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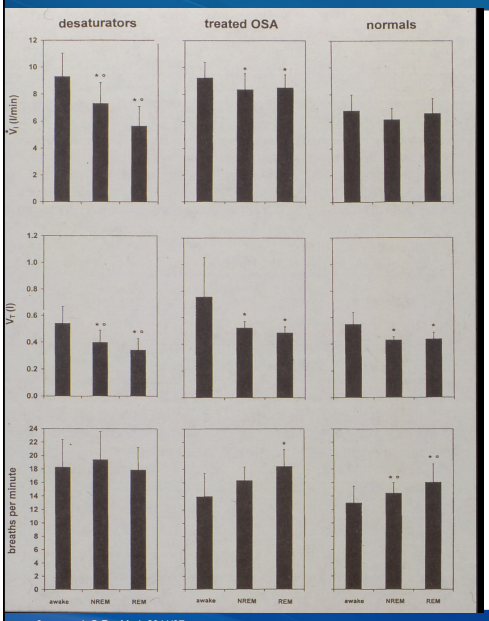
## Respiratory Physiology During Sleep



## Normal Physiology During Sleep

- Small decrease in metabolic demands
- Significant increase in load
  - Increased upper airways resistance
  - Displacement of abdominal contents
- Loss in muscle tone
- Blunted response to oxygen and carbon dioxide



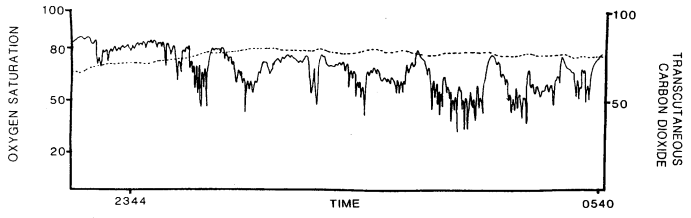

- Typically a small decrease in ventilation during sleep
- Increased load is counteracted by increased effort
- Reductions in tidal volume compensated by increased respiratory rate

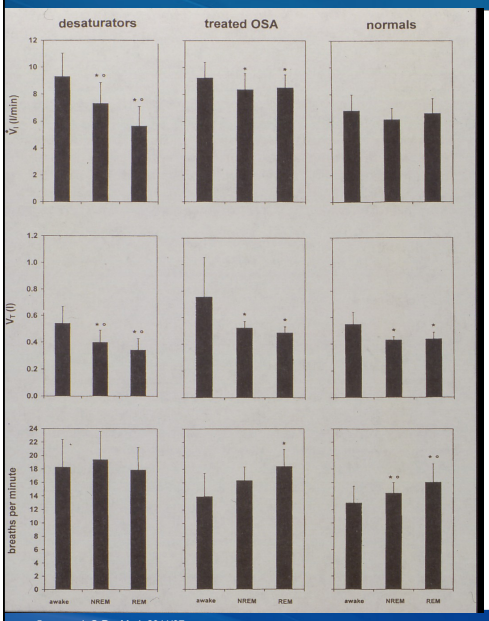
**Becker et al. *AJRCCM* 1999**



## Why Hypoventilation Occurs

- REM sleep is the most vulnerable period
  - Upper airways resistance and hypotonia
- When demand cannot be met hypoventilation occurs causing sleep disruption and increased carbon dioxide levels
- Gradual resetting of the respiratory drive over time






- Respiratory failure pts have a much larger decrease in ventilation
- Further reduction in REM sleep
- Decreasing tidal volume not counteracted by an increased respiratory rate



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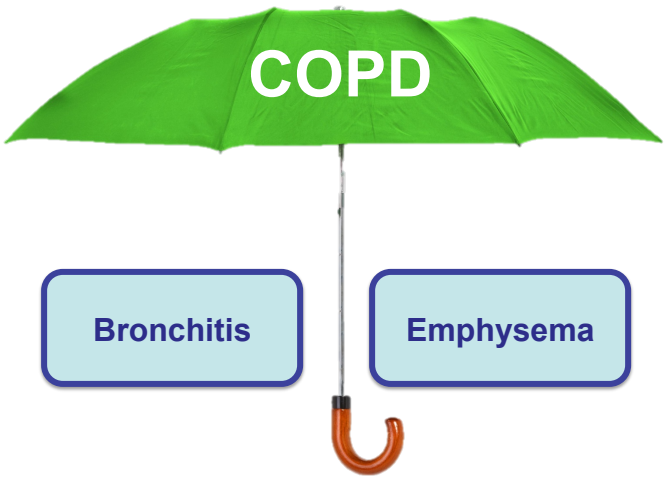
## COPD

## COPD Defined




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



## COPD Defined

Chronic obstructive pulmonary disease (COPD) is a preventable and treatable disease.

COPD is characterized by airflow limitation that is not fully reversible.

Airflow limitation is usually progressive and is associated with an abnormal inflammatory response of the lungs to noxious particles or gases.

COPD is primarily caused by cigarette smoking.

Gold Executive Summary 2007

## COPD Market Size

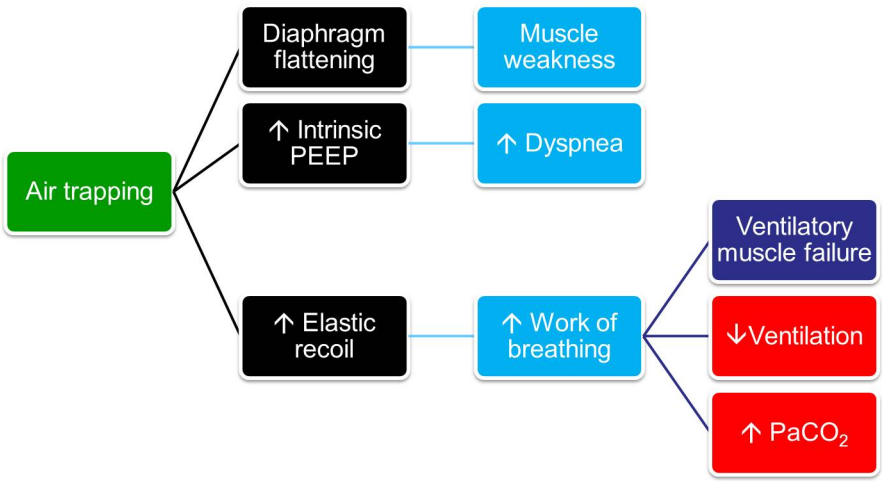
### What is the size of the market?

- Over 12M people in the U.S. diagnosed with COPD[1]
- Estimated 12M to be undiagnosed with COPD[1]
- Third leading cause of death in the U.S.[1]
- Major leading cause of disability[1]
- Estimated 49.9B direct and indirect costs to healthcare system in 2010[2]
- Around 20% of COPD Medicare beneficiaries are readmitted to the hospital within 30 days of discharge[3]
- Almost 50% of elderly people (≥ 65 years) have at least three comorbidities, and 20% have five or more comorbidities[4]

1. National Heart, Lung and Blood Institute 2011
2. American Lung Association 2010
3. Jencks et al. *New Eng J Med* 2009
4. Fabbri et al. *Eur Respir J* 2008



## Pathophysiology of COPD




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

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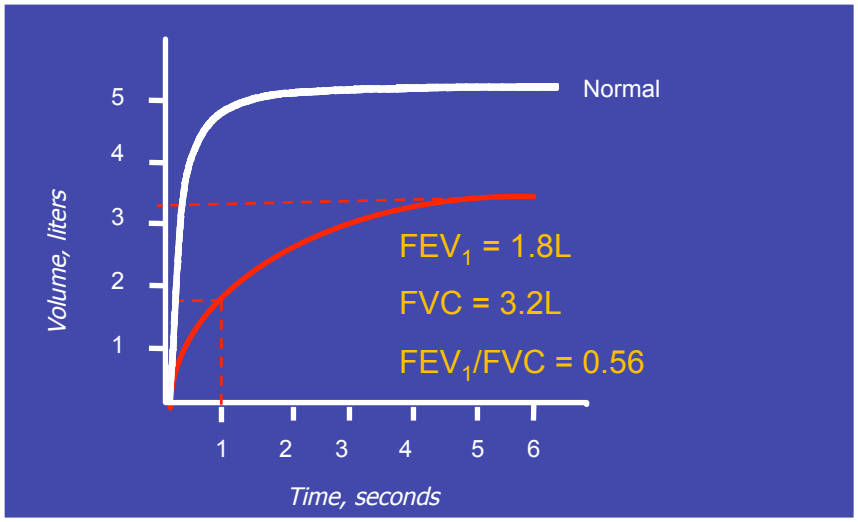
## Diagnosis and Treatment of COPD Patients



## COPD Patient Spirometry



## Treatment for COPD Patients

- Smoking cessation
- Pulmonary rehabilitation
- Medication
  - **Bronchodilators**
  - **Corticosteroids**
  - **Oxygen**
  - **Antibiotics**
- Lung volume reduction surgeries
- Noninvasive ventilation



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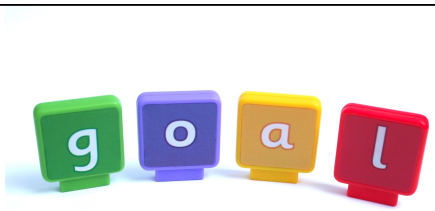



## Goals of Non-Invasive Ventilation (NIV)

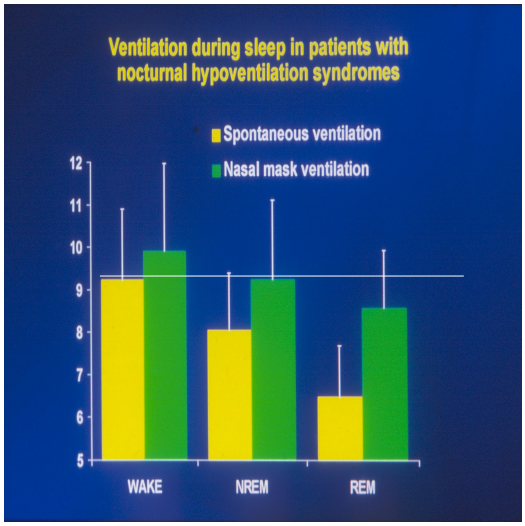
## How Does NIV Work?

- ✓ Prevents nocturnal hypoventilation
- ✓ Improves ventilation
- ✓ Stabilizes upper airway
- ✓ Rests respiratory muscles
- ✓ Decreases daytime sleepiness by correcting sleep architecture



## Non-invasive Ventilation

- Minimize the difference between awake and REM sleep ventilation
- On therapy, ventilation during nREM is close to awake ventilation.
- PS leads to a degree of hyperventilation during awake periods.



## NIV Outcomes

Decreased mortality

Reduced hospital admissions

Improved blood gases

**Studies have shown the use of NIV in COPD and ALS patients will contribute to improved quality of life.**



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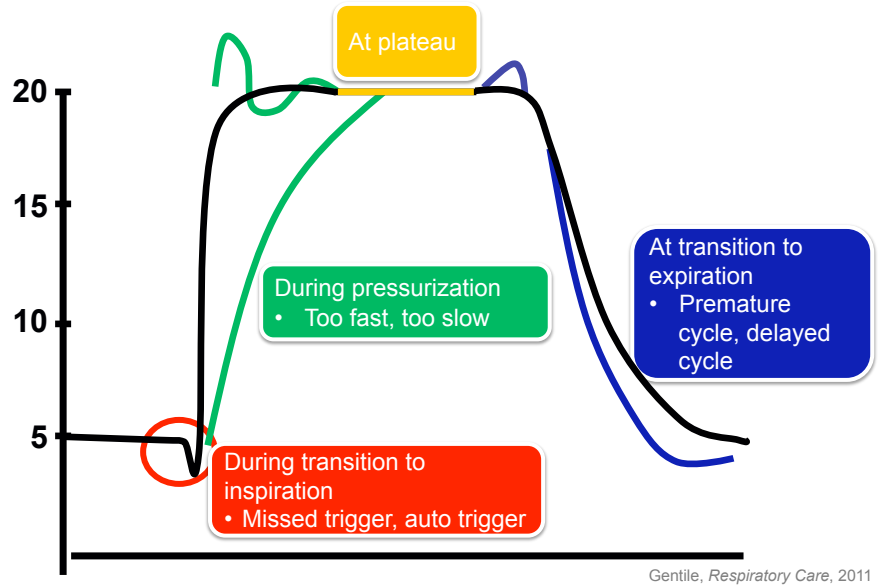
## Using Ti Controls to Protect Every Breath

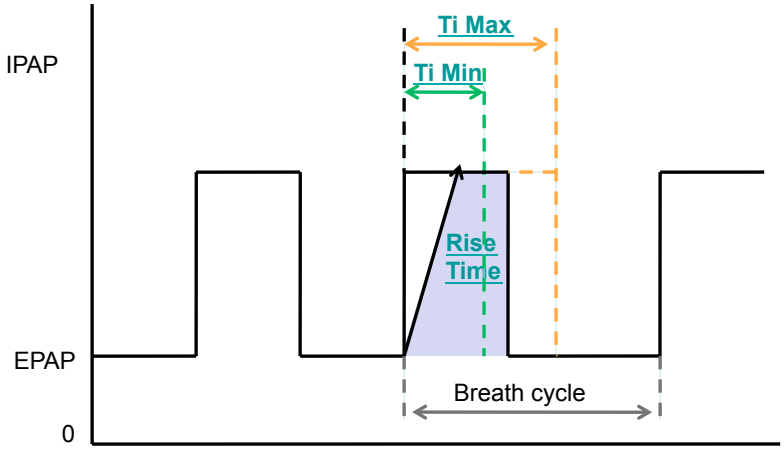
## Types of Asynchrony



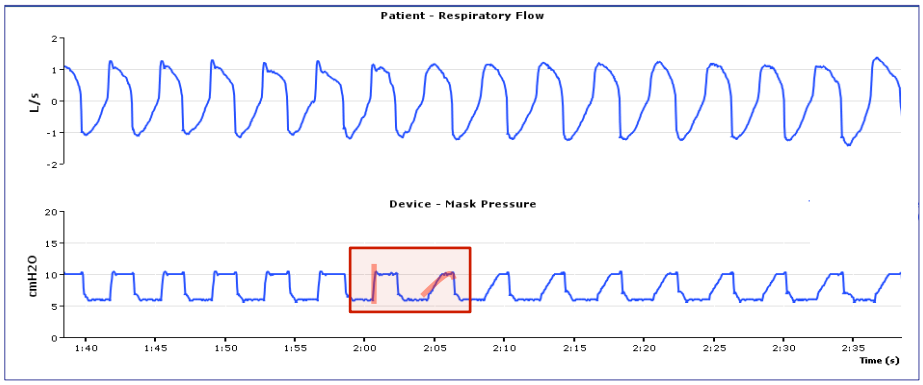

Gentile, *Respiratory Care*, 2011



## How Can Ti Control Help Increase NIV Tolerance?



## Rise Time: How Quickly Pressure Increases EPAP to IPAP




**Problem: Patient says "Pressure is too STRONG!"**

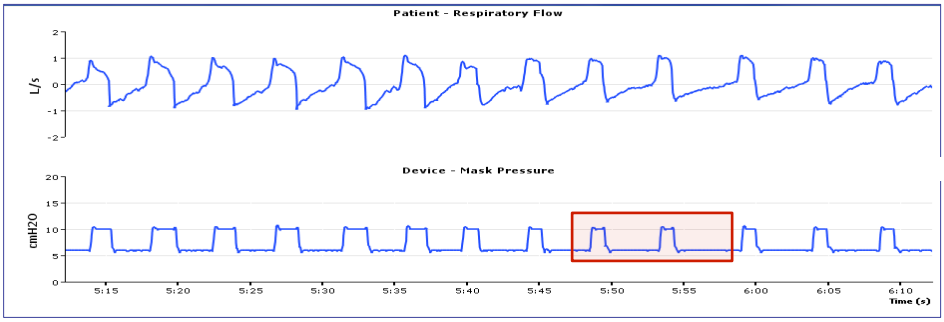
**Solution: Increase Rise Time**



## Obstructive Pulmonary Disease

- COPD patients typically require a longer expiratory time to avoid or minimize air trapping.
- Failure to cycle to expiration can occur due to high airway resistance and/or a high leak condition.
- A safety system, Ti Max, is available in all VPAP products and the Stellar to prevent late cycling.

## Ti Max: Maximum Time the Device Will Remain in IPAP




**Problem:** Patient requires longer expiratory time (i.e. COPD)

**Solution:** Best option – Shorten Ti Max time

Additional options – Select higher cycle sensitivity,
Select faster Rise Time

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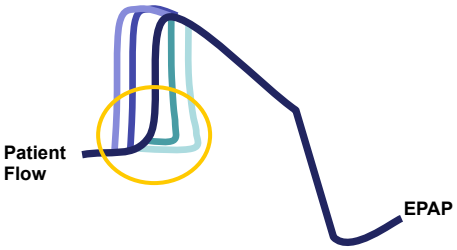
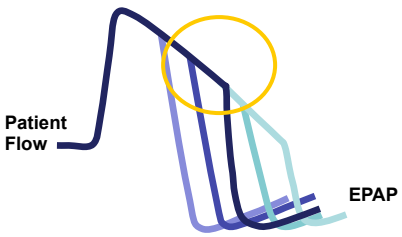
## Trigger & Cycle Sensitivities

**Adjustable Trigger Sensitivity**




| | | |
|---|---|---|
| Very High | Quick to trigger | 2.4 L/min |
| High | More sensitive | 4 L/min |
| Med | Default | 6 L/min |
| Low | Less sensitive | 10 L/min |
| Very Low | Slow to trigger | 15 L/min |

**Adjustable Cycle Sensitivity**




| | | |
|---|---|---|
| Very High | Quick to cycle | 50% of peak flow |
| High | More sensitive | 35% |
| Med | Default | 25% |
| Low | Less sensitive | 15% |
| Very Low | Slow to cycle | 8% |

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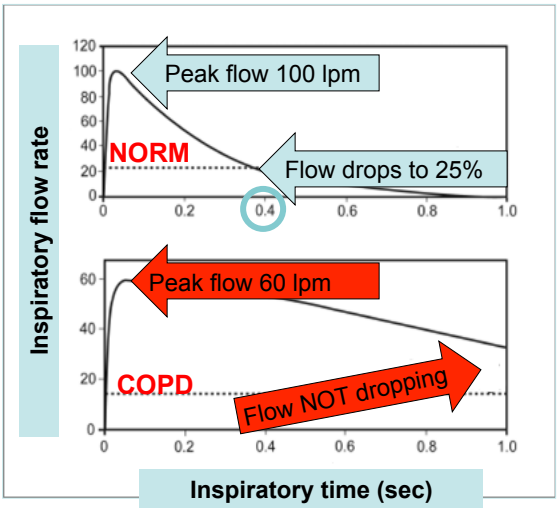
## Cycling is Not "One Size Fits All"

"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."



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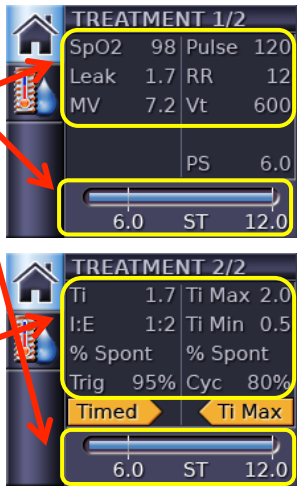
## NIV Monitoring

## Treatment Screen

- Pressure bar graph is displayed at the bottom of the treatment screens
- Patient data (Leak, RR, MV and Vt) are displayed in Treatment screen 1
- Patient-ventilator synchrony (Ti, I:E, % Spont Trig, % Spont Cyc and trigger/cycle indicators) can be easily identified in Treatment screen 2



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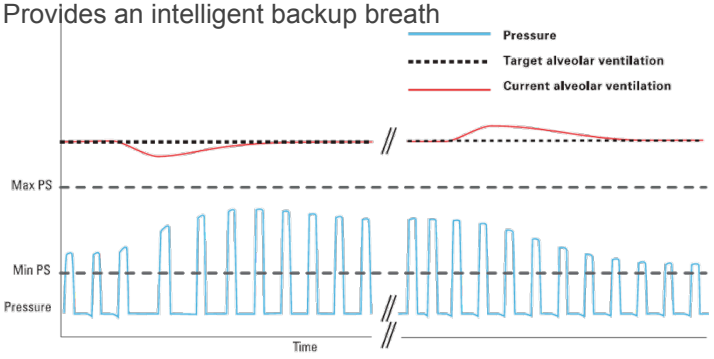
**ResMed VPAP ST-A with iVAPS**

iVAPS algorithm

## iVAPS (intelligent Volume Assured Pressure Support)

- Intelligent. Personalized. Automatic.
- iVAPS is designed to maintain a preset target alveolar minute ventilation
  - Monitors delivered ventilation
  - Adjusts pressure support
  - Provides an intelligent backup breath






## How iVAPS Maintains Alveolar Ventilation

**Two mechanisms** independent of one another

| | |
|---|---|
| **Variable Pressure Support to guarantee Alveolar Ventilation** | **iBR: intelligent Back-up rate** |

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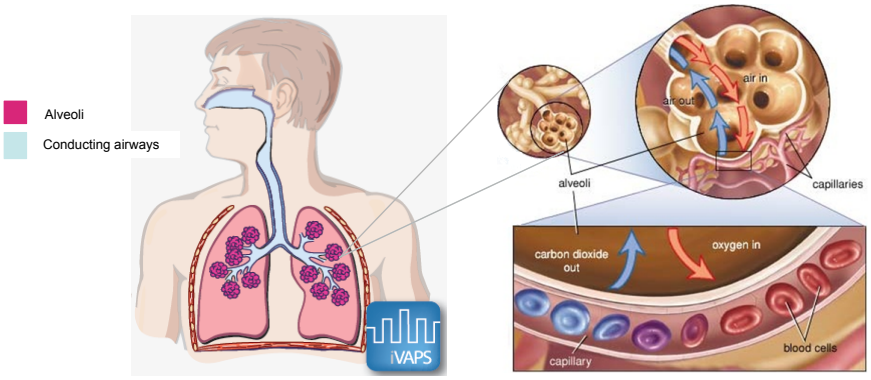
## Why Alveolar Ventilation?



## Alveolar Ventilation

- Gas exchange only occurs at alveolar level
  - We have a continuous demand for a supply of $O_2$ and removal of $CO_2$




Conducting airways do NOT participate in gas exchange

## Anatomical Deadspace

- Height is used to calculate anatomical deadspace (Vd) for each breath of air (Tidal Volume)
  - Example Vd : 120 ml for 1m75 or 70 inches

| Height cm | 125 | 135 | 145 | 155 | 165 | 175 | 185 | 195 |
|---|---|---|---|---|---|---|---|---|
| Height in inches | 50 | 54 | 58 | 62 | 66 | 70 | 74 | 78 |
| Vd | 55 | 65 | 75 | 90 | 105 | 120 | 135 | 155 |



## Why Alveolar Ventilation?

| RR | 10 | 12 | 15 | 20 | 24 |
|---|---|---|---|---|---|
| Vt (mls) | 500 | 500 | 500 | 500 | 500 |
| MV (l/min) | 5.0 | 6.00 | 7.5 | 10.0 | 12.0 |
| Va (l/min) | 3.9 | 4.68 | 5.85 | 7.0 | 8.4 |

MV/Vt can be an unreliable target/indicator of good ventilation :

- At decreased RR, adequate Va cannot be assured
- At higher RR, the patient will be over ventilated.

Note: Ht = 170 cm; VTd 110ml

## VPAP ST-A: iVAPS - Why Alveolar Ventilation?

| RR | 10 | 12 | 15 | 20 | 24 |
|---|---|---|---|---|---|
| Vt (mls) | 690 | 595 | 500 | 405 | 358 |
| MV (l/min) | 6.9 | 7.14 | 7.5 | 8.1 | 8.58 |
| Va (l/min) | 5.7 | 5.7 | 5.7 | 5.7 | 5.7 |

Alveolar Ventilation (Va) is a good target and indicator of effective gas exchange

Note: Ht = 175 cm; Vd 120ml

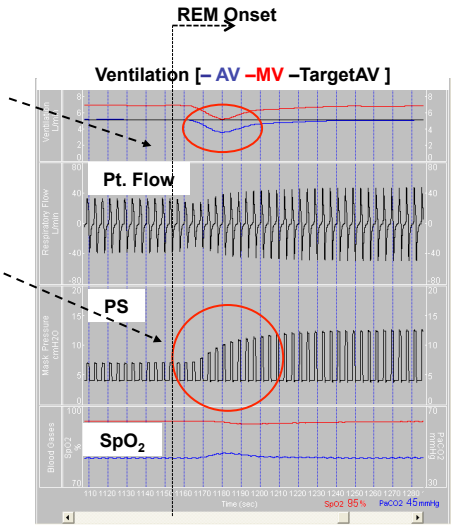


## The iVAPS Algorithm: Example

Example:

**Alveolar Ventilation drops**

- patient moves into REM sleep
- iVAPS rapidly increases PS until target Va is reached

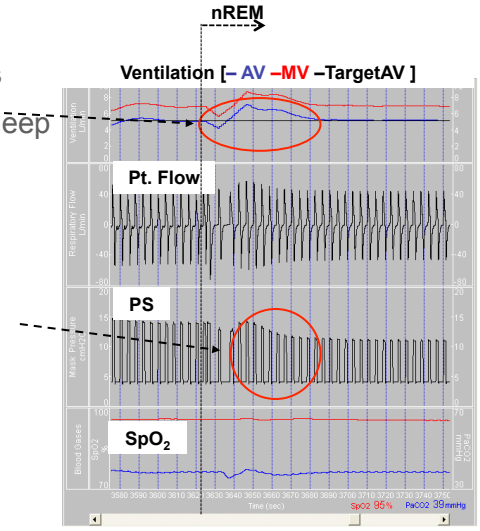


## The iVAPS Algorithm: Example

Example :

**Alveolar Ventilation increases**

- patients moves into nREM sleep
- iVAPS responds by rapidly decreasing PS

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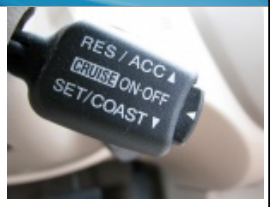
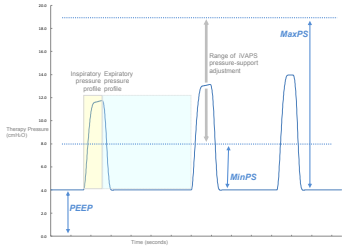
## iVAPS– Like cruise control




- Just like cruise control on a car you set the "speed you want" = alveolar ventilation and the rest is automatic:
  - downhill PS ↓ (awake breathing, lateral position..)
  - uphill : PS ↑ (REM sleep, supine position...)
  - Flat: PS ≈ (normal breathing)

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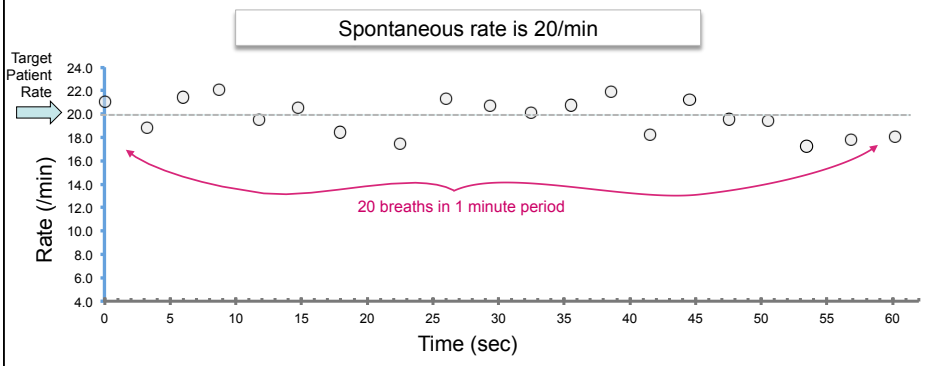
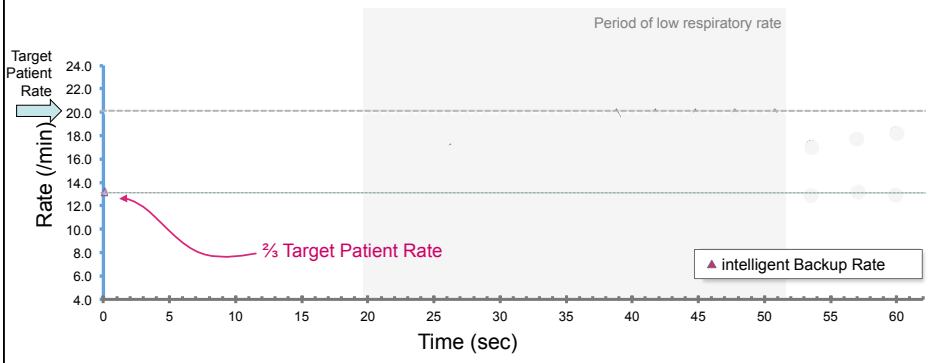
## iVAPS – intelligent Backup Rate (iBR)

- ***iVAPS*** offers a new method of providing backup breaths
- ***Improves patient- ventilator synchrony, <u>WITHOUT</u> compromising ventilation***
- ***Target Patient Rate*** set to the spontaneous rate during ventilation

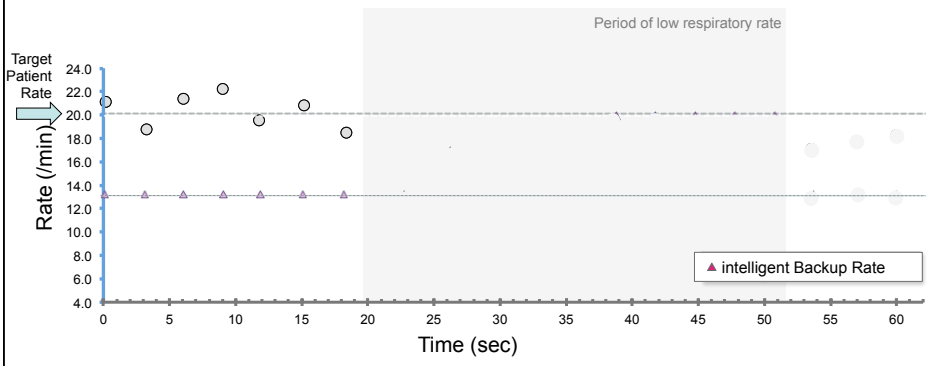





## iVAPS – intelligent Backup Rate (iBR)



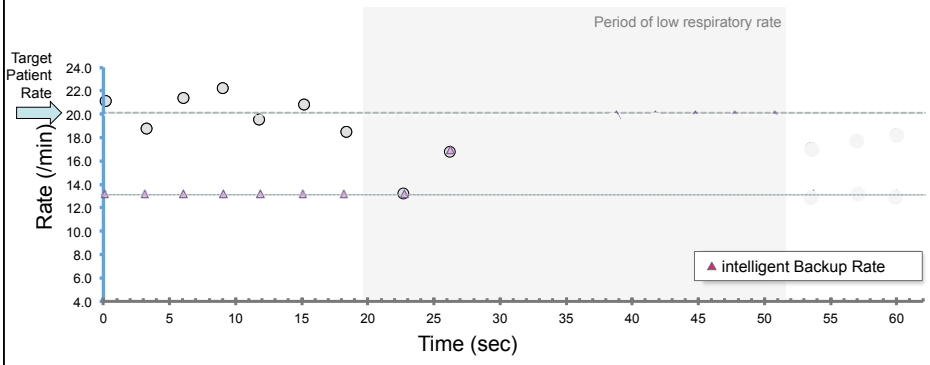
## iVAPS – intelligent Backup Rate




***iBR*** remains *out-of-the-way* at ⅔ ***spontaneous rate***, whenever patient spontaneously triggers above 2/3 of the Target rate

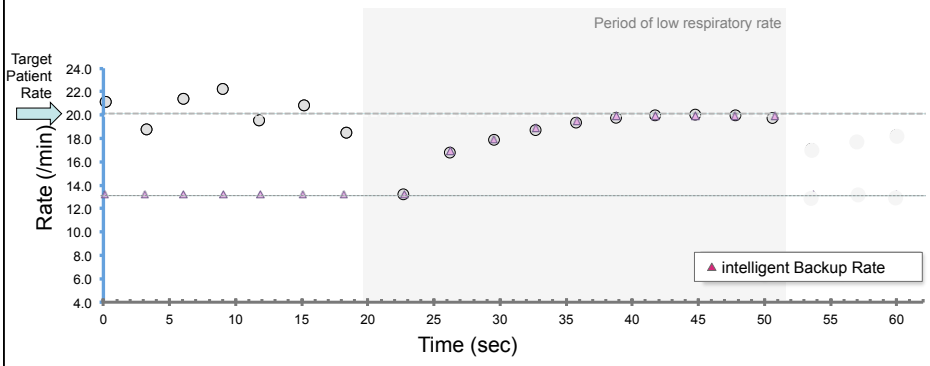


## iVAPS – intelligent Backup Rate




Once the patients rate reaches the min back-up rate, (2/3 of target) ***iBR*** increases towards patients ***spontaneous rate*** to ***maintain alveolar ventilation***

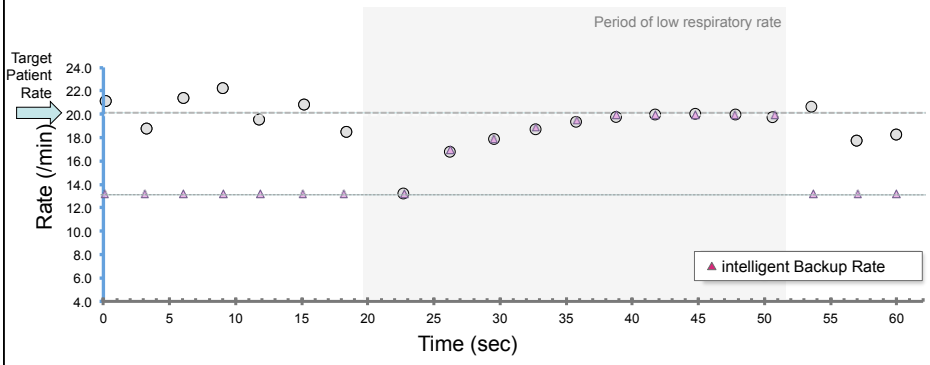
## iVAPS – intelligent Backup Rate




The increase towards the patient's spontaneous rate provides the best opportunity to maintain ventilation during periods of ***low respiratory rate or apnea***

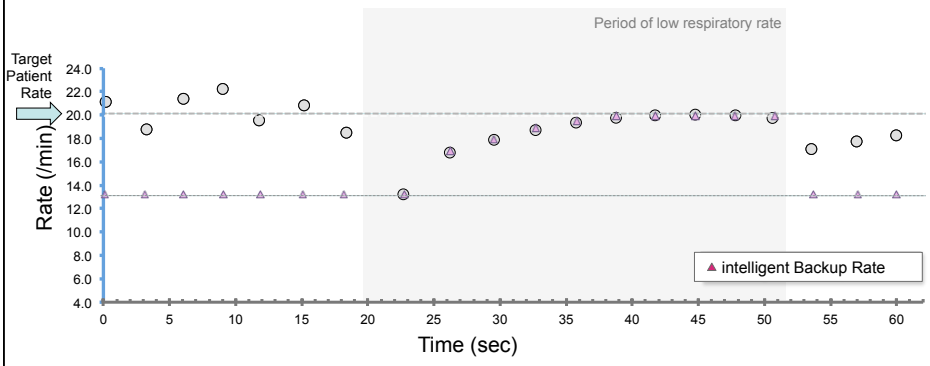


## iVAPS – intelligent Backup Rate




Once ***spontaneous triggering returns***, iBR drops back to ⅔ ***target/spontaneous rate***

## iVAPS – intelligent Backup Rate




The combined response; ***Targeting Alveolar Ventilation*** and ***intelligent*** provision of ***backup breaths***, ensures iVAPS can maintain ventilation when required, while maintaining the optimal level of pressure support



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## Qualifying Patients

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# Respiratory Assist Device (RAD) Qualifying Guidelines

CMS guidelines
February 2011

## I. Restrictive Thoracic Disorders

**Documentation of neuromuscular disease or severe thoracic cage abnormality** → **Perform one of the following:**
- **ABGs** (done while awake) $PaCO_2$ ≥ 45 mm Hg (patient's prescribed $FiO_2$) or
- **Sleep oximetry** Oxygen saturation ≤ 88% for ≥ 5 minutes, minimum 2 hours recording time (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) $PaCO_2$ ≥ 52 mm Hg (patient's prescribed $FiO_2$) → **Sleep oximetry** Oxygen saturation ≤ 88% for ≥ 5 minutes, minimum 2 hours 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 → **(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) shows $PaCO_2$ worsens ≥ 7 mm Hg compared to original ABG result (on patient's prescribed $FiO_2$); PSG demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes, minimum 2 hours recording time, on an E0470, not caused by obstructive upper airway events (ie, AHI < 5).

**Situation 2**
No sooner than 61 days after initial use of E0470; ABG (done while awake) shows $PaCO_2$ ≥ 52 mm Hg (on patient's prescribed $FiO_2$); Sleep oximetry on an E0470 demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes, minimum 2 hours 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**
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
- VPAP™ Auto
- VPAP S

E0471–Bilevel with a backup rate
- VPAP ST
- VPAP Adapt



## III. Central Sleep Apnea or Complex Sleep Apnea

**Full PSG, attended in sleep lab** → **Dx: Central sleep apnea or complex sleep apnea** → Improvement of sleep-associated hypoventilation with use of E0470 or E0471 device on:
- Settings that will be prescribed for initial use at home
- Patient's prescribed $FiO_2$

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

## IV. Hypoventilation

**ABGs** (done while awake) $PaCO_2$ ≥ 45 mm Hg (patient's prescribed $FiO_2$) → **Spirometry** FEV1/FVC ≥ 70% and an FEV1 ≥ 50% of predicted *Refer to SEVERE COPD category for information about device coverage for patients with FEV1/FVC <70% or FEV1 <50% of predicted* →
- **ABGs** (done during sleep or immediately upon awakening) $PaCO_2$ worsened ≥ 7 mm Hg compared to original ABG (patient's prescribed $FiO_2$) or
- PSG demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes, minimum 2 hours recording time not caused by obstructive upper airway events (ie, AHI < 5)

→ **(E0470)**

**Covered E0470 being used** → **Spirometry** FEV1/FVC ≥ 70% and an FEV1 ≥ 50% of predicted *Refer to SEVERE COPD category for information about device coverage for patients with FEV1/FVC <70% or FEV1 <50% of predicted* →
- **ABGs** (done while awake) $PaCO_2$ worsens ≥ 7 mm Hg compared to ABG result used to qualify for E0470 (patient's prescribed $FiO_2$) or
- PSG demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes, minimum 2 hours recording time, on E0470, not caused by obstructive upper airway events (ie, AHI < 5)

→ **(E0471)**

A diagnosis of **central sleep apnea (CSA)** requires all of the following:
1. An apnea hypopnea index > 5
2. Central apneas/hypopneas > 50% of the total apneas/hypopneas
3. Central apneas or hypopneas ≥ 5 times per hour
4. Symptoms of either excessive sleepiness or disrupted sleep

**Complex sleep apnea (CompSA)** is a form of central apnea
- Identified by the persistence or emergence of central apneas or hypopneas upon exposure to CPAP or an E0470 device when obstructive events have disappeared
- CompSA patients have predominately obstructive or mixed apneas during the diagnostic sleep study occurring at ≥ 5 times per hour
- With use of a CPAP or E0470 device, they show a pattern of apneas and hypopneas that meets the definition of CSA

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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## Challenges of Standard NIV Therapy

- Asynchrony can occur at multiple points in NIV therapy
- Traditional NIV therapy is incapable of automatically adjusting
- Higher pressures may lead to intolerance
- Non-compliance