Expanding Non-Invasive Potentials: The New Intelligent Volume Assured Pressure Support
Objectives

- Review normal breathing and Nocturnal Hypoventilation
- Understand the clinical indications for volume assured therapy
- Review IVAPS algorithm
- Identify IVAPS titration and qualification criteria
- Recognize the benefits of therapy monitoring
Normal Breathing
Breathing and Respiratory Muscles

**Inhalation**
- Air enters
- Ribcage expands
- Lungs expand
- Diaphragm downward

**Exhalation**
- Air exits
- Ribcage contracts
- Lungs contract
- Diaphragm upward
Breathing functions

The 2 basic functions of the Respiratory System are:
1. Ventilation (movement of air into and out of the lungs)
2. Respiration (gas exchange at the alveoli)

Goals of respiration

- Bring oxygen to the body
- Remove carbon dioxide from the body

Difference Between Ventilation and Respiration
Nocturnal Hypoventilation
Nocturnal Ventilation Characteristics

- “Normals” have about a 5% decrease in ventilation during sleep
- Increased load is counteracted by increased effort
- Small reductions in tidal volume are compensated by an increase in rate
- 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
Hypoventilation Is Usually the Result of

Obstructive Lung Diseases

COPD

Restrictive Lung Diseases

Obesity Hypoventilation Syndrome

Neuromuscular diseases
Hypoventilation First Appears During Sleep--Nocturnal Hypoventilation

- **Breathing load is increased**
  - Upper airway dysfunction
  - Obesity
  - Lung disease
  - Chest wall stiffness

- **Capacity to maintain ventilation is reduced**
  - Obesity
  - Lung disease
  - Respiratory muscle weakness

- **Impaired respiratory drive**
  - Brainstem control of breathing abnormalities
  - Severe sleep fragmentation
  - Long-term sleep apnea
Clinical Indications for Volume Assured Therapy
Non-invasive ventilation (NIV) is a well-established therapy for nocturnal hypoventilation in chronic respiratory disease.

**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 for NIV.

However, these 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
Understanding the iVAPS Algorithm
iVAPS

intelligent Volume-Assured Pressure Support
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.
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
Hybrid automatic mode of NIV that has a variable backup rate

- Servo-ventilation pressure support algorithm for the treatment of *hypercapnic* respiratory failure/insufficiency

- Targets pressure within breath, modulates pressure over several breaths to target alveolar ventilation
  - Pressure Support = COMFORT
  - Ventilation target = ASSURANCE
Who is iVAPS Suitable For?

Continuous or intermittent ventilatory support for patients weighing more than 66 pounds (30 kg) — with respiratory conditions including COPD, obesity hypoventilation, and neuromuscular diseases.

- Chronic obstructive pulmonary disease
- Obesity hypoventilation
- Neuromuscular disease & restrictive conditions
Why Target Alveolar Ventilation?

The importance of targeting alveolar ventilation

Some ventilation modes target tidal volume without taking into account the anatomical dead space in the patient’s airways.

iVAPS targets alveolar ventilation, which best represents the useful portion of ventilation that reaches the alveoli.

Because iVAPS takes into account both tidal volume and respiratory rate, you can better control the effect of respiratory rate variation on ventilatory support.
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
Automatically Adjusted Pressure Support

- The delivered pressure support depends on the current ventilation estimate compared with the target.
- How much patient is above or below target Va determines the rate of change in pressure support adjustment.
- Pressure support cannot move beyond configurable boundaries MinPS, MaxPS.

Diagram:
- Pressure
- Target alveolar ventilation
- Current alveolar ventilation
- Time
- Max PS
- Min PS

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- iVAPS offers a new method of providing backup breaths (iBR)
- iBR provides support when needed
- Simply enter the patient’s spontaneous breath rate and iBR does the rest

Spontaneous rate is 20/min
iVAPS – intelligent Backup Rate (iBR)

Target Patient Rate

Rate (min)

Time (sec)

Period of low respiratory rate

Δ intelligent Backup Rate

⅔ Target Patient Rate
iBR is not triggered at \( \frac{2}{3} \) spontaneous rate, whenever patient spontaneously triggers above 2/3 of the Target rate.

<table>
<thead>
<tr>
<th>Target Rate</th>
<th>Patient Rate</th>
</tr>
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<tbody>
<tr>
<td>4.0</td>
<td>6.0</td>
</tr>
<tr>
<td>8.0</td>
<td>12.0</td>
</tr>
<tr>
<td>16.0</td>
<td>24.0</td>
</tr>
</tbody>
</table>

Diagram showing the relationship between Target Rate, Patient Rate, and Time (sec). The graph illustrates the period of low respiratory rate and the intelligent Backup Rate (iBR).
Once the patients rate reaches the min back-up rate, (2/3 of target) *iBR* increases towards patients *spontaneous rate* to *maintain alveolar ventilation*. 
The increase towards the patient’s spontaneous rate provides the best opportunity to maintain ventilation during periods of low respiratory rate or apnea.

Target Rate

Patient Rate

Rate (/min)

Spontaneous Rate

intelligent Backup Rate

Time (sec)
Once *spontaneous triggering returns*, iBR drops back to \( \frac{2}{3} \) target/spontaneous rate
The combined response; **Targeting Alveolar Ventilation** and *intelligent* provision of *backup breaths*, allows iVAPS to maintain ventilation when required, whilst maintaining the optimal level of pressure support.
Traditional Fixed Backup Rate

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

Breath-by-breath backup-rate – traditional S/T

- Patient triggering
  - Backup rate 3-4 below interaction

- Loss of patient trigger
  - Backup breaths at a rate 3-4 lower than

- No patient effort – backup breaths

Graph showing:
- Nominal spontaneous rate
- Breathing Frequency (per minute)
- Time (seconds)
- Average patient spontaneous rate
- Traditional S/T actual rate
- Traditional S/T Backup Rate (user input)
Asynchrony

- Discomfort
- Compliance
- Ineffective Treatment
- Accessory Muscle Use
- Work of Breathing
• TiControl is used to fine-tune synchrony to match the needs of the patient based on their lung-mechanics.

• Ti Min & Ti Max can be used to limit or prolong the inspiratory time

• Ti Min can prevent premature cycling in restrictive lung disorders

• Ti Max can prevent late cycling in obstructive pulmonary disease patients who fail to cycle resulting in air-trapping.
Fine-tuning: Rise Time

- Rise Time is used to adjust the rate of pressure increase between EPAP and IPAP to fine-tune comfort.
- The shorter the rise time, the higher the flow rate.
- Assist patients to fill their lungs, e.g. obesity hypoventilation patients.
## Trigger and Cycle Sensitivities

### Adjustable Trigger Sensitivity

<table>
<thead>
<tr>
<th>Level</th>
<th>Sensitivity</th>
<th>Flow Rate</th>
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</thead>
<tbody>
<tr>
<td>Very High</td>
<td>Quick to trigger</td>
<td>1.8 L/min</td>
</tr>
<tr>
<td>High</td>
<td>Sensitive</td>
<td>3.3 L/min</td>
</tr>
<tr>
<td>Med</td>
<td>Default</td>
<td>4.8 L/min</td>
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<tr>
<td>Low</td>
<td>Less sensitive</td>
<td>8.1 L/min</td>
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<tr>
<td>Very Low</td>
<td>Slow to trigger</td>
<td>13.2 L/min</td>
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</table>

### Adjustable Cycle Sensitivity

<table>
<thead>
<tr>
<th>Level</th>
<th>Quick to cycle</th>
<th>50% of peak flow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very High</td>
<td>Sensitive</td>
<td>35%</td>
</tr>
<tr>
<td>High</td>
<td>Sensitive</td>
<td>35%</td>
</tr>
<tr>
<td>Med</td>
<td>Default</td>
<td>25%</td>
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<tr>
<td>Low</td>
<td>Less sensitive</td>
<td>15%</td>
</tr>
<tr>
<td>Very Low</td>
<td>Slow to cycle</td>
<td>8%</td>
</tr>
</tbody>
</table>
Titrating iVAPS
Addressing NIV Titration Challenges

**iVAPS**

- Simpler and more consistent titrations
- More rapid response to changes
  - Positional
  - Sleep state
- Maximize patient-ventilator synchrony
  - Provide backup rate only when you need it
  - Handle substantial mask leaks without losing synchrony
  - Customize breath delivery
# iVAPS Titration Protocol

| Set iVAPS settings to: | • Set **Patient Height** (e.g., 70 inches for 5’ 10”)
| | • Set **Target Patient Rate** equivalent to patient’s spontaneous respiratory rate (recommended no less than 15 bpm)
| | • Set **Target Va** such that \( Vt \) is equal to 6ml/kg IBW
| | • **EPAP** = 5 cm H\(_2\)O
| | • **Min PS** = 4 cm H\(_2\)O
| | • **Max PS** = 20 cm H\(_2\)O

| Evaluate and titrate: | Based on **Target Pt Rate**, **Target Va**, \( Vt \), **SpO\(_2\)** and **CO\(_2\)** compared to baseline

| For obstructive apneas: | **Increase EPAP** by \( \geq 1 \) cm H\(_2\)O every \( \geq 5 \) min to eliminate obstructive apneas, hypopneas and flow limitation

| For **SpO\(_2\)** <90% with all respiratory events eliminated: | **Increase Target Va** by 0.3 every \( \geq 5 \) min until desaturations are resolved.

| Evaluate if Target Pt Rate is adequate: | If central events persist, **increase Target Pt Rate** by 1 – 2 bpm every 20 min as needed
Respiratory Assist Device (RAD) Qualifying Guidelines

CMS revision effective date: December 2014

I. Restrictive Thoracic Disorders

Perform one of the following:
- ABGs (done while awake and on prescribed FIO2) PaCO2 ≥ 45 mm Hg or
- Sleep oximetry
  Oxygen saturation ≤ 98% for ≥ 5 minutes, minimum 2 hours of recording time (on patient’s prescribed FIO2)
  or
- For neuromuscular disease only:
  Either FVC < 50% of predicted or MIP < 60 cm H2O

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 FIO2) PaCO2 ≥ 52 mm Hg

Sleep oximetry
Oxygen saturation ≤ 88% for ≥ a cumulative 5 minutes, minimum 2 hours nocturnal recording time (on 2 L/min O2 or patient’s prescribed FIO2, 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 FIO2) shows PaCO2 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 FIO2) shows PaCO2 ≥ 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 O2 or patient’s prescribed FIO2, whichever is higher).

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 inpatient use, code E0472.

ResMed E0470 and E0471 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

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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):
- Based on the treating physician’s judgment

(E0470) or (E0471)

IV. Hypoventilation

- ABGs (done while awake and on prescribed FiO2): PaCO₂ ≥ 45 mm Hg
- FEV1/FVC ≥ 70%
- 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) PaCO₂ worsened ≥ 7 mm Hg compared to original ABG or
- PSO or HST demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes, minimum 2 hours nocturnal recording time not caused by obstructive upper airway events (i.e., AHI < 5)

(E0470)

- Covered E0470 is being used
- Spirometry: FEV1/FVC ≥ 70%
- 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 FiO2): PaCO₂ worsens ≥ 7 mm Hg compared to ABG result used to qualify for E0470 or
- PSO or HST demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes, minimum 2 hours nocturnal recording time, and not caused by obstructive upper airway events (i.e., 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 sleep 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.


This information is provided as of the date issued and all coding and reimbursement information is subject to change without notice. It is the provider’s responsibility to verify coding and coverage with payers directly. For a full description of the policy go to www.cms.hhs.gov ResMed reimbursement hotline, call 1-800-424-0777 and select option 4.
1. Targets alveolar ventilation
2. Effective rate of response$^{1,2}$
3. Intelligent backup rate
   - Efficacy, synchrony and comfort
4. ResMed’s synchrony features
   - $V_{SYNC}$
   - Trigger and Cycle Sensitivity
   - TiControl
   - Rise Time

2. Ekkernkamp E et al. *Respiration* 2014
Patients treated with iVAPS had more restful sleep at home

• Results from a study¹ investigating the effects of iVAPS on sleep quality in stable hypercapnic patients with COPD reported a trend towards
  
  • More restful sleep at home with iVAPS than HI-NPPV and
  • Nocturnal hypercapnia was effectively treated with iVAPS.

Clinical trials have shown that iVAPS improve daytime blood gases and nocturnal oxygenation and increases compliance.²,³

¹ Ekkernkamp E et al. Respiration 2014
² Oscroft NS et al. COPD J 2010
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Patients prefer iVAPS to standard pressure support (PS) ventilation\(^1\) which can lead to longer use of non-invasive ventilation (NIV). iVAPS was found to help patients adhere to therapy 60 minutes longer per session than when treated with standard PS ventilation.

• **Conclusion:** iVAPS is as effective as PS ventilation initiated by a skilled health-care professional and produced better overnight adherence in nocturnal hypoventilation patients newly adjusting to NIV.

*Kelly JL et al. Respirology 2014*
Benefits of Therapy Monitoring
Imagine:

- Knowing which patients are not using their therapy on a day to day basis, particularly in light of:
  - Audits
  - COPD readmissions
- Eliminating manual downloads
- The efficiencies in having access to device settings and therapy data in advance
Making Data Available to Providers and Patients

**AirView™**

**Data for Physicians/Clinicians and Providers**

- View detailed data, make remote setting changes, troubleshoot remotely with Remote Assist

**myAir™**

**Automated coaching and support for Patients**

- Patient access to individualized coaching, education, and therapy data

Remote setting changes do not apply to life support ventilator devices

myAir is only for AirSense and AirCurve devices
AirView Reports (Sample Data)

- AirView offers a variety of reporting types that allow you to see how a patient is doing on therapy, and to easily share with their care network:
  - Compliance reports to Insurers
  - Therapy reports to Physicians
  - Detailed Data reports for clinical insight

One-Click Compliance Reporting
With just a single click you can generate compliance reports, meaning more time for patient care and less time spent on administration.
Results from World’s Largest Study on Sleep Apnea and Digital Connected Care

New! myAir clinical evidence published!

- Observational study that included more than 128,000 people!

Malhotra A et al. Chest 2017