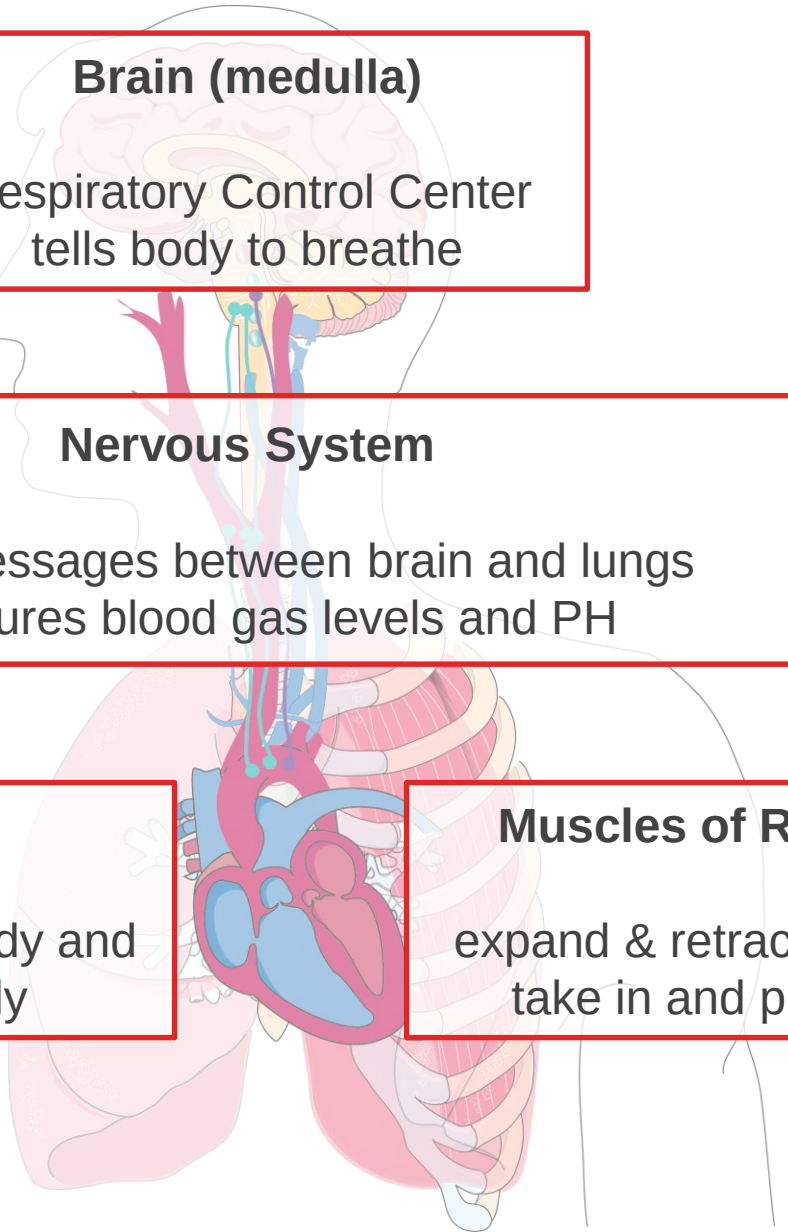
Ventilation Central Control



Brain (medulla)

Respiratory Control Center
tells body to breathe

Nervous System

sends messages between brain and lungs
measures blood gas levels and PH

Lungs

transport O_2 into the body and
CO_2 out of the body

Muscles of Respiration

expand & retract the lungs to
take in and push out air

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Normal Breathing During Sleep

Non-Rapid Eye Movement (NREM)	Rapid Eye Movement (REM)
Divided into multiple stages	Breathing (Vt & RR) irregular
↓ blood pressure & heart rate	Loss of muscle tone (atonia)
↓ eye movement	Ventilatory response further reduced
Muscles relaxed, not paralyzed	

McNicholas WT, Phillipson EA. UK, Saunders 2002

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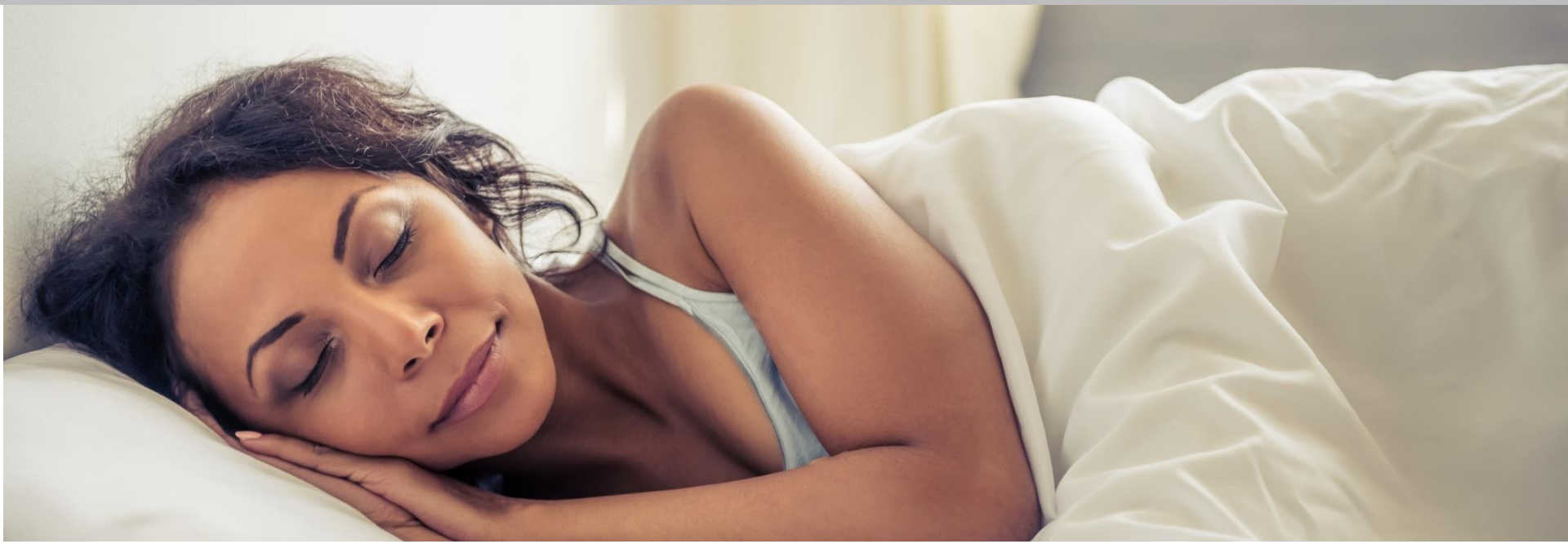
Ventilation Changes During Sleep



- Decreased respiratory drive with a small fall in ventilation and rise in carbon dioxide (CO_2)
- Small reductions in tidal volume are compensated by an increase in breath rate
- Alterations in respiratory system mechanics
  - Increased upper airway resistance
  - Altered chest wall mechanics
- Depressed arousal responses to chemical stimuli

Becker HF et al. *Am J Respir Crit Care Med* 1999

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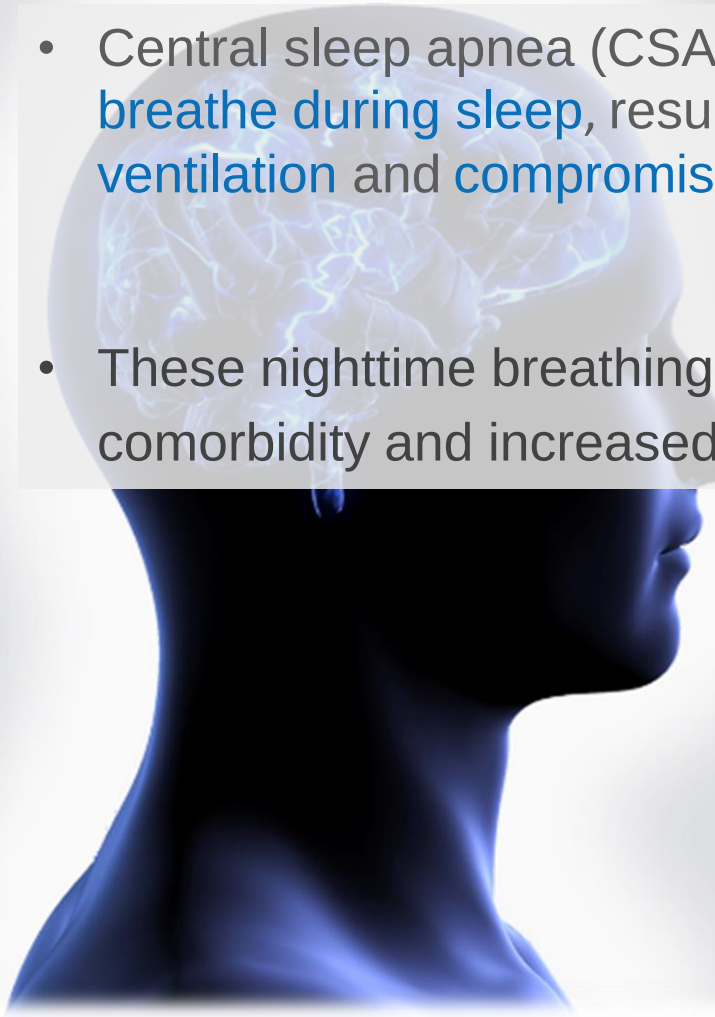
Central Sleep Apnea

- 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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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

iVAPS Ventilatory Support

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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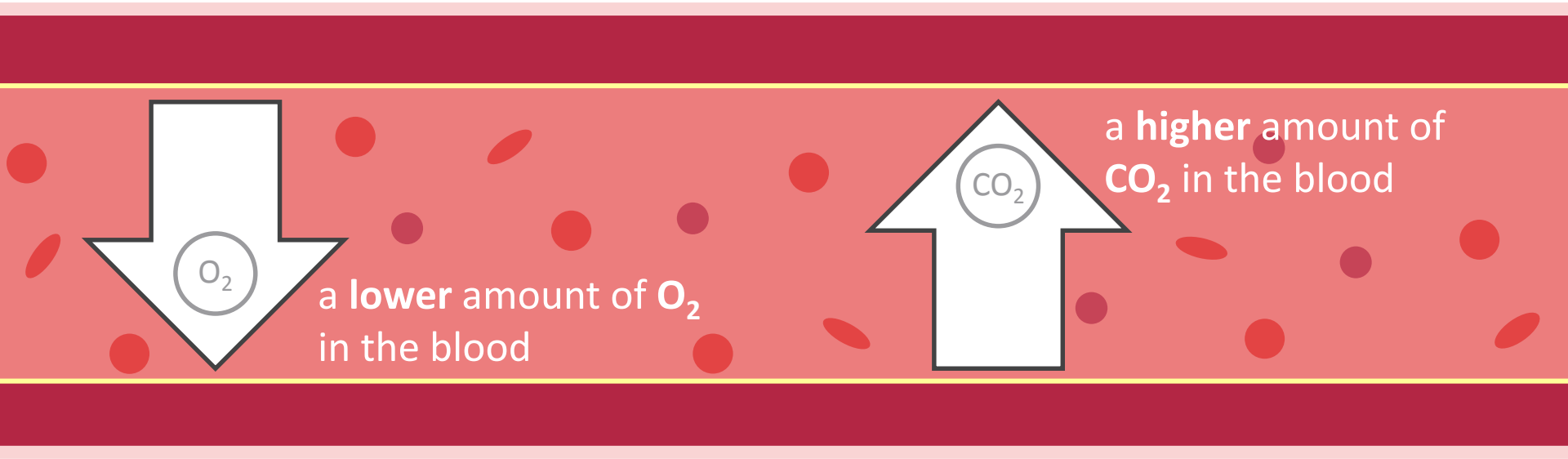
What Is Hypoventilation?

Hypo = less than normal

ventilation = movement of air into and out of the body



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Hypoventilation

Alveolar hypoventilation is defined as insufficient ventilation leading to **hypercapnia,** ($PaCO_2$ ≥45mmHg). It may be an acute or chronic and is caused by several mechanisms

- Alveolar hypoventilation may be **acute** or **chronic** and may be caused by several disorders.
- Night time and Daytime Hypoventilation
- Respiratory insufficiency patients have an additional 10–15% drop in ventilation at sleep onset (SO)
  - Further reduction in REM sleep (10–20%), due to falling tidal volumes not counteracted by increased respiratory rate

Becker HF et al. *Am J Respir Crit Care Med* 1999

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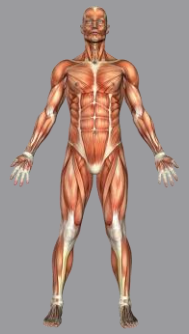
When Does Hypoventilation Occur?

- Activity of respiratory muscles is impaired
  - Respiratory muscle weakness
  - Obesity
- Mechanics of chest wall and lungs are compromised
  - Chest wall stiffness
  - Lung disease
  - Upper airway dysfunction
  - Obesity
- Impaired ventilatory control
  - Neurological conditions
  - Central Sleep Apnea Syndromes

Learn more about nocturnal ventilation in different conditions

COPD



Neuromuscular Disease (NMD)

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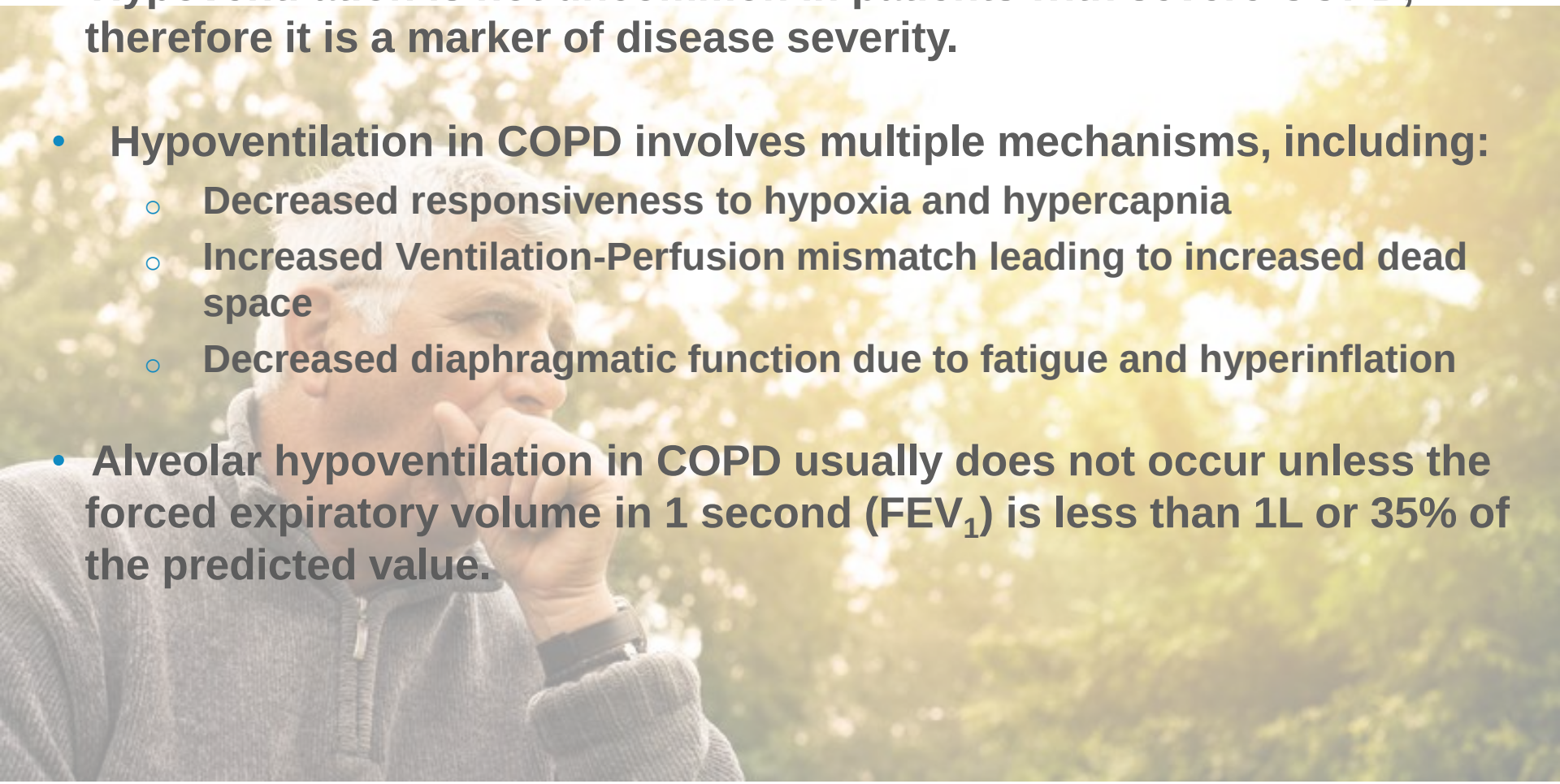
Hypoventilation & COPD



- **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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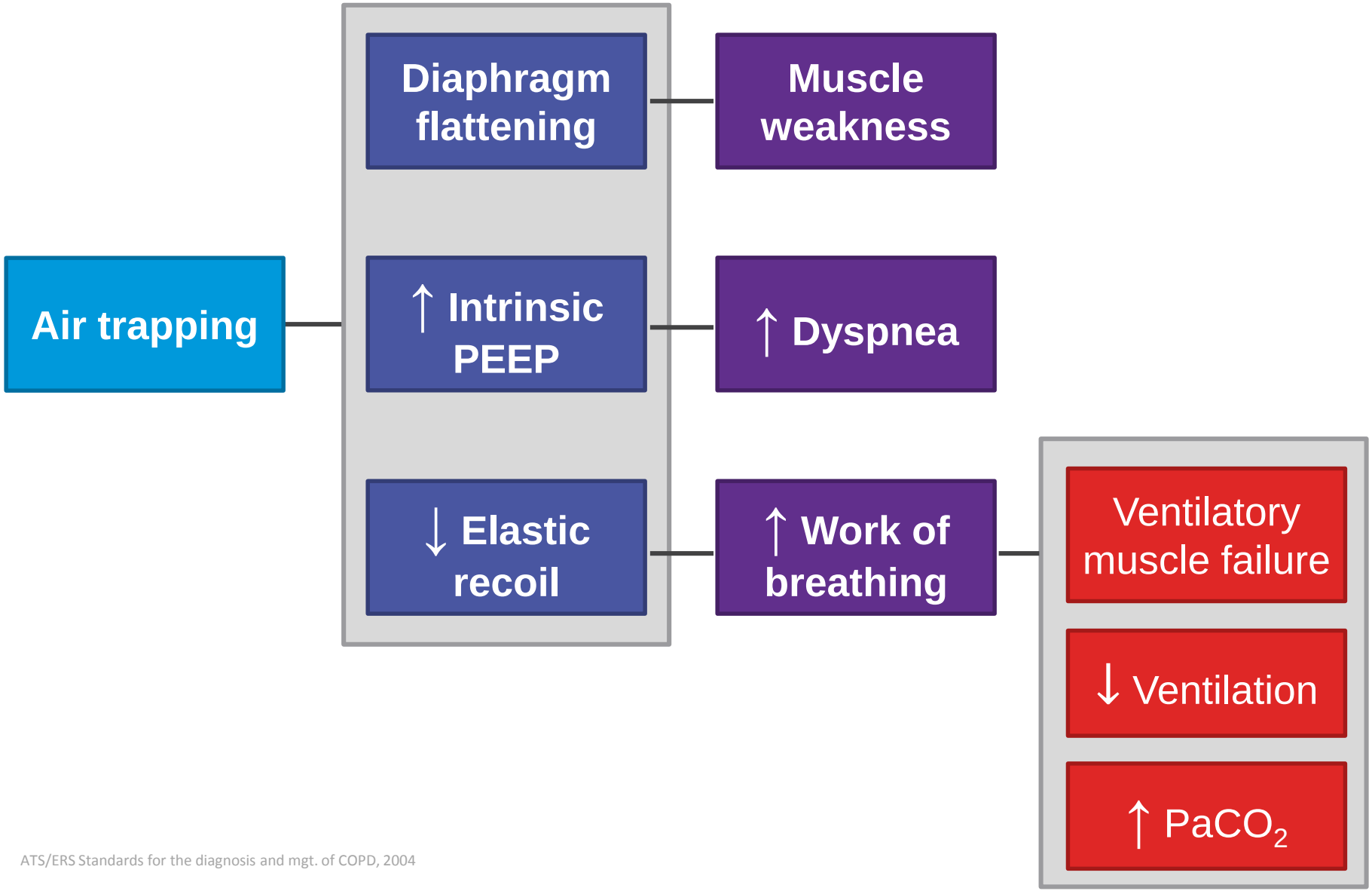
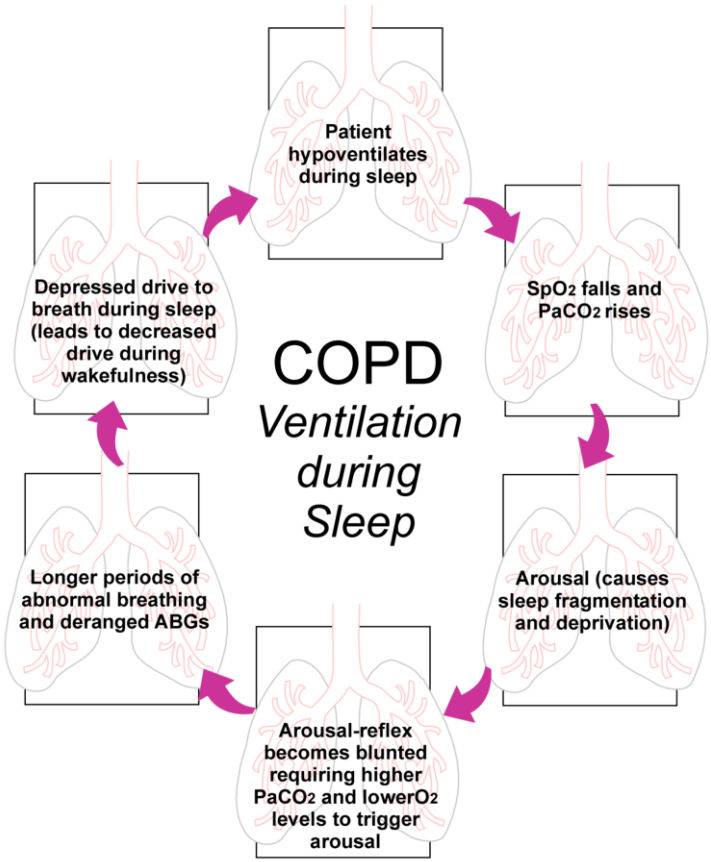
Pathophysiology of COPD



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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Overlap Syndrome

- Consists of both:
  - Upper airway obstruction (OSA) during sleep
  - Nocturnal hypoventilation (COPD)
  - Studies indicate that over 30% of COPD patients will also have Obstructive Sleep Apnea (OSA)[1]

- May demonstrate prolonged hypoxemia during sleep
- SpO_2 often does not recover between episodes of repetitive apnea
- If left untreated, morbidity and mortality much higher than for either disease process alone

1. Soler X et al. *Ann Am Thorac Soc* 2015

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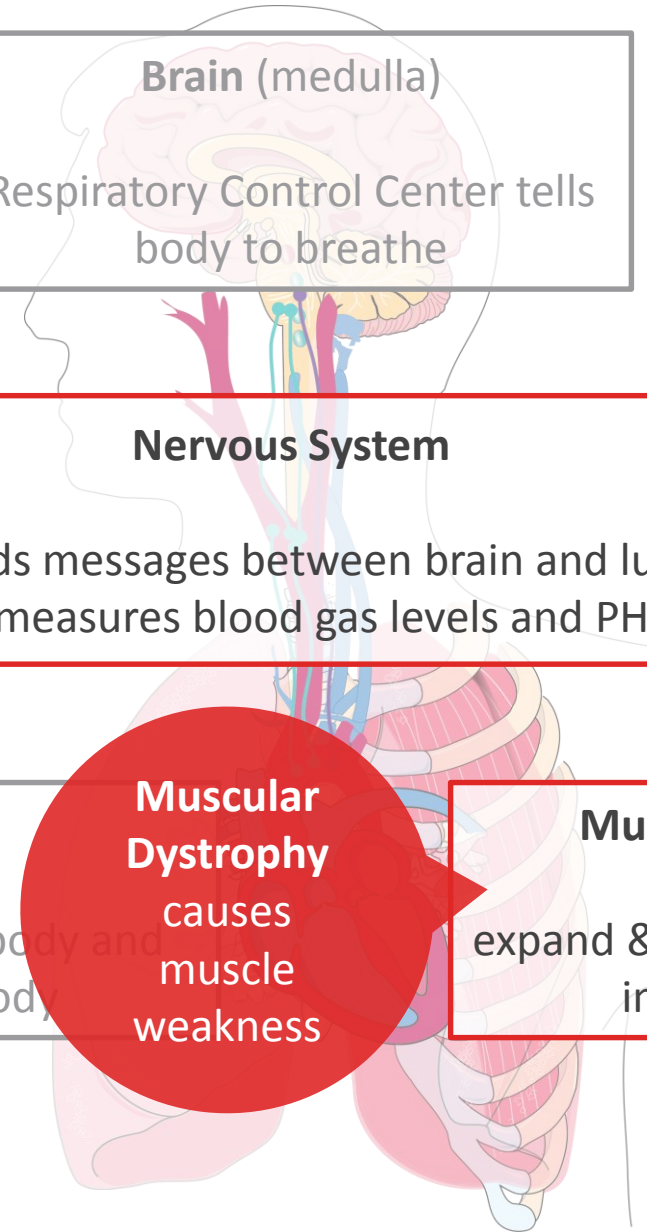
Hypoventilation & NMD



Brain (medulla)

Respiratory Control Center tells body to breathe

ALS is a disease of the nerve cells

Nervous System

- sends messages between brain and lungs
- measures blood gas levels and PH

Lungs

transport O2 into the body and CO2 out of the body

Muscular Dystrophy causes muscle weakness

Muscles of Respiration

expand & retract the lungs to take in and push out air

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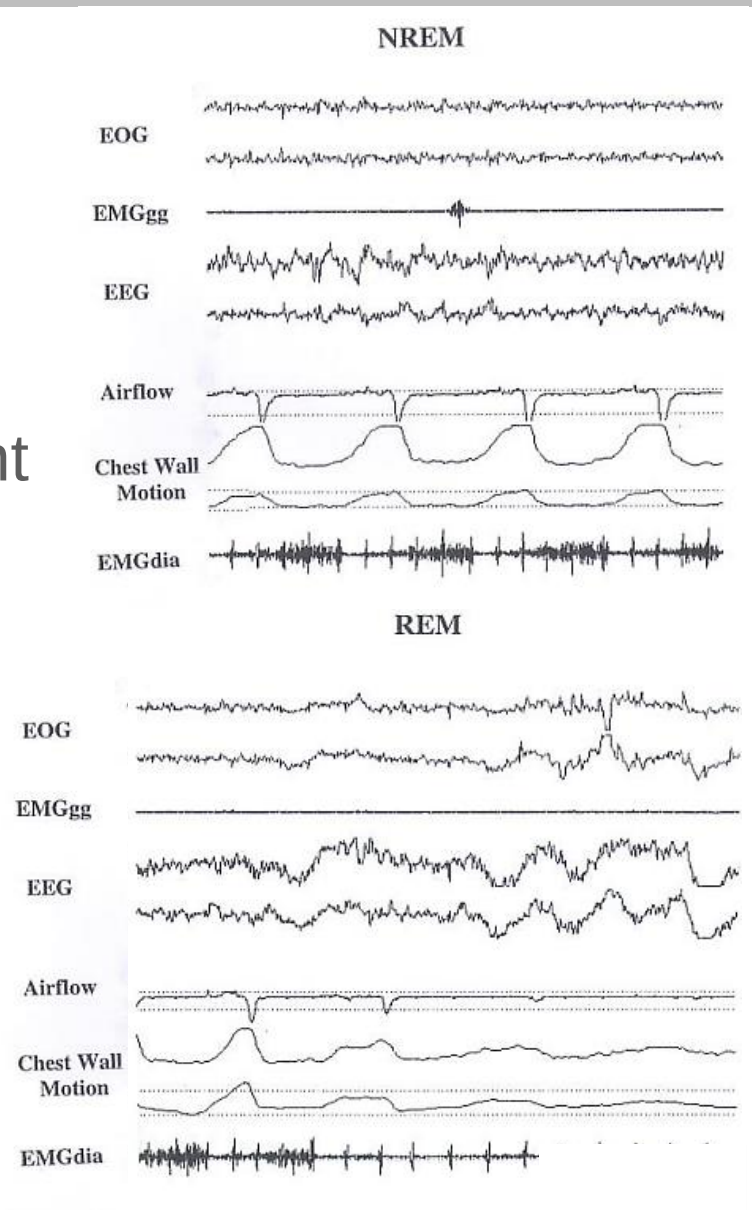
Nocturnal Ventilation in NMD

- 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

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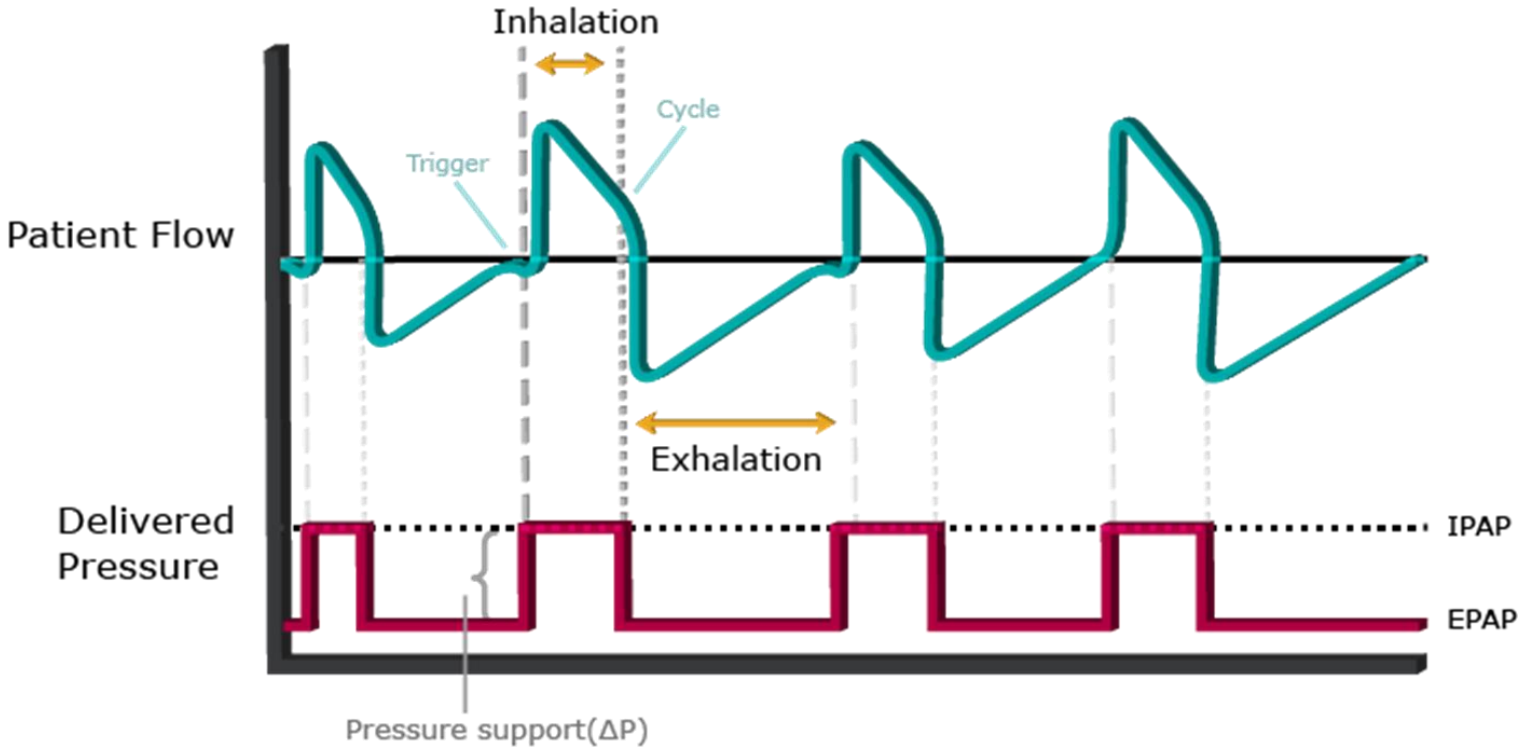
Bilevel Therapy

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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How Does Bilevel Work?

- Prevents nocturnal hypoventilation and hypoxia
  - Cardiovascular consequences
- Improves ventilation (gas exchange)
  - Reduces nocturnal CO_2 levels
  - Increases nocturnal O_2 levels
  - Improves daytime blood gases
- Stabilizes upper airway
- Rests respiratory muscles
- 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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Bilevel Provides a Breath with Two Pressures

IPAP

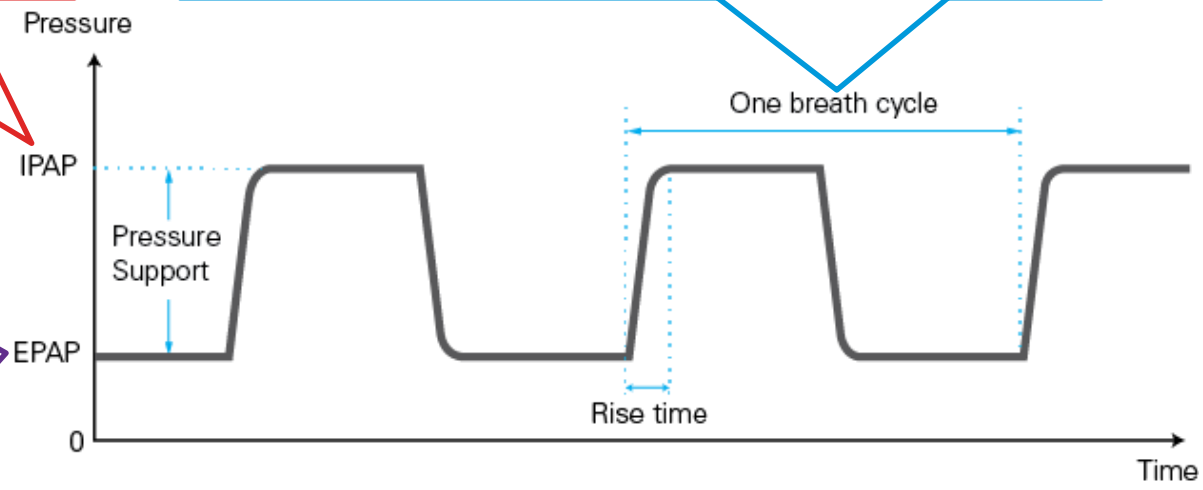
- Pressure during inspiration.
- Give appropriate volume of air.
- Decrease work of breathing.
- Reduce level of CO_2 in arterial blood ($PaCO_2$).

Breath Cycle

- Pressure delivery matches the breath cycle (breathe in, breathe out).
- Settings in the breathe cycle can be adjusted to meet patient needs.
- Normal I:E ratio is 1:2 (you exhale twice as long as you inhale)

EPAP

- Pressure during expiration.
- Keeps airway open.
- Improves oxygenation.



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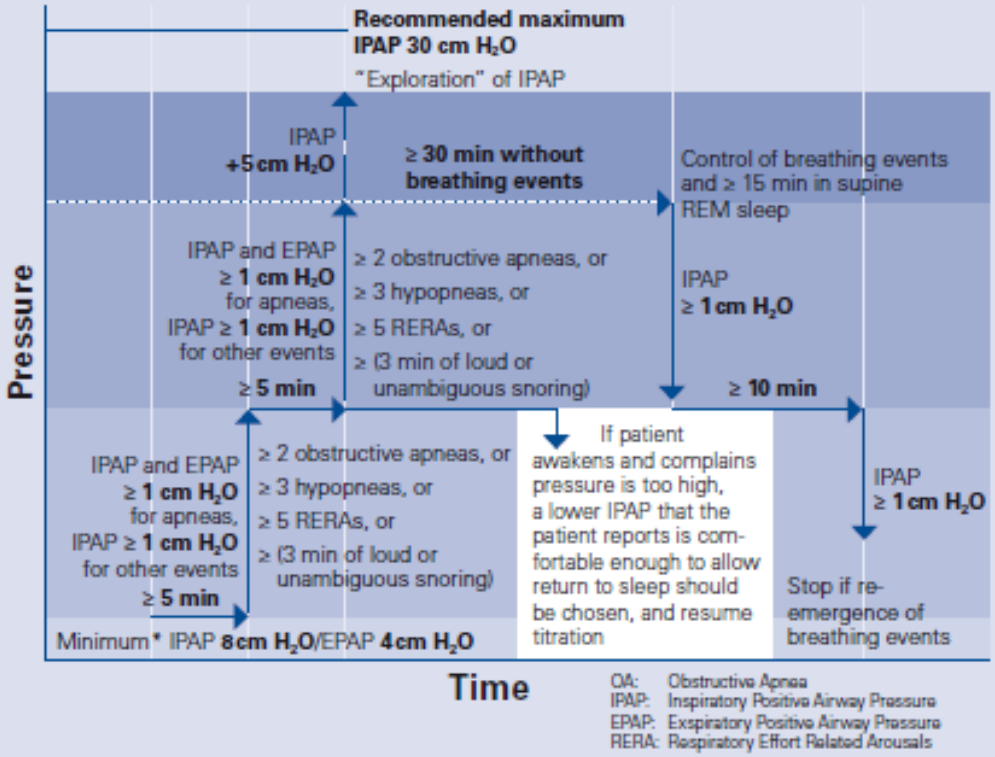
AASM Bilevel Titration Guidelines

BPAP Titration Algorithm for Patients ≥ 12 years during Full- or Split-Night Titration Studies



OA: Obstructive Apnea
IPAP: Inspiratory Positive Airway Pressure
EPAP: Exspiratory Positive Airway Pressure
RERA: Respiratory Effort Related Arousals

Note: Upward titration of IPAP and EPAP ≥ 1 cm H_2O for apneas and IPAP ≥ 1 cm for other events over ≥ 5 min periods is continued until ≥ 30 min without breathing events is achieved. A decrease in IPAP or setting BPAP in spontaneous-timed mode with backup rate may be helpful if treatment-emergent central apneas are observed.

* A higher starting IPAP and EPAP may be selected for patients with an elevated BMI and for retitration studies. When transitioning from CPAP to BPAP, the minimum starting EPAP should be set at 4 cm H_2O or the CPAP level at which obstructive apneas were eliminated. An optimal minimum IPAP-EPAP differential is 4 cm H_2O and an optimal maximum IPAP-EPAP differential is 10 cm H_2O.

Positive Airway Pressure Titration Task Force of the American Academy of Sleep Medicine; Kushida CA, Chediak A, Berry RB, Brown LK.; Gozal D; Iber C; Parthasarathy S; Quan SF; Rowley JA; Clinical Guidelines for the Manual Titration of Positive Airway Pressure in Patients with Obstructive Sleep Apnea; Journal of Clinical Sleep Medicine, Vol. 4, No. 2, 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]
- Patient has Central Sleep Apnea (CSA)
- 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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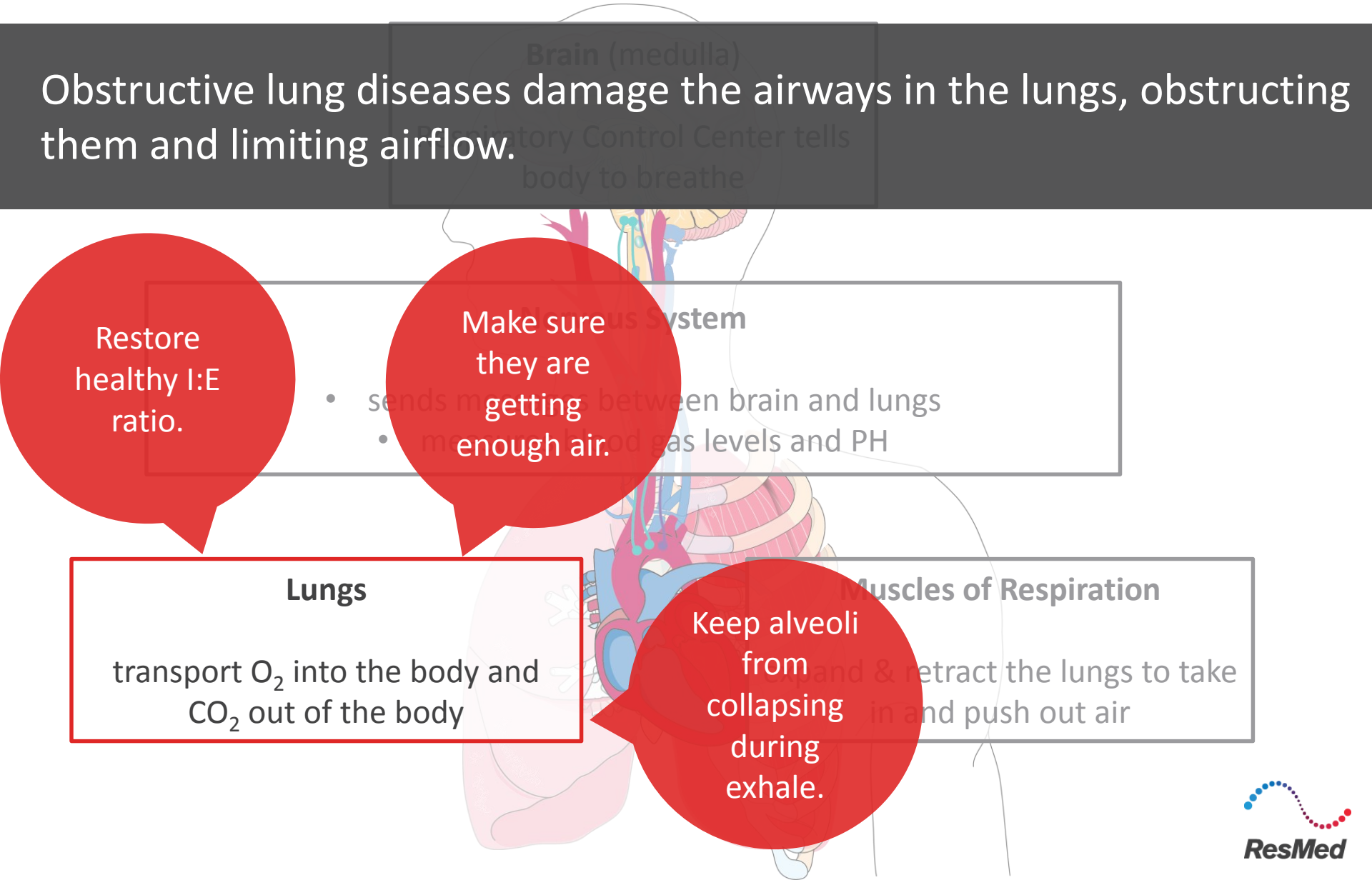
Goals of Bilevel Therapy for COPD

Obstructive lung diseases damage the airways in the lungs, obstructing them and limiting airflow.



Restore healthy I:E ratio.

Make sure they are getting enough air.

Lungs

transport O_2 into the body and CO_2 out of the body

Keep alveoli from collapsing during exhale.

Muscles of Respiration

& retract the lungs to take in and push out air

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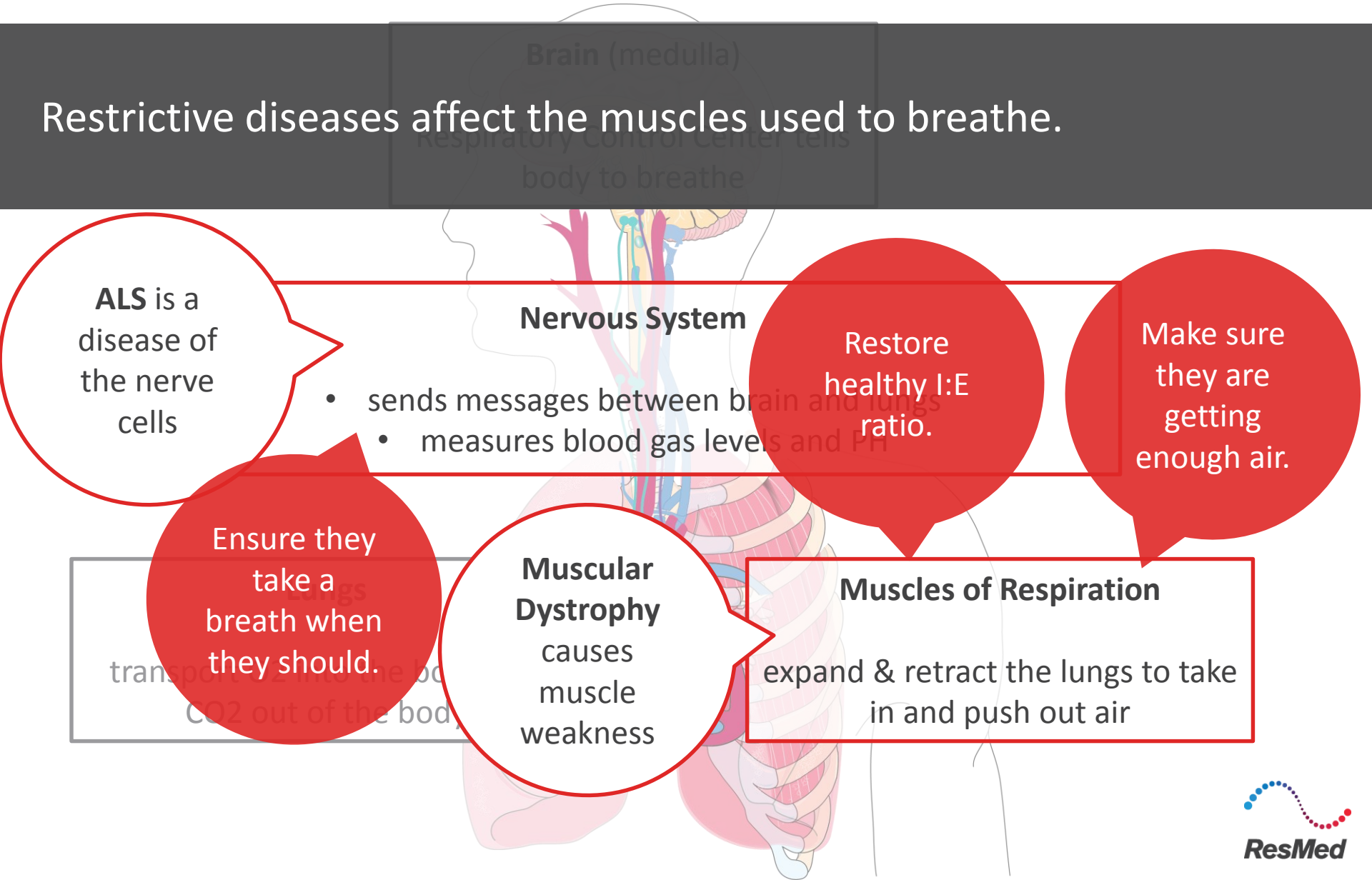
Goals of Bilevel Therapy for NMD

Restrictive diseases affect the muscles used to breathe.



ALS is a disease of the nerve cells

Nervous System

- sends messages between brain and lungs
- measures blood gas levels and PH

Restore healthy I:E ratio.

Make sure they are getting enough air.

Ensure they take a breath when they should.

Muscular Dystrophy causes muscle weakness

Muscles of Respiration

expand & retract the lungs to take in and push out air

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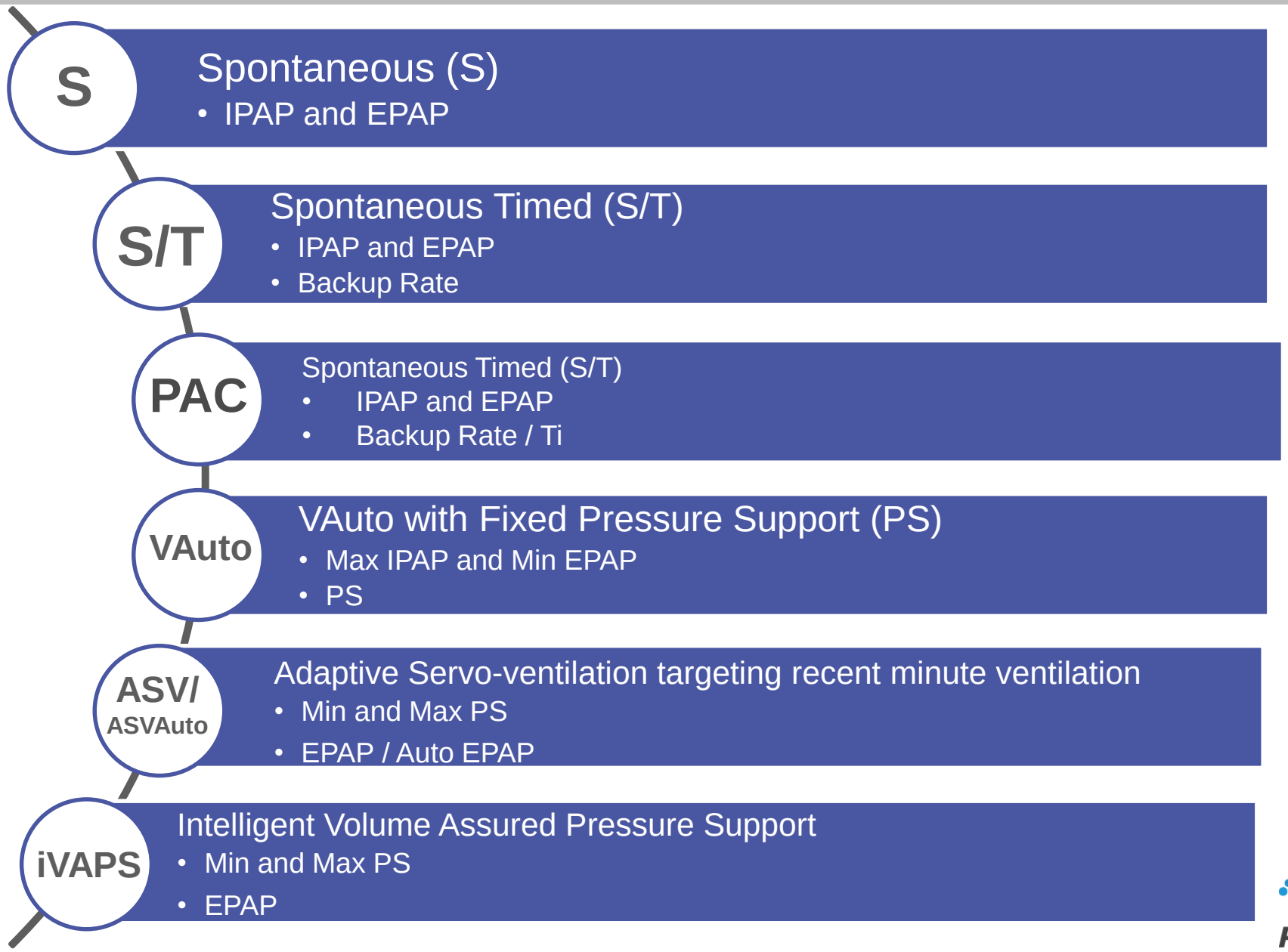
Bilevel Modes of Therapy



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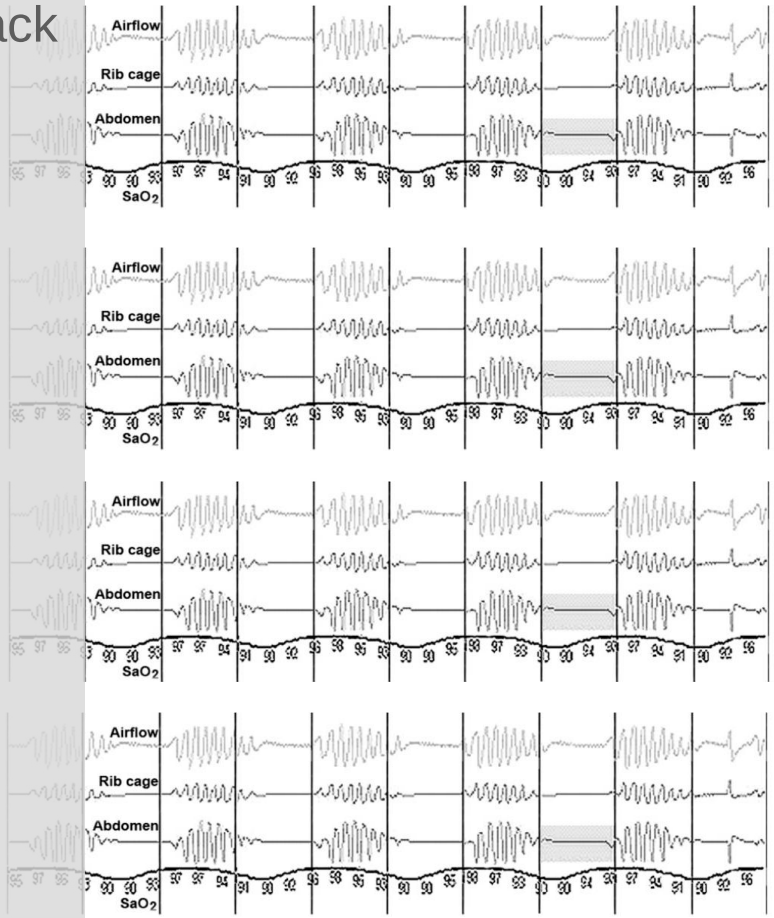
Adaptive Servo Ventilation

- The term “servo” is often used in reference to an automatic device that uses sensing feedback to correct the performance of a mechanism.

- **Therapeutical goals** of ASV are:
  - Counterbalance ventilator instability by automatically adjusting

    inspiratory pressure support
  - Maintain a stable minute ventilation
  - Stabilize arterial oxygen and carbon dioxide levels,
  - Reduce respiratory events
  - Address upper airway collapse



Javaheri S et al. *CHEST* 2014

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Who Are the Right Patients for ASV Therapy?

ASV Indication For Use

- The AirCurve 10 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.

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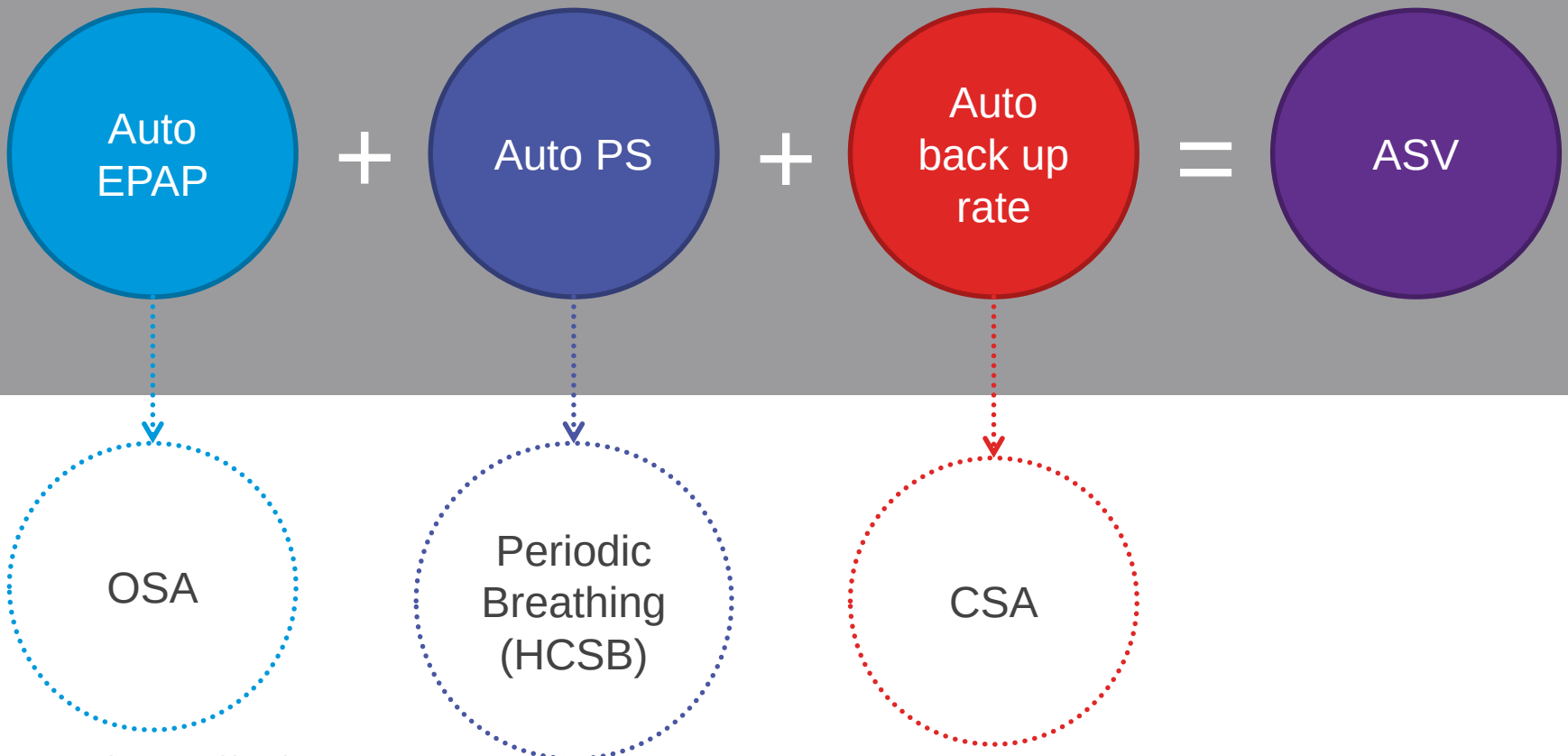
ASV Algorithm in Summary

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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AirCurve 10 ASV Algorithm

Learn:
- 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.

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

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

Optimize:
- Synchrony with breath mapping means device isn't getting in the way.
- Easy-Breathe replicates natural wave shape of normal breathing.

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Hypoventilation

Effective treatment relies on a balance between **improvements in arterial blood gas** tensions, **symptomatic benefits** and **tolerance of NIV**

Common Practices lead physicians to treat with fixed bilevel modes of therapy. However, fixed bilevel modes may present the following disadvantages:

- Asynchrony can occur at multiple points in bilevel therapy
- Incapable of automatically adjusting to ventilation changes due to sleep states, changing respiratory mechanics, changing respiratory rate or leak
- Patient may be unable to tolerate the continuous high pressures required for adequate ventilation
- Lack of compliance due to inappropriate settings
- Cannot guarantee volume, only pressures

Epstein K. *Respir Care* 2011

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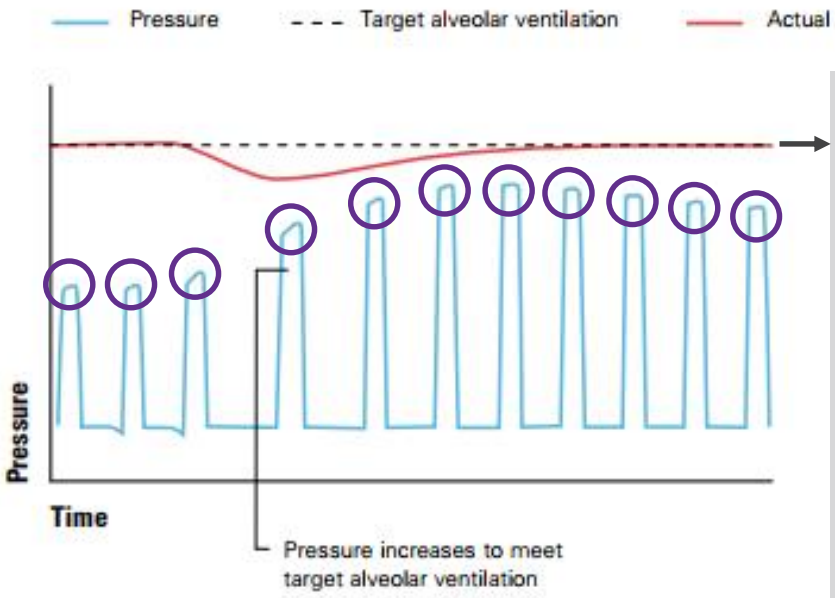
Volume Assured Therapy

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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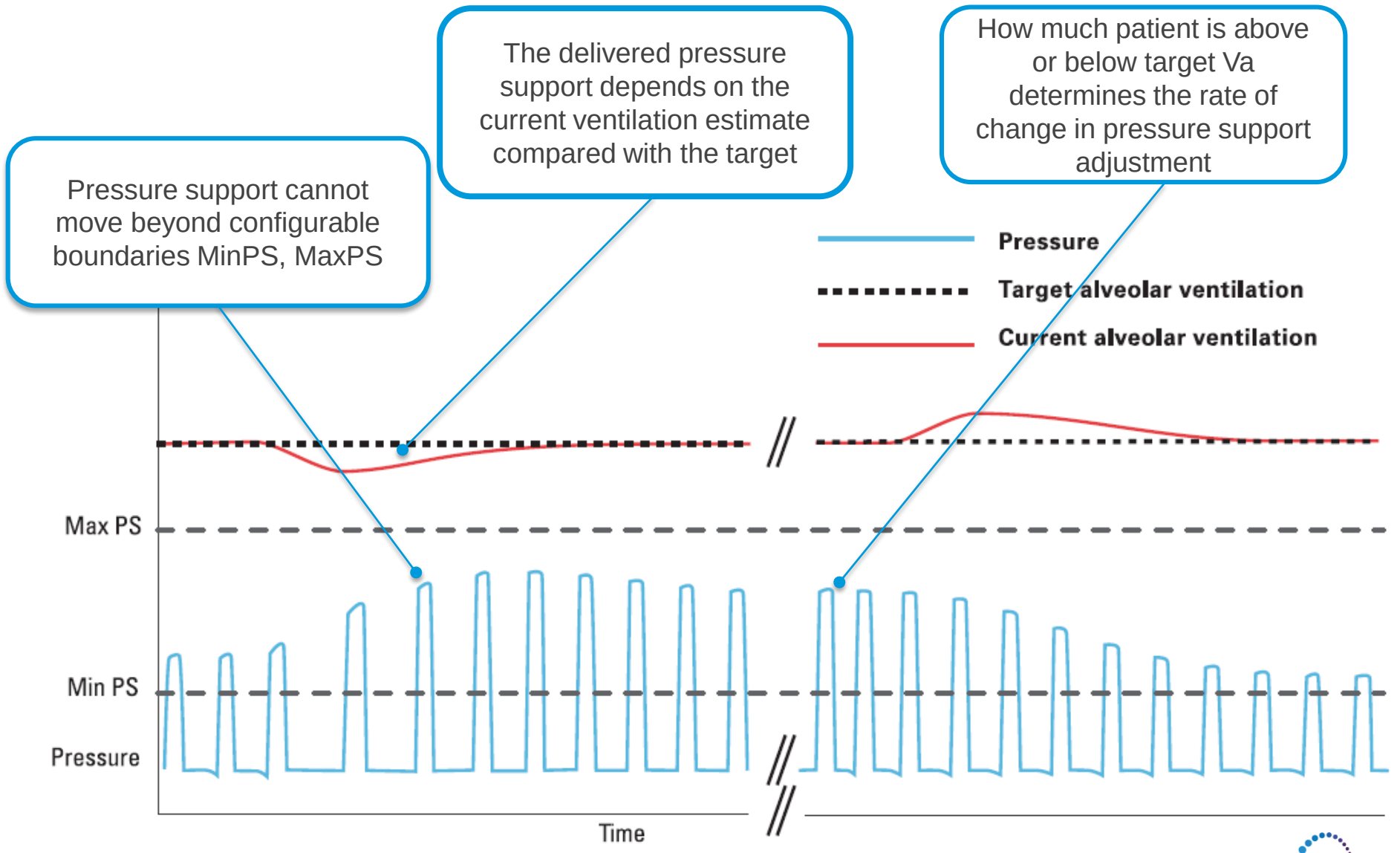
Automatically Adjusted Pressure Support



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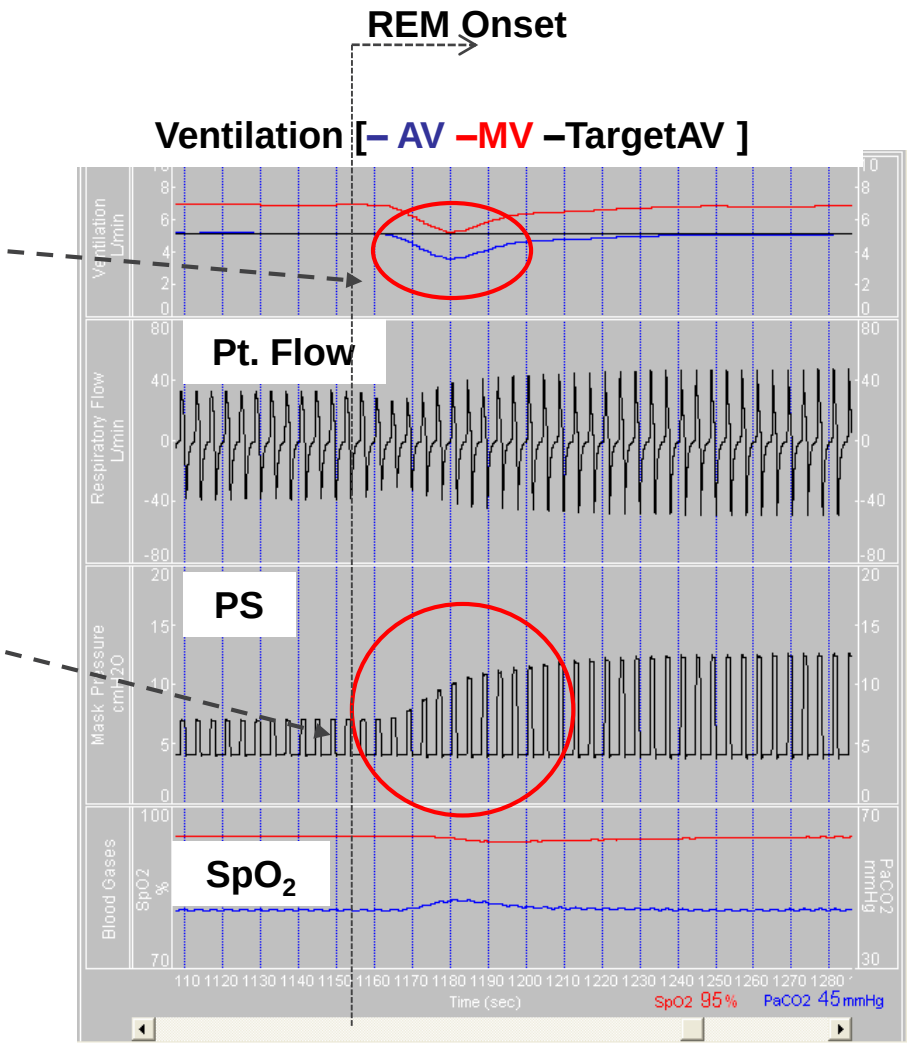
The iVAPS Algorithm: Example 1

Example:

- Alveolar Ventilation drops below target (patient moves into REM sleep)

- iVAPS rapidly increases pressure support until target Va is reached ensuring the patient is not under-ventilated



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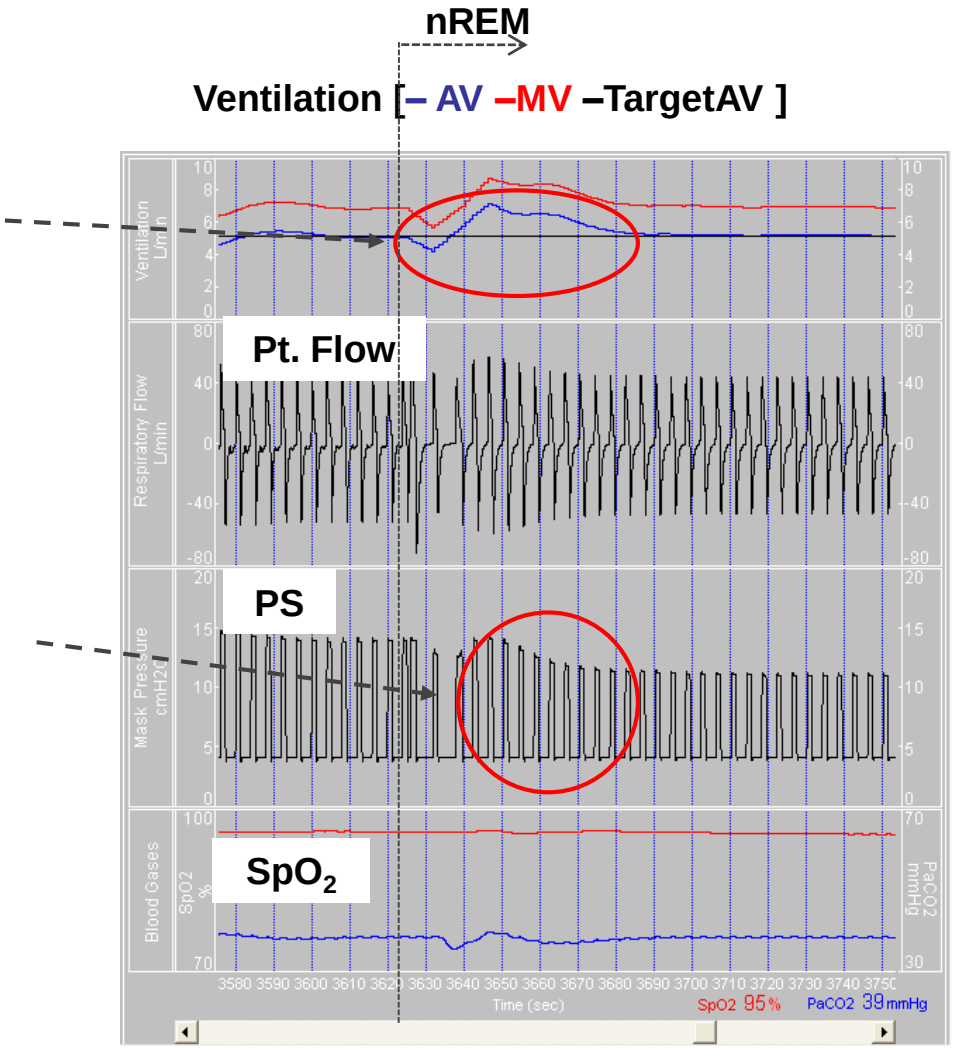
The iVAPS Algorithm: Example 2

Example :

- Alveolar ventilation increases above target (patients moves from REM to nREM sleep)

- iVAPS responds by rapidly decreasing pressure support to minimum support if necessary ensuring the patient is not over-ventilated.



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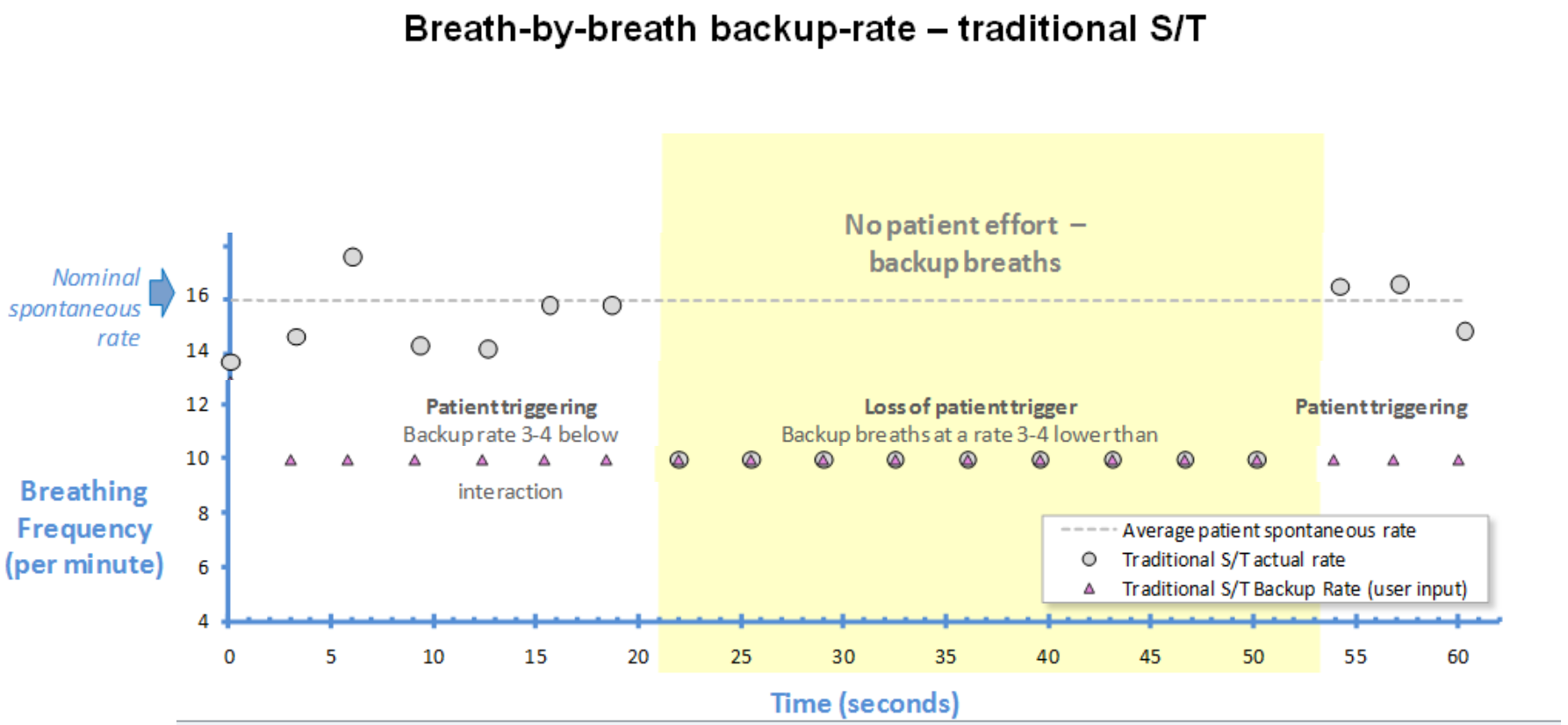
Traditional Fixed Backup Rate

- BR set too high – therapy may over-ride patient effort
- BR set too low – during apnea/hypoventilation, under ventilate patient



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Synchrony Challenges

NIV patients often remain ineffectively treated:

- 40% of NIV patients experience asynchrony in 10% or more of their breaths

- Patients can experience
  - Discomfort
  - Ineffective ventilation
  - Treatment refusal

Vignaux L et al. *Intensive Care Med* 2009

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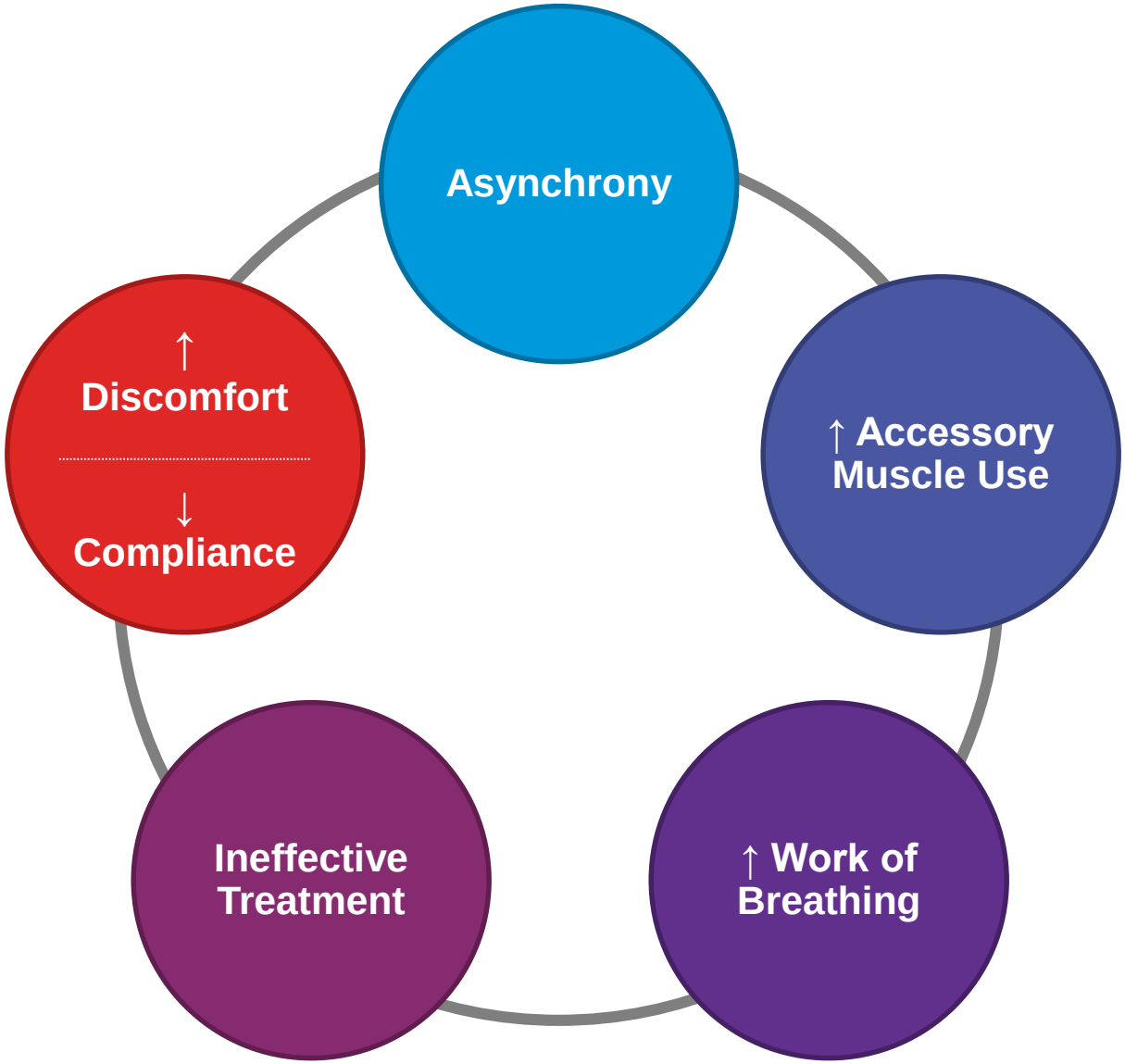
Asynchrony



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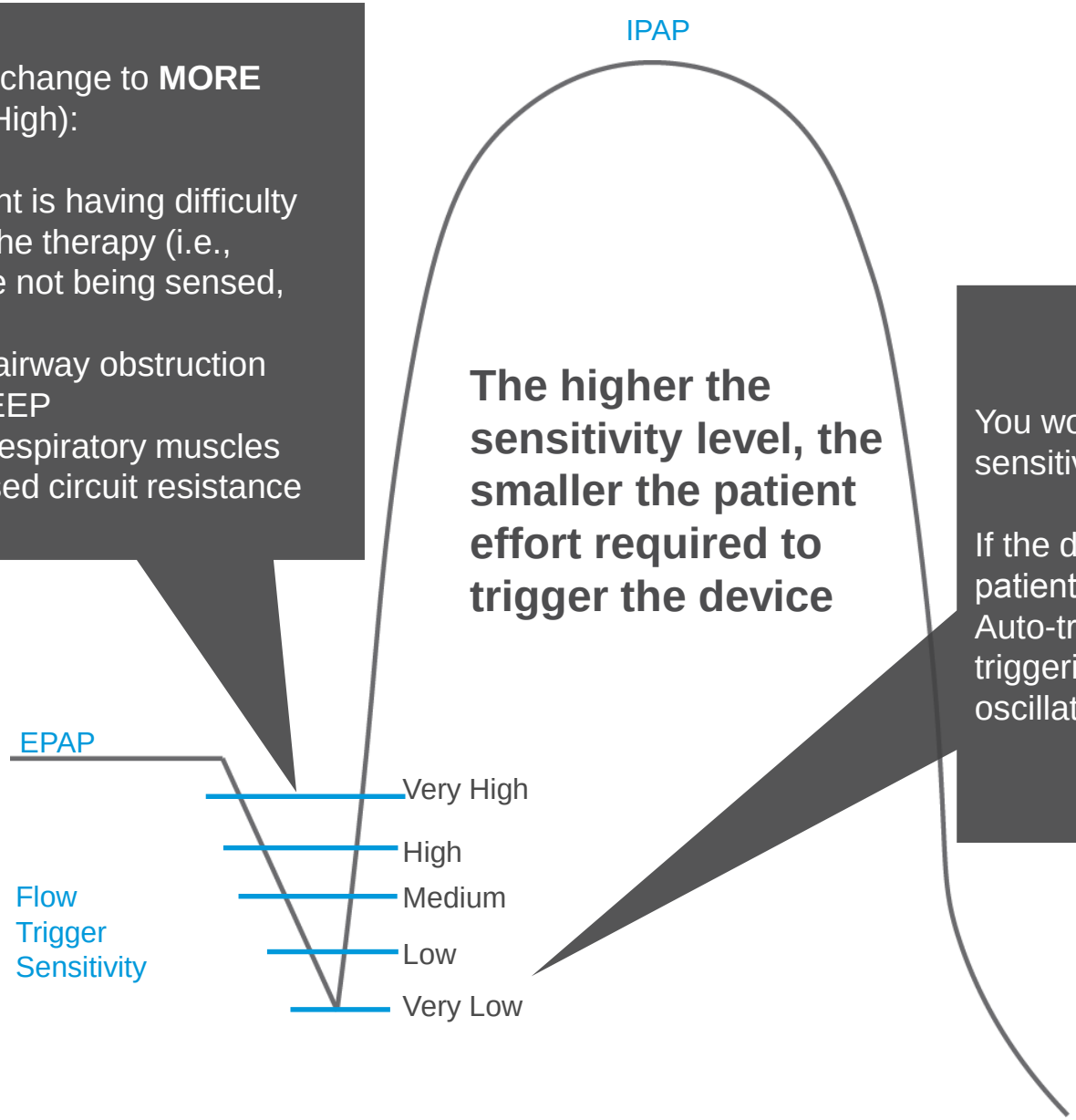
1. Transition to Inspiration: Trigger Sensitivity Settings

You would change to **MORE** sensitive (High):

If the patient is having difficulty triggering the therapy (i.e., breaths are not being sensed, due to:

- Upper airway obstruction
- AutoPEEP
- Weak respiratory muscles
- Increased circuit resistance



The higher the sensitivity level, the smaller the patient effort required to trigger the device

You would change to **LESS** sensitive (Low):

If the device is too sensitive to the patient, causing “auto-triggering. Auto-triggering or noticeable extra triggering may be due to cardiac oscillations.

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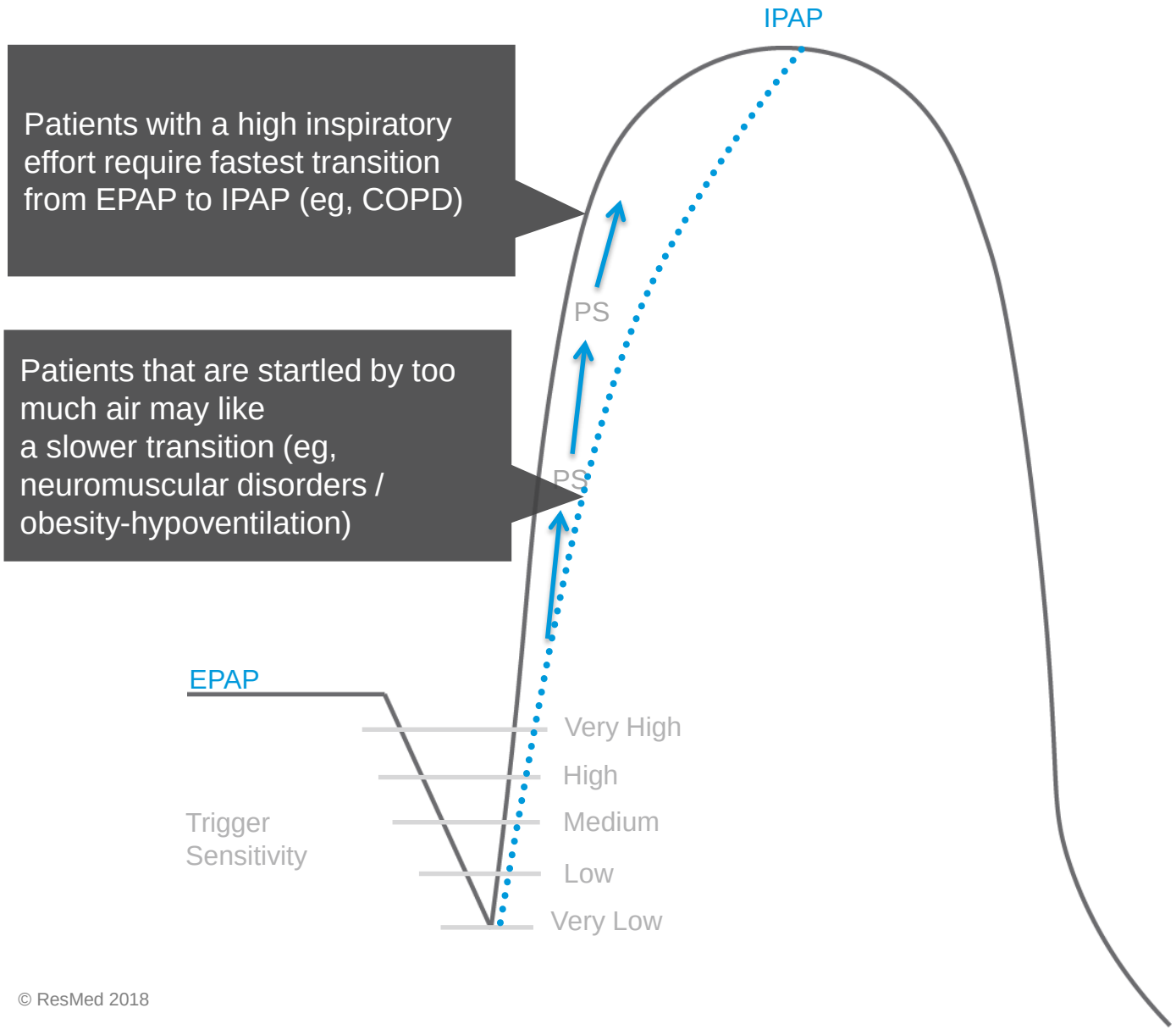
2. During Pressurization: Rise Time



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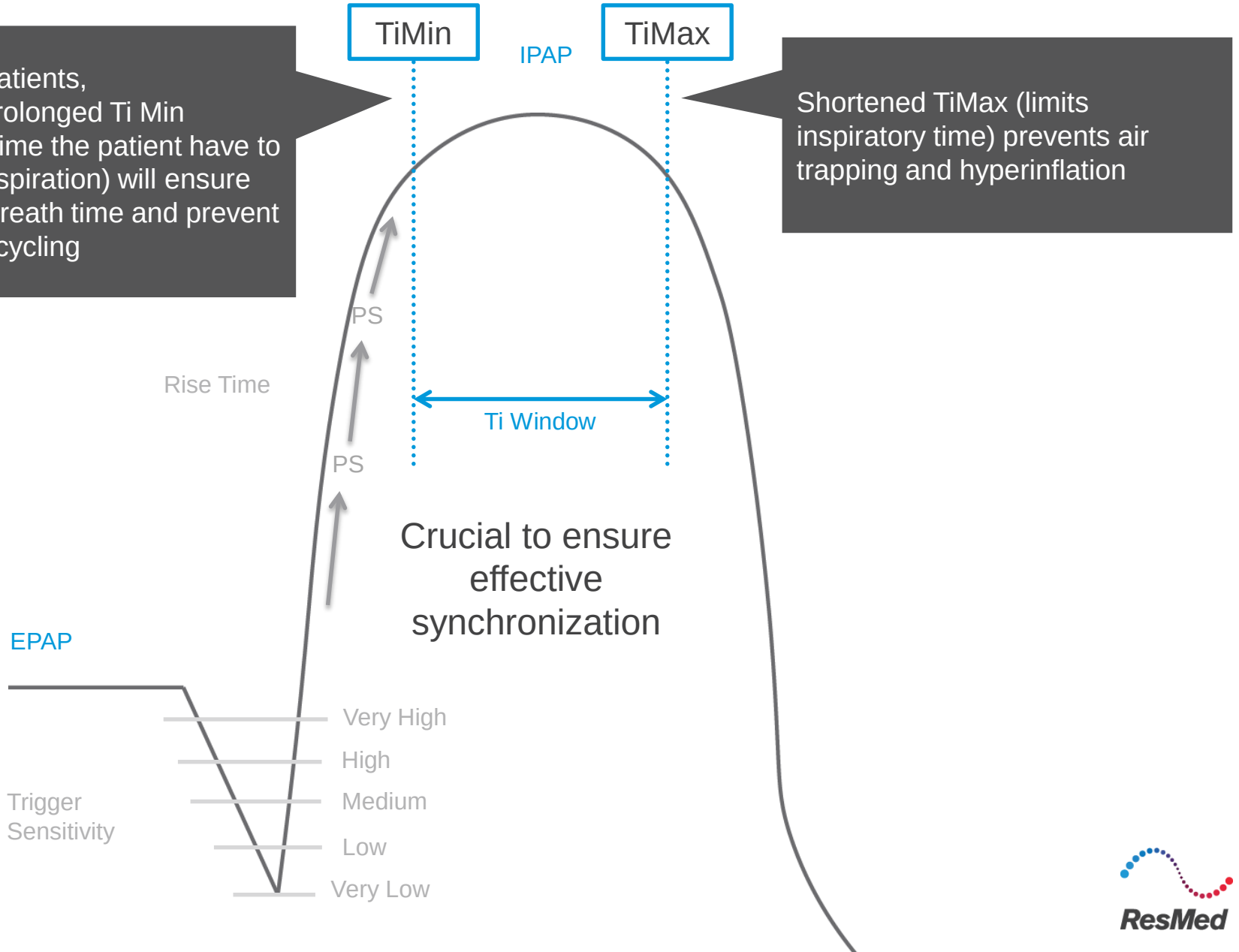
3. During Inspiration: Ti Controls

For NMD patients,
Setting a prolonged Ti Min (minimum time the patient have to spend in inspiration) will ensure adequate breath time and prevent premature cycling

Shortened TiMax (limits inspiratory time) prevents air trapping and hyperinflation



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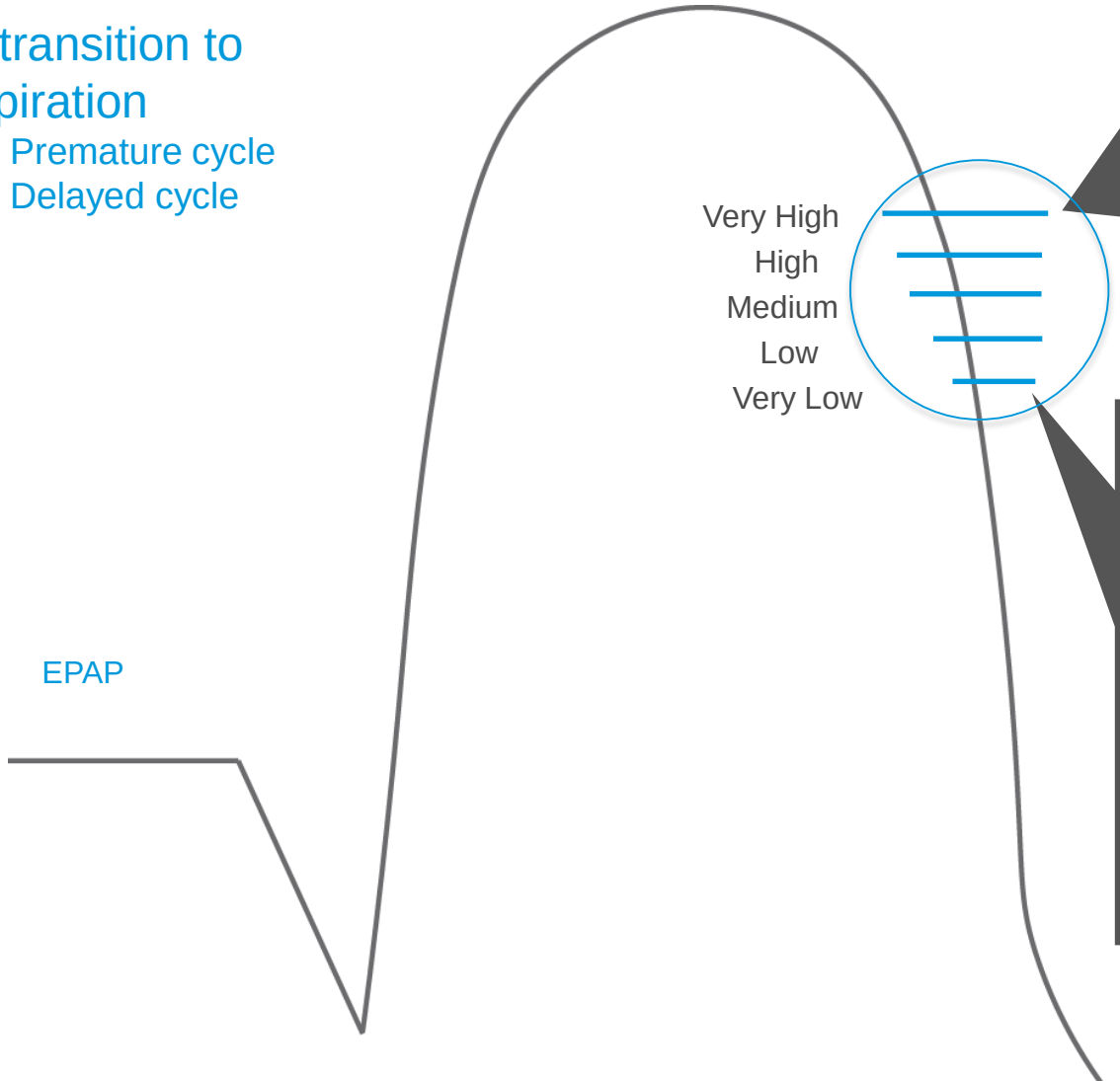
Types of Asynchrony

4. At transition to expiration

- Premature cycle
- Delayed cycle



May need to be adjusted to be **MORE** sensitive…

Earlier spontaneous cycling may be helpful in some patients with severe acute exacerbation of COPD who **require exhalation to occur sooner**

May need to be made **LESS** sensitive…

In patients with restrictive disorders. A frequent complaint in these patients is early cycling (they haven't finished inspiring and the machine ended inspiration) giving a feels that **exhalation needs to occur later**

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RAD Guidelines – Qualification Criteria

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Respiratory Assist Device (RAD) Qualifying Guidelines

CMS revision effective date: December 2014

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 $PaCO_2 \geq 52$ 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.

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

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**.
ResMed reimbursement hotline, dial **1-800-424-0737** and select **option 4.**

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