BiPAP autoSV Advanced—System One Clinical applications guide
Philips Respironics would like to acknowledge the following individuals for their gracious efforts without which the case studies in this guide would not have been possible. We extend a special thank you to Andrew Wellman, MD for his contributions, not only for reviewing the data, but also for adding valuable insight and thought-provoking discussions into the individual cases. Thanks also to Winfried Randerath, PhD, Adrian Reed, MD and Paul Wylie, MD who contributed the patient data analyzed in the cases. Philips Respironics would also like to thank David White, MD for his review and input.

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Servo ventilation
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How servo ventilation differs from CPAP and bi-level therapies

What is servo ventilation?
Servo ventilation is a form of noninvasive ventilation that applies three different support functions based on the patient’s ventilatory patterns and upper airway needs during sleep. The features of servo ventilation include the application of EPAP to maintain upper airway stability during sleep, inspiratory support for patients with unstable and fluctuating tidal volumes or breathing patterns, and a back up breath rate for patients who experience central apnea at night. These three features together, applied in the right pattern, smooth out the fluctuations in nighttime breathing, decreasing the patient’s overall AHI and improving sleep efficiency for patients with complicated breathing patterns.

How is servo ventilation different from CPAP?
CPAP delivers a constant positive pressure throughout inspiration and expiration. CPAP is effective in patients with predominantly obstructive sleep apnea, because it mechanically splints the upper airway open. However, it is generally less effective in patients with predominantly central sleep apnea or those with combined central and obstructive apnea. Servo ventilation delivers varying levels of inspiratory pressure above the baseline level of EPAP to help with ventilation that may occur during the night.

How is servo ventilation different from bi-level PAP in spontaneous mode?
Spontaneous bi-level PAP delivers a constant preset inspiratory pressure above the baseline level of EPAP rather than varying levels of support with each breath. If the IPAP to EPAP difference is large, then small breaths will be appropriately amplified. However, large breaths will also be amplified which can exacerbate an unstable breathing pattern and worsen, or even precipitate, central apneas. In addition, with spontaneous bi-level PAP S, there is currently not a consistently effective treatment for mixed and central apneas. BiPAP autoSV Advanced—System One was designed to fill this void.

What patient groups can benefit from servo ventilation?
Patients with compromised control and regulation of breathing, may include:
- Cheyne-Stokes respiration
- Complex sleep apnea
- Opioid-induced central apneas

To understand the mechanisms causing these disorders, and the benefit of servo ventilation in treating them, the control of breathing during sleep should be reviewed.

Control of breathing during sleep
Chemical control feedback loop
During sleep, ventilation is controlled primarily by the chemically-controlled feedback loop for carbon dioxide. In sleeping subjects, reduction of the PCO₂ by a few mm Hg leads to a temporary cessation of breathing. The three major components of this loop are the “plant”, the “circulation delay,” and the “controller” (Figure 1.1). The “plant” is the lungs, blood and body tissues where carbon dioxide is stored. The “circulation delay” is the...
time it takes for pulmonary capillary blood to reach the chemoreceptors and is primarily influenced by the cardiac output. The “controller” represents all the structures responsible for converting chemoreceptor stimuli into ventilation.

The stability of the above system can be quantified as the “loop gain”. Loop gain is the ratio of the ventilatory response to a ventilatory disturbance. A reduction in ventilation \( \Delta \text{VE (disturbance)} \) produces an increase in alveolar \( \text{PACO}_2 \) \( \Delta \text{PACO}_2 \). With a normal circulatory delay, the increase in \( \text{CO}_2 \) in the blood produces an increase in chemoreceptor \( \text{PCO}_2 \) \( \Delta \text{PcrCO}_2 \) signalling a ventilation response \( \Delta \text{VE (response)} \). The \( \Delta \text{VE} \) ventilation (response) tries to correct this disturbance (VE disturbance) by increasing rate and depth of breathing. As a result, it will lower both \( \text{PACO}_2 \) and \( \text{PaCO}_2 \).

Overcorrection of the \( \text{PACO}_2 \) and \( \text{PaCO}_2 \), induces an unstable system prone to large swings in ventilation (e.g., hyperventilation alternating with central apneas). In addition, it takes time for ventilatory drive (the response) to reach its final, steady-state value. Loop gain is not a single number, but rather it is a function of the duration of the disturbance, and the time it takes for the response to reach a steady state.

In general, a more prolonged disturbance means more time for the correlating response to reach a steady state. (Figure 1.2)

The \( \text{PCO}_2 \) level at which this phenomenon occurs is known as the “apnea threshold.” During wakefulness, however, a reduction in \( \text{PCO}_2 \) does not produce central apnea due to wake-active influences that stimulate breathing even in the absence of chemical stimuli. Of note, ventilation is higher during wakefulness than during sleep as a result of these additional wake-active stimuli. The awake \( \text{PCO}_2 \) is typically at or near the \( \text{PCO}_2 \) apnea threshold during sleep. At sleep onset, when the wake-active stimuli are removed, there may be a brief central apnea or hypopnea while the \( \text{PCO}_2 \) readjusts. Such “sleep onset central apneas” are not considered pathologic unless they occur too frequently throughout the night.

Complex breathing patterns that may occur at night

Cheyne-Stokes respiration
This breathing pattern is characterized by a crescendo–decrescendo ventilatory pattern of tidal volumes with a central apnea or hypopnea at the nadir, and it is almost entirely a product of ventilatory control system instability resulting primarily from a prolonged circulation time. As previously discussed, a prolonged circulation delay means that ventilatory disturbances (e.g., apnea or hyperpnea) go unrecognized, and therefore uncorrected, for a longer period of time.

Complex sleep apnea
The term complex sleep apnea has been used by some to describe patients who initially have obstructive sleep apnea during a diagnostic sleep study but develop > 5 central apneas per hour of sleep during administration of therapeutic CPAP. The pathogenesis of this phenomenon is not known, but several hypotheses have been proposed. One is that patients with complex sleep apnea have an elevated loop gain in combination with a narrow upper airway. When CPAP is applied, it eliminates the upper airway obstruction but does not correct the ventilatory control instability so cyclic breathing with central apnea emerges and persists.

Another possibility is that activation of the Hering-Bruer reflex by increased lung volume on CPAP produces prolonged expiration to the point of central apnea in some patients. While this reflex is weak in humans during wakefulness, Hamilton et al showed that it is quite active during sleep and that an increase in lung volume of 1-1.5 liters (roughly 10-15 cm H2O) can prolong expiration by several seconds. This is consistent with the fact that central apneas seem to be more common in patients that are “over-titrated” where the high lung volumes may be eliciting reflex prolongation of expiration.

Lastly, central events on CPAP could potentially be due to maladaptation to the device, with frequent arousals causing hyperventilation and sleep onset central apneas. The extent to which any or all of these mechanisms participate in the pathogenesis of complex sleep apnea awaits further study.
The prevalence of CPAP-emergent central sleep apnea is between seven and 20 percent of patients, and the clinical picture becomes virtually indistinguishable from OSA patients. Recent studies have shown good success in treating complex sleep apnea with ASV.

**Opioid CSA**

Several recent studies indicate that opioid medications, particularly long-acting opioids like methadone, are associated with central apneas. The prevalence of a central apnea index ≥ 5 is between 30 and 75 percent in patients taking around-the-clock opioids for chronic pain or narcotic addiction. The strongest predictor is dose, with the central apnea index increasing as a function of morphine dose equivalent.

The cause of opioid-induced central apneas is not known, but opioids are well-known respiratory suppressants. If the respiratory suppression produced by these drugs is the result of a reduced controller gain (i.e., low or absent hypoxic/hypercapnic responsiveness), then periodic central apneas would be unexpected due to the low loop gain. If, however, respiratory suppression is due to a general reduction in the drive to breath without a significant change in the controller gain, (i.e., a rightward shift in the controller gain line), then cycling central apneas would be expected. This is likely to be the case in patients taking opioid medications, in whom central apneas, in association with hypoventilation, are frequent.

For patients with central sleep apnea due to opioids, lowering the opioid dose may be helpful since the effect on central apneas is dose dependent. Of note, CPAP alone is not helpful in this patient population, as it generally tends to worsen the number of central apneas (for unclear reasons) and does not improve the nocturnal hypoxemia. If the dose cannot be decreased, the application of auto servo ventilation may be beneficial.

**Figure 1.2 - Ventilatory response to disturbance ratio (loop gain) as a function of time.** The ventilatory control system is disturbed by reducing ventilation (solid line) from the baseline of 6 L/min to 5 L/min. Therefore, the magnitude of the disturbance (downward arrow) is 1 L/min. This produces an increase in ventilatory drive (dotted line), which is the ventilation desired by the ventilatory control system in response to the disturbance. Loop gain is calculated by dividing the magnitude of the response (upward arrows) by the magnitude of the disturbance. Note that this ratio depends on the time at which the response is measured. If the response is measured at time = 60 seconds, then the loop gain ratio is 1.6. However, if the response is measured at time = 120 seconds, then the loop gain ratio is 2.5.
Figure 1.3 - Hypoventilation during sleep could be due to: A. a reduction in controller gain without a change in the PCO₂-apnea threshold, B. an increase in the apnea threshold without a change in controller gain, or a combination of the two. Note that the PCO₂ (where the lines cross) is high in both conditions. However, an increase in ventilation is not likely to lower PCO₂ below the apnea threshold in A. On the other hand, to the extent that hypoventilation is due to an increase in apnea threshold with a preserved controller gain (B), the likelihood of periodic central apneas increases.


References


BiPAP autoSV Advanced—System One design elements
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Introduction
The BiPAP autoSV Advanced—System One takes Philips Respironics’ clinically proven technologies and combines them into one advanced device designed to treat complicated forms of sleep-disordered breathing. Over the past 10 years, Philips Respironics has developed auto servo-ventilation technology based on clinician feedback and emerging market needs. The BiPAP autoSV Advanced features four algorithmic design elements:

• Auto EPAP adjustment versus manual adjustment
• Identification of open versus closed airway apnea detection
• Rapid breath-by-breath IPAP adjustment
• Flexible back-up rate systems to quickly normalize the patient’s breathing pattern regardless of when it emerges during the night

These features are only useful if the patient is compliant with his or her therapy. That is why the BiPAP autoSV Advanced—System One now incorporates the Bi-Flex waveform to offer the most comfortable and synchronous pressure waveform for patients today, and offers wireless communication to monitor patient usage.
Four key attributes of the BiPAP autoSV Advanced—System One

1) Auto EPAP
At the core of the BiPAP Auto EPAP technology is the proven REMstar Auto algorithm. The REMstar Auto CPAP algorithm has been clinically validated and contains both a proactive analysis of a patient’s upper airway dynamics along with a safety net in case of sleep apnea events.

*Figure 2.1*

The algorithm is able to achieve a higher pressure level proactively prior to the occurrence of an event.

The foundation of the Auto EPAP algorithm is an analysis to determine the best pressure for the patient’s upper airway throughout the entire night. The three features of this algorithm is a \( P_{\text{opt}} \) search, the \( P_{\text{ther}} \) period and \( P_{\text{crit}} \) search.

At the beginning of the night, the device provides a proactive search \( (P_{\text{opt}}) \) where the EPAP level is slowly increased over a series of minutes. After this increase, the patient’s airflow signal is evaluated to look for improvements in airflow. If an improvement is found, the pressure continues to be increased. If no improvement is found, the pressure is lowered back to the start point.

Following a \( P_{\text{opt}} \) search, the EPAP will then deliver the identified EPAP pressure \( (P_{\text{ther}}) \) for approximately five minutes. After completion of the \( P_{\text{ther}} \) session, the device will initiate a \( P_{\text{crit}} \) search. The \( P_{\text{crit}} \) search is a slow decrease in the EPAP pressure until flow limitation is noted. Once identified, the pressure will be slightly increased to a level where no flow limitation is documented and the device initiates another five-minute \( P_{\text{ther}} \) session.

These searches are provided throughout the night to stabilize the airway at the lowest possible airway pressure.

While the proactive algorithm is working throughout the night, if the device detects a series of airway obstructions, hypopneas, airway vibration (vibratory snore) or flow limitation beyond a hypopnea, the device will automatically initiate a pressure change over the next 20-second period until airflow improves back to baseline. With this latest technology, the device has the ability to determine if an apnea is associated with an open or closed airway to determine the best course of treatment.
2) Apnea detection and differentiation between obstructed vs. clear airway apneas

The BiPAP autoSV Advanced—System One algorithm has the ability to detect and differentiate between an obstructed airway apnea (OA) versus a clear (or open) airway apneas (CA). This feature is critical in determining whether the upper airway needs to have a higher EPAP adjustment or if the patient needs ventilatory support via a rapid IPAP adjustment. Simply, if an apnea is detected by the device, it will determine if the airway is currently opened vs. obstructed via delivery of a backup breath. Based on the results of this pressure flow response, the machine response will vary.

**Obstructed airway apnea (OA)**

With apnea detection, if there is an 80 percent reduction in flow lasting at least 10 seconds AND limited or no response from the flow signal with the introduction of a back-up breath, the machine will record an obstructed airway apnea or OA. When the airway is considered to be closed or nearly closed, an increase in EPAP is needed to treat the patient’s ventilatory needs better. This opening of the airway will allow the delivery of rapid IPAP adjustments to the lower airway. In addition, if a back-up breath is needed, the upper airway is opened, further allowing this support to occur.

See Figure 2.2 for a sample of the OA detection.

**Clear airway apnea (CA)**

A clear airway apnea is recorded when there is an 80 percent reduction in flow lasting at least 10 seconds and a response from the flow signal with the introduction of the back-up breath. This indicates the airway is open allowing the device to continue to provide rapid IPAP fluctuations breath-by-breath to help normalize the patient’s respiratory pattern and rate.

See Figure 2.3 for a sample of the CA detection.
3) Normalization of breathing (Servo-ventilation algorithm)

The clinically-proven servo-ventilation algorithm uses peak flow as the primary control to manage a patient’s ventilation. Peak flow is captured on a breath-by-breath basis and monitored over a moving four-minute window. As one breath is added, the initial breath falls off. At every point within this four-minute period an average peak flow is calculated. Using a patented calculation, the peak flow target is established around that average. Based on that target, the IPAP level is changed on each breath (if necessary) to hit that target. As the patient’s peak flow decreases, the IPAP level (or PS level) is increased. And as the patient’s peak flow increases, the level of IPAP (or PS) is decreased.

See Figure 2.4 for sample of the servo-ventilation algorithm.

4) Flexible auto back-up rate

The enhanced back-up rate allows for flexibility with the breath rate in the BiPAP autoSV Advanced—System One. The device offers a multi-layered approach to help clinicians manage with a variety of complex sleep-disordered patients. The auto breath rate systems run in parallel to determine the patient’s needs. The device also continues to offer a preset back-up rate if the clinician chooses to set a fixed rate versus relying on the auto back-up rate.

See Figure 2.5 for sample of the flexible auto back-up rate.
Complicated sleep-disordered breathing patients can present new challenges for sleep clinicians. Whether the patient has central sleep apnea, complex sleep apnea, or both, bi-level therapy may be the appropriate treatment for the disorders. Understanding device function and the required titration techniques are critical in treating patients effectively. In addition, capturing the right information from the sleep study is also critical in deciding the best settings to treat the patient long term.
Setting up your sleep system to capture the right data
Data recording and reporting

Advanced therapy devices—such as the BiPAP autoSV Advanced—System One that offer “rapid” IPAP and/or EPAP varying fluctuations, pose unique challenges in the diagnostic world. Philips Respironics is working hard to help the sleep team capture the critical information to monitor the rapidly changing IPAP and EPAP settings, along with providing information about support through the back-up breaths or auto back-up rate.

Implementation of the following channels is suggested for any patient being titrated on the BiPAP autoSV Advanced—System One or OmniLab titration system. These channels will provide additional information about fluctuation of PAP levels and back-up breath-rate support throughout the entire night.

The Alice 6 System and Sleepware G3 offer the ability to present what is referred to as a “composite channel.” The composite channel represents multiple parameters/settings within a single channel versus multiple channels in today’s Sleepware. This channel includes EPAP Range (Min and Max), Max Pressure, Patient Pressure range, and Pressure Support (Min and Max).

See figures 3.1 and 3.2

Figure 3.1:

Sample montage of Alice 6 and G3 Sleepware

Trends also reflect the same parameters, and we can show a new digital panel with actual figures.

Figure 3.2

Sample montage of Alice 6 and G3 Sleepware
For diagnostic systems from manufacturers other than Philips Respironics, we suggest the following channels be displayed during a titration and captured for review: IPAP range, EPAP range, patient pressure, and tidal volume. This will allow you to capture information regarding back-up breaths being delivered, IPAP fluctuations and auto EPAP adjustments throughout the night. See Figure 3.3.

Suggested channels to implement for all BiPAP autoSV Advanced titrations include: tidal volume, patient pressure, patient flow and/or leak. These channels can record what is occurring during the titration, and how the patient is responding to the rapid fluctuations in IPAP and EPAP.

**Figure 3.3**

Sample of non-Philips sleep montage with BiPAP autoSV
### Advanced therapy report

**Alice 5/6 G3 software report with setting up sleep system**

#### Reporting

With Alice G3 Sleepware, reporting data is provided in an advanced therapy table. A row in the table is defined by the EPAP Min, EPAP Max, PS Min, PS Max and Max Pressure settings. The reporting table contains columns for each combination of settings that appear in the study. Columns in the table are sorted in ascending order by comparing the EPAP Min, EPAP Max, PS Min, PS Max, and Max Pressure settings, respectively. EPAP Max settings are compared only if the EPAP Min settings are equal. PS Min settings are compared only if both the EPAP Min and EPAP Max setting were equal, etc. See Figure 3.4

The table does not represent a chronological ordering of the advanced therapy settings as they occur during the study. If a particular combination of EPAP Min, EPAP Max, PS Min, PS Max and Max Pressure occurs multiple times in the study, there is only a single column in the table. The Periods column specifies the number of distinct times the combination of settings occurred. The software is also capable of presenting data in chronological order, if desired.

#### Figure 3.4

<table>
<thead>
<tr>
<th>EPAP Min (cm H$_2$O)</th>
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<th>Pressure Support Min (cm H$_2$O)</th>
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<th>Max Pressure (cm H$_2$O)</th>
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<th>Total Duration (min)</th>
<th>Sleep Duration (min)</th>
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Sample Alice 5/6 G3 software report
Titration protocol for BiPAP autoSV Advanced—System One

GOAL: Adjust user-set parameters for optimal efficacy and adherence

Set mode to BiPAP autoSV Advanced

- Establish initial settings as indicated below or as ordered by physician
- Ensure proper mask fit to allow algorithm to work effectively
- Have patient breathe on autoSV Advanced at basic settings below
- Adjust EPAP<sub>max</sub>, Bi-Flex and PS<sub>min</sub> settings to patient comfort

EPAP<sub>max</sub> 4 cm H<sub>2</sub>O<sup>*</sup> Max Pressure 25 cm H<sub>2</sub>O
EPAP<sub>min</sub> 15 cm H<sub>2</sub>O Rate auto
PS<sub>min</sub> 0 cm H<sub>2</sub>O Bi-Flex to patient
PS<sub>max</sub> 20 cm H<sub>2</sub>O comfort

*If patient has known CPAP pressure of < 10 set EPAP<sub>max</sub> at 4 cm H<sub>2</sub>O or patient comfort
*If patient has known CPAP pressure of > 10 set EPAP<sub>max</sub> at 6-8 cm H<sub>2</sub>O or patient comfort

Monitor patient PSG

Wait… Watch… Observe… Think
Patience is the key to successful titration

At lights out observe for patient's inability to maintain sleep due to server obstructive apneas
If yes
For patient comfort and to allow sleep onset increase BPAP<sub>min</sub> to open the airway
Return to ⭐

and

At lights out observe for indications of therapy intolerance
If yes
For patient comfort and to allow sleep onset adjust Bi-Flex settings or increase PS<sub>min</sub>
Return to ⭐

If no
Observe for peak respiratory pressure being limited by PS<sub>min</sub>
If no
Observe for inadequate breathing rate
If no
Set fixed rate to a minimum 8-10 bpm or 2 below reading respiratory rate including apneas: bet I-Time for 1.5 seconds
Return to ⭐

Wait a minimum of 20 minutes to indicate effect before making another change.

BiPAP autoSV Advanced prescription

EPAP<sub>max</sub> = _____ cm H<sub>2</sub>O
EPAP<sub>min</sub> = _____ cm H<sub>2</sub>O
PS<sub>min</sub> = _____ cm H<sub>2</sub>O
PS<sub>max</sub> = _____ cm H<sub>2</sub>O
Max pressure = _____ cm H<sub>2</sub>O

Rate = Auto or _____ BPM
I-Time = ____ sec (with fixed rate only)
Rise time and Bi-Flex = to patient comfort
Interface: __________________________
Introduction to Case Studies

Cheyne-Stokes respiration patient with upper airway obstruction
Central, mixed and obstructive sleep apnea patient
Pain patient with sleep-disordered breathing
Cheyne-Stokes respiration (CSR) patient with upper airway obstruction

Clinical scenario:
A 70-year-old man with atrial fibrillation and 2+ edema was previously referred to the sleep clinic for evaluation of continued daytime sleepiness. (Epworth Sleepiness Score 13/24). He is slightly overweight (BMI 27.5 kg/m²), and PMH history is limited. The only available data about the previous study are the sleep parameters listed below which were faxed by his primary physician.

<table>
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<th>Sleep parameters</th>
<th>Diagnostic study</th>
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<td>Sleep efficiency</td>
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<td>Apnea-hypopnea index ( episodes/hr)</td>
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<td>Central apnea index ( episodes/hr)</td>
<td>10</td>
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<tr>
<td>Obstructive apnea index ( episodes/hr)</td>
<td>19</td>
</tr>
<tr>
<td>Hypopnea index ( episodes/hr)</td>
<td>14</td>
</tr>
<tr>
<td>Mixed apnea index ( episodes/hr)</td>
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</table>

These data indicate that the patient has severe sleep apnea. However, it is not predominantly obstructive or central, and many of the events are hypopneas which cannot be easily classified as either obstructive or central. It appears that the patient has “mixed” sleep apnea (both obstructive and central events), even though the mixed apnea index is 0/hr.

There is limited information on the CPAP titration which was completed at a different facility. The patient was titrated from 4 to 12 cm H₂O. The interpreting physician reported that the “obstructive” component resolved with 8 cm H₂O, but that central apnea, specifically Cheyne-Stokes respiration (CSR), persisted at all pressures including 12 cm H₂O. The patient was subsequently issued a CPAP device set at 8 cm H₂O. With consistent use, the patient showed minimal improvement in clinical symptoms.

The patient was then provided a repeat CPAP titration because:

1. There is no raw data of the CPAP study and it is unknown if the titration was adequate, (e.g., under-titration or over-titration, high leak, fragmented sleep with central apneas at the sleep-wake transition.)
2. There is recent data suggesting that central apneas improve over time in some patients with consistent CPAP use.
3. It is often difficult to determine the CPAP necessary to eliminate upper airway obstruction in the setting of persistent central apneas. The repeat titration will help to confirm the previous physician’s interpretation.
The patient is breathing on a CPAP of 8 cm H₂O, which is adequate for eliminating the obstructive component. The tracing shows a strong periodic crescendo-decrescendo with central apneas and hypopneas with a cycle period of one minute. This is highly suggestive of CSR. In addition, it is important to note there is no significant desaturation associated with this pattern of breathing. CPAP is clearly not effective in treating this pattern for the patient since it is not obstructive in nature.

<table>
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<th>CPAP study</th>
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Figure 4.1 A 10-minute tracing of the CPAP study
Figure 4.2 CPAP study while patient in REM sleep

Note the stable breathing during REM sleep on a CPAP of 8 cm H₂O. This is not unusual in patients with CSR in whom an elevated loop gain and prolonged circulation delay are the primary underlying abnormalities. The reason breathing stabilizes during REM sleep is not entirely clear but may be partly due to the well documented reduction in loop gain during REM sleep.
Upon completion of the CPAP study and subsequent therapy failure, the patient was titrated on the BiPAP autoSV Advanced—System One. There is a slight fluctuation in the CFLOW tracing, the patient flow signal, but central apneas are absent and breathing is more stable than previously seen with the CPAP titration. Note how the PatPress the “patient pressure” at the nasal mask signal is out of phase with the CFLOW signal. Small CFLOW breaths are augmented by large inspiratory pressures, whereas large breaths receive little to no additional inspiratory pressure. BiPAP autoSV Advanced—System One is counteracting the fluctuations in CSR.
10-minute tracing from BiPAP autoSV Advanced—System One study

One of the features of the BiPAP autoSV is the automatic EPAP adjustment for obstructive events. In this graphic you can see the EPAP adjusts automatically to reduce upper airway resistance from 6 to 6.5 to 7.0 cm H2O when upper airway resistance was identified. Also note how EPAP increases (baseline of the PatPress signal increases) during flow limited breaths in REM sleep (indicated by the red grouping above).
This second figure demonstrates another example of the automatically adjusting EPAP during a different time of the night. As the patient transitions from wake to sleep, the device detects an increase in resistance and adjusts the EPAP accordingly (arrowheads).

The BiPAP autoSV Advanced—System One was able to perform substantially better than CPAP and the original version of the BiPAP autoSV in this patient with CSR and variable upper airway obstruction.

Upon completion, the BiPAP autoSV Advanced—System One completely resolved the patient’s sleep-disordered breathing. This can be seen from the study results outlined to the right:

<table>
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</tr>
<tr>
<td>Hypopnea index (episodes/hr)</td>
<td>0</td>
</tr>
<tr>
<td>Mixed apnea index (episodes/hr)</td>
<td>0</td>
</tr>
</tbody>
</table>
Central, mixed and obstructive sleep apnea patient

Clinical scenario:
A 57-year-old male with a history of TMJ, bruxism and arthritis is not on any daily medications but takes a daily multivitamin and Tylenol PM as needed.

In April, 2008, a sleep study was completed and the following information was provided about the patient:

<table>
<thead>
<tr>
<th>Sleep parameters</th>
<th>Diagnostic study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sleep efficiency</td>
<td>84.9%</td>
</tr>
<tr>
<td>Apnea-hypopnea index (episodes/hr)</td>
<td>27.5</td>
</tr>
<tr>
<td>Central apnea index (episodes/hr)</td>
<td>5.6</td>
</tr>
<tr>
<td>Obstructive apnea index (episodes/hr)</td>
<td>1.1</td>
</tr>
<tr>
<td>Hypopnea index (episodes/hr)</td>
<td>18.4</td>
</tr>
<tr>
<td>Mixed apnea index (episodes/hr)</td>
<td>2.4</td>
</tr>
</tbody>
</table>

The above data indicated that the patient had mild-to-moderate sleep apnea with a mixture of both obstructive and central events. He was sent home on a CPAP therapy of 9 cm H₂O. The patient returned to the sleep center due to increased complaints of Excess Daytime Sleepiness (EDS) and morning headaches. A repeat study was ordered and the following information was found:

CPAP study
Early in the night, during a CPAP titration, the patient was not on enough CPAP to eliminate obstructive hypopneas. The obstructive nature of the hypopneas was suggested by snoring (see Micro channel) and the “peak-plateau” inspiratory flow pattern (red arrow, and shown in detail in the next figure). Thoracic-abdominal paradox could also be used to indicate obstruction, but the thoracic channel had cardioballistic and other artifacts that made it hard to interpret.

A close up of the cardioballistic artifact is shown below on the THO channel.

An example of inspiratory flow limitation is indicated by the red arrow. Most of the breaths in this one-minute tracing are flow limited. Flow-limited breaths have a “peak-plateau” or “scooped out” inspiratory flow pattern. In the breath marked by the arrow, there is an initial peak in inspiratory flow, then a relative flattening, followed sometimes by a secondary peak at the end of inspiration (zero flow is marked with the dashed line). This type of inspiratory flow pattern is specific for upper airway obstruction.
Thoracic-abdominal paradox could also be used to indicate upper airway obstruction. However, cardioballistic artifact in the thoracic belt made this difficult to identify in this patient. Note that each heart beat can be seen in the thoracic (THO) channel.

Regardless, it is clear that PAP was not adequate and needs to be increased to treat the obstructive apneas and hypopneas.
Later in the night, CPAP at 8 cm H₂O appeared to eliminate upper airway obstruction. There was no snoring, flow limitation, or thoracic-abdominal paradox (the cardioballistic artifact improved). Central apneas became apparent. The patient had “CPAP-emergent central apneas” in which central apneas seemed to “emerge” from obstructive hypopneas/apneas when CPAP was administered. The cause of these central apneas was not clear but may have involved instability in the ventilatory control feedback loop or volume feedback from mechanoreceptors in the lung.

Upon completion of the CPAP study, the following was documented:

<table>
<thead>
<tr>
<th>Sleep parameters</th>
<th>Titration study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sleep efficiency</td>
<td>88.7%</td>
</tr>
<tr>
<td>Apnea-hypopnea index (episodes/hr)</td>
<td>22.7</td>
</tr>
<tr>
<td>Central apnea index (episodes/hr)</td>
<td>10.6</td>
</tr>
<tr>
<td>Obstructive apnea index (episodes/hr)</td>
<td>0.4</td>
</tr>
<tr>
<td>Hypopnea index (episodes/hr)</td>
<td>11.7</td>
</tr>
<tr>
<td>Mixed apnea index (episodes/hr)</td>
<td>0</td>
</tr>
</tbody>
</table>
Since patient was previously on an auto CPAP device and having recurrent symptoms of a sleep disorder with an elevated central apnea count, the physician tried the patient on a BiPAP autoSV Advanced—System One device.

Prior to the biocalibrations, the patient is drifting off to sleep and having sleep-onset central apneas. This is a common occurrence as patients transition from awake drive-to-breathe to a chemical drive-to-breathe. BiPAP autoSV Advanced—System One is detecting the central apneas and administering breaths. These ventilator-triggered breaths are recognized by the downward spike in the PatPress channel.
This is a nice example of how the BiPAP autoSV Advanced—System One works. During the biocalibration procedure, the patient was asked to hold his breath. After 4.5 seconds of apnea, the ventilator provided a ventilator-triggered breath. Note that there was no resulting inspiratory flow (downward arrow) because the glottis is closed. Then the patient exhaled (upward arrow) and another ventilator-triggered breath was given. This time, the airway was open and there was high flow. The next breath was patient-triggered and only received half the inspiratory support as the previous breath.
Once the patient is asleep, BiPAP autoSV Advanced—System One helps to produce stable, regular breathing. Notice the variation in inspiratory pressure (PatPress channel). The EPAP is 5 cm H₂O. The patient has a stable and regular flow pattern (CFLOW) without central apneas. In this five-minute tracing, there are no ventilator-triggered breaths however, there are many pressure support-triggered breaths supporting the patient while he sleeps.
There are ventilator-triggered breaths in the first portion of this figure (indicated by downward spike in PatPress channel). BiPAP autoSV Advanced—System One was preventing long expiratory pauses and central apneas. The middle and last portions of the figure were patient-triggered breaths with progressively decreasing inspiratory pressure; the patient is taking over more control of respiration. The flow rate is stable without pauses, apneas, or variations.

Upon completion of the BiPAP autoSV Advanced—System One study, the following parameters were found:

<table>
<thead>
<tr>
<th>Sleep parameters</th>
<th>BiPAP autoSV study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sleep efficiency</td>
<td>93.7%</td>
</tr>
<tr>
<td>Apnea-hypopnea index (episodes/hr)</td>
<td>6.4</td>
</tr>
<tr>
<td>Central apnea index (episodes/hr)</td>
<td>2</td>
</tr>
<tr>
<td>Obstructive apnea index (episodes/hr)</td>
<td>8</td>
</tr>
<tr>
<td>Hypopnea index (episodes/hr)</td>
<td>2.8</td>
</tr>
<tr>
<td>Mixed apnea index (episodes/hr)</td>
<td>0</td>
</tr>
</tbody>
</table>
**Clinical scenario:**

A 50-year old female with a history of acid reflux, fibromyalgia, spinal stenosis and degenerative disk disease s/p C3/C4 disk fusion, depression and 30-lb weight gain also takes Prevacid QD, Fentanyl patch 50 mg every 36 hrs, Oxycodone 30 mg QID, Effexor 150 mg QD.

The data below reflect the patient’s previous titration:

<table>
<thead>
<tr>
<th>Sleep parameters</th>
<th>Diagnostic study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sleep efficiency</td>
<td>54.9%</td>
</tr>
<tr>
<td>Apnea-hypopnea index (episodes/hr)</td>
<td>61</td>
</tr>
<tr>
<td>Central apnea index (episodes/hr)</td>
<td>21</td>
</tr>
<tr>
<td>Obstructive apnea index (episodes/hr)</td>
<td>11</td>
</tr>
<tr>
<td>Hypopnea index (episodes/hr)</td>
<td>73</td>
</tr>
<tr>
<td>Mixed apnea index (episodes/hr)</td>
<td>17</td>
</tr>
</tbody>
</table>

The data indicate that the patient has severe sleep apnea with a mix of obstructive and central events. Predominately, the patient has hypopneas which cannot be easily classified as either obstructive or central apneas.

**Diagnostic study**

On the diagnostic night, the patient experienced periodic central apneas. The cycle period was short (25 seconds), indicating that the central apneas are not due to a prolonged circulation delay caused by congestive heart failure.
At various times, the patient experienced periods of stable breathing, indicating that the factors causing the central apneas varied. This is a five-minute screenshot from the same diagnostic night, and the patient is in the same sleep stage and position. There was also some indication of mild upper airway obstruction with snoring, but no chest-abdomen paradoxing or obstructive hypopneas. Upper airway obstruction was not a prominent factor in this patient's physiology.
**CPAP titration**

During the CPAP titration, a pressure of 8 cm H\(_2\)O controlled the obstructive events; however, it did not control the central events. The patient continued to have significant central events and most events that were previously hypopneas were now classified as either central or mixed.

While using CPAP therapy, the patient’s breathing appeared virtually the same as the diagnostic night, and the central apneas were better defined. In this screen shot, the CPAP is just above 10 cm H\(_2\)O. In patients with central apneas, CPAP is often titrated to high levels in an attempt to eliminate sleep-disordered breathing. As upper airway obstruction is not a pathophysiologic component, it typically does not help or make the central apneas worse. This patient was taking Fentanyl and Oxycodone which often causes a “respiratory dysrhythmia” and hypoventilation.
Upon completion of the CPAP titration, the patient was trialed on a BiPAP S/T device with an IPAP of 14, EPAP of 4 and back-up rate of 12 bpm. The change in devices eliminated the patient’s obstructive events; however, central apnea became the predominant disorder. These problems continued in supine and non-supine positions and an equal distribution of events occurred in the patient’s REM and non-REM.

<table>
<thead>
<tr>
<th>Sleep parameters</th>
<th>Titration study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sleep efficiency</td>
<td>93%</td>
</tr>
<tr>
<td>Apnea-hypopnea index (episodes/hr)</td>
<td>48</td>
</tr>
<tr>
<td>Central apnea index (episodes/hr)</td>
<td>42</td>
</tr>
<tr>
<td>Obstructive apnea index (episodes/hr)</td>
<td>0</td>
</tr>
<tr>
<td>Hypopnea index (episodes/hr)</td>
<td>12</td>
</tr>
<tr>
<td>Mixed apnea index (episodes/hr)</td>
<td>3</td>
</tr>
</tbody>
</table>
BiPAP autoSV Advanced—System One

titration

If BiPAP autoSV Advanced—System One works properly, it should fill in the missed breaths and regulate the breathing pattern. It also should augment small breaths to prevent hypoventilation.

As seen previously, the patient has frequent episodes where she is not breathing. The device senses a prolonged expiration and initiates a breath (indicated by downward spike in the CPAP pressure). This produces inspiratory flow approximately equal to the previous breaths.

Note that the subsequent breaths during sleep receive greater inspiratory support than the “awake” breaths. The result is rhythmic tidal breathing. Later in slow wave sleep, the patient’s respiratory rate was decreased to 10 breaths per minute.
To maintain adequate ventilation, BiPAP autoSV Advanced—System One applies varying pressures of pressure support to substantially augment the patient’s breathing. Without the dynamic pressure support of servo ventilation, it is likely that the patient would start to hypoventilate.

This adjustment of pressure support continues throughout the entire night. Data upon completion of the study with the BiPAP autoSV Advanced—System One, shows the following:

<table>
<thead>
<tr>
<th>Sleep parameters</th>
<th>BiPAP autoSV study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sleep efficiency</td>
<td>94%</td>
</tr>
<tr>
<td>Apnea-hypopnea index (episodes/hr)</td>
<td>5</td>
</tr>
<tr>
<td>Central apnea index (episodes/hr)</td>
<td>0.2</td>
</tr>
<tr>
<td>Obstructive apnea index (episodes/hr)</td>
<td>0</td>
</tr>
<tr>
<td>Hypopnea index (episodes/hr)</td>
<td>5</td>
</tr>
<tr>
<td>Mixed apnea index (episodes/hr)</td>
<td>0</td>
</tr>
</tbody>
</table>

This type of varying inspiratory support is necessary for stabilizing the breathing pattern and can only be provided by a device such as BiPAP autoSV Advanced—System One. The patient is discharged on the following settings which were the final settings of the night: Max Pressure 25 cm H₂O, PS min - 3 cm H₂O, PS max – 15 cm H₂O, EPAP min – 7 cm H₂O, EPAP max – 13 cm H₂O, Auto rate & BI-Flex setting of two.
BiPAP autoSV Advanced – System One in the Treatment of Sleep-Disordered Breathing

The comparison of two automatic servo ventilation devices to standard CPAP in the treatment of central sleep apnea

Authors: Shahrokh Javaheri, MD¹, Mark Goetting, MD², Paul Wylie, MD³

Introduction: To evaluate the therapeutic performance of a new servo ventilation (SV) device (BiPAP autoSV Advanced – System One, Philips Respironics) for the treatment of Central Sleep Apnea (CSA).

Study design: A prospective multicenter randomized controlled trial.

Setting: Professional sleep laboratories – three (3) sites in the United States (US).

Participants: Fourteen (14) participants with CSA.

Measurements and results: Participants were required to have a central apnea index of at least five events per hour of sleep using a continuous positive airway pressure (CPAP) device. Eligible participants were randomly assigned to complete two full-night attended polysomnograms (PSG) while treated with either the BiPAP autoSV Advanced (Philips Respironics, Murrysville PA) or the new BiPAP autoSV Advanced – System One device. During each PSG, standard sleep and breathing variables were collected.

There were no significant differences in total sleep time, sleep efficiency, and wake after sleep onset. Both the BiPAP autoSV Advanced – System One and the BiPAP autoSV Advanced reduced the apnea hypopnea index (CPAP = 31.9 ± 23.2, BiPAP autoSV Advanced 12.2 ± 16, System One 8.0 ± 9, p <0.001) and the central apnea index (CPAP = 6.8 ± 7.7, BiPAP autoSV Advanced 1.0 ± 1.8, System One 0.7 ± 0.8, p = 0.004) significantly compared to CPAP.

Conclusions: The BiPAP autoSV Advanced – System One provides effective treatment of sleep-disordered breathing. These results indicate that recent improvements to Philips Respironics’ current auto servo-ventilation technology lead to a successful reduction of obstructive and central breathing events. The reductions are at least as good as those achieved with the earlier auto servo-ventilation platform.

¹Sleepcare Diagnostics, Mason, Ohio; ²Sleep Health, Portage, Michigan; ³Arkansas Center for Sleep Medicine, Little Rock, Arkansas.
Introduction
Obstructive sleep apnea (OSA) is a disorder where there is intermittent partial or total collapse of the upper airway resulting in repeated episodes of hypoxemia, activation of the sympathetic nervous system, and disruption of sleep. Continuous positive airway pressure (CPAP) is currently the treatment of choice and when used, is highly effective in stabilizing the airway and permitting the patient to breathe normally during sleep. In addition to airway instability, some reports have identified a component of breathing instability in patients with OSA as evidenced by the development of central apnea (CA) following the treatment of OSA with CPAP\textsuperscript{1,2,3}. Additionally, some patients may experience Cheyne-Stokes Respiration (CSR) where breathing effort waxes and wanes with periods of apnea. Treating these cases with CPAP is not always successful.

As an alternative to CPAP auto servo-ventilation (ASV) adjusts inspiratory support based on sensing airflow and increasing support with decreasing patient generated airflow and decreasing support with increasing patient airflow. The key features of ASV are presented in Table 1. A potential advantage of ASV over fixed pressure modes is that the amount of support is constantly adjusted and pressures are less likely to be inadequate or excessive at any given moment. Ideally, the ASV device will also provide and adjust expiratory pressure to stabilize the airway and prevent partial or total airway obstruction.

Table 1. Key features of ASV
- Stabilization of ventilation by automatically adjusting inspiratory positive airway pressure support (IPAP) to achieve or maintain a target peak flow.
- Backup breaths during central apneas. The backup rate is automatically determined by the device based on the patient’s breathing pattern.
- Continuous monitoring and adjustments to treat both obstructive and non-obstructive breathing events.

Abbreviations: ASV – auto servo ventilation; PSG – polysomnogram; PAP – Positive Airway Pressure; EPAP – Expiratory PAP; IPAP – Inspiratory PAP; CPAP – Continuous PAP; BiPAP – Bi-level PAP; SDB – Sleep-Disordered Breathing; OSA – Obstructive Sleep Apnea; CA – Central Apnea; CSR – Cheyne-Stokes Respiration; CSA – Central Sleep Apnea; CAI – Central Apnea Index; OAI – Obstructive Apnea Index; AHI – Apnea Hypopnea Index.

Key words: BiPAP autoSV Advanced—System One; BiPAP autoSV Advanced; Bi-Level Positive Pressure Ventilation, Servo Ventilation, Auto EPAP, Pressure Support.
Recently, a third generation ASV device has been introduced (BiPAP autoSV Advanced – System One, Philips Respironics, Murrysville PA). This device is deployed with the same algorithms as the previous version, the BiPAP autoSV Advanced. With the BiPAP autoSV Advanced – System One, pressure control is achieved with motor speed adjustments instead of a valve. The new system enhances patient adherence monitoring by providing wireless modem connectivity to EncoreAnywhere, a patient compliance monitoring system.

This study was undertaken to evaluate the performance of the BiPAP autoSV Advanced – System One device compared to the previous version of the ASV device, the BiPAP autoSV Advanced, in patients with central sleep apnea.

**Methods**

Participants with a known history of central apnea were selected from the participating sleep centers. Each participant was confirmed to have a central apnea index (CAI) of at least five events per hour during full attended polysomnography (PSG) while on CPAP. Participants meeting that requirement who met the remaining eligibility criteria (Table 2) were then randomized to a full attended PSG on one of the ASV devices followed by a full PSG while being treated with the alternate device. Participants were blinded to treatment.

### Table 2. Eligibility criteria

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Age 21-80</td>
<td>• Major medical or psychiatric condition that would interfere with the demands of the study, adherence to positive airway pressure, or the ability to complete the study. For example, unstable or end-stage heart failure; severe chronic lung disease or neuromuscular disease with known daytime hypercapnea; cancer; or poorly managed or end stage renal disease.</td>
</tr>
<tr>
<td>• Ability to provide written, informed consent</td>
<td>• Systolic blood pressure &lt; 80 mmHg at baseline visit.</td>
</tr>
<tr>
<td>• Medically stable as determined by the investigator</td>
<td>• Participants in whom PAP therapy is otherwise medically contraindicated.</td>
</tr>
<tr>
<td>• Subjects who currently have been on PAP therapy for ≥ 4 weeks and who previously had a CPAP titration with CAI ≥ 5. OR</td>
<td>• Participants who expressed an unwillingness to use CPAP</td>
</tr>
<tr>
<td>• Subjects who currently have been on PAP therapy for ≥ 4 weeks and who had a diagnostic study done, with a CAI ≥ 5, and were prescribed PAP therapy without a CPAP titration.</td>
<td>• Currently using oxygen therapy (as needed, nocturnal, or continuous)</td>
</tr>
<tr>
<td>• Willingness to perform all study related procedures</td>
<td>• Participants with previously diagnosed respiratory failure or respiratory insufficiency and who are known to have chronically elevated arterial carbon dioxide levels while awake (PaCO₂ ≥ 45mmHg).</td>
</tr>
<tr>
<td></td>
<td>• Participants who have had surgery of the upper airway, nose, sinus, or middle ear within the previous 90 days.</td>
</tr>
<tr>
<td></td>
<td>• Participants with untreated, non-OSA/CSA sleep disorders, including but not limited to; insomnia, periodic limb movement syndrome, or restless legs syndrome (PLM Arousal Index &gt; 15).</td>
</tr>
</tbody>
</table>
Device settings for both arms of the investigation are listed in Table 3. Both ASV device algorithms automatically adjust the inspiratory positive airway pressure (IPAP), expiratory positive airway pressure (EPAP), and the back-up respiratory rate.

### Table 3. Device settings

<table>
<thead>
<tr>
<th>Device setting</th>
<th>BiPAP Auto SV Advanced</th>
<th>BiPAP Auto SV Advanced – System One</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum Pressure (MaxPres)</td>
<td>30 cm H₂O (Range: 4 – 30 cm H₂O)</td>
<td>25 cm H₂O (Range: 4 – 25 cm H₂O)</td>
</tr>
<tr>
<td>Maximum Pressure Support (MaxPS)</td>
<td>26 cm H₂O (Range: 0 to “MaxPres minus EPAPmin” cm H₂O)</td>
<td>21 cm H₂O (Range: 0 to “MaxPres minus EPAPmin” cm H₂O)</td>
</tr>
<tr>
<td>Minimum Pressure Support (MinPS)</td>
<td>Allow 0 cm H₂O Pressure Support</td>
<td>Allow 0 cm H₂O Pressure Support</td>
</tr>
<tr>
<td>Maximum EPAP (EPAPmax)</td>
<td>25 cm H₂O (Range: 4 – 25 cm H₂O)</td>
<td>25 cm H₂O (Range: 4 – 25 cm H₂O)</td>
</tr>
<tr>
<td>Minimum EPAP (EPAPmin)</td>
<td>4 cm H₂O (Range: 4 – 25 cm H₂O)</td>
<td>4 cm H₂O (Range: 4 – 25 cm H₂O)</td>
</tr>
<tr>
<td>Backup Rate</td>
<td>Determined automatically</td>
<td>Determined automatically</td>
</tr>
</tbody>
</table>

Polysomnography was carried out following 2007 AASM recommended criteria. PSG’s were scored without knowledge of participant medical information and without revealing treatment allocation.

### Results – Demographic data

A total of 31 patients were screened for participation, and 14 participants were randomized. Data are presented from the completed-cases population which consisted of 11 males and 3 females with an average age of 58 ± 15.8 years, and an average BMI of 32.6 ± 6.6 kg/m².

From an analysis of sleep in each PSG, no significant differences were found in total sleep time, sleep efficiency, and wake after sleep onset (WASO) (Table 4).

### Table 4. Sleep quality

<table>
<thead>
<tr>
<th>Total sleep time (mins.)</th>
<th>Mean Value (± SD)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPAP</td>
<td>367.5 ± 73.3</td>
<td>.789</td>
</tr>
<tr>
<td>BiPAP autoSV Advanced</td>
<td>366.0 ± 66.9</td>
<td></td>
</tr>
<tr>
<td>BiPAP autoSV Advanced – System One</td>
<td>369.4 ± 67.7</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sleep efficiency (% TST)</th>
<th>Mean Value (± SD)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPAP</td>
<td>84.1 ± 10.4</td>
<td>.510</td>
</tr>
<tr>
<td>BiPAP autoSV Advanced</td>
<td>81.8 ± 10.6</td>
<td></td>
</tr>
<tr>
<td>BiPAP autoSV Advanced – System One</td>
<td>81.7 ± 7.5</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>WASO (mins.)</th>
<th>Mean Value (± SD)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPAP</td>
<td>52.0 ± 37.5</td>
<td>.526</td>
</tr>
<tr>
<td>BiPAP autoSV Advanced</td>
<td>62.2 ± 46.0</td>
<td></td>
</tr>
<tr>
<td>BiPAP autoSV Advanced – System One</td>
<td>55.2 ± 30.0</td>
<td></td>
</tr>
</tbody>
</table>
Therapy efficacy data are in Table 5 for the completed-cases analysis. Data from each PSG (CPAP Titration (CPAP); BiPAP autoSV Advanced); and the BiPAP autoSV Advanced – System One are presented. Compared to the CPAP titration, treatment with the BiPAP autoSV Advanced – System One resulted in a statistically significant reduction in AHI, CAI and OAI (p < 0.05).

**Table 5: Comparison of therapy efficacy (N=14)**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean</th>
<th>Std. deviation</th>
<th>Median</th>
<th>Min</th>
<th>Max</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AHI</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPAP</td>
<td>31.9</td>
<td>23.2</td>
<td>30.1</td>
<td>10.9</td>
<td>98.9</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>BiPAP autoSV Advanced</td>
<td>12.2</td>
<td>16.0</td>
<td>5.7</td>
<td>1.1</td>
<td>50.2</td>
<td></td>
</tr>
<tr>
<td>BiPAP autoSV Advanced – System One</td>
<td>8.0</td>
<td>9.1</td>
<td>6.1</td>
<td>.0</td>
<td>36.2</td>
<td></td>
</tr>
<tr>
<td><strong>CAI</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPAP</td>
<td>6.8</td>
<td>7.7</td>
<td>3.7</td>
<td>.1</td>
<td>24.3</td>
<td>.004</td>
</tr>
<tr>
<td>BiPAP autoSV Advanced</td>
<td>1.0</td>
<td>1.8</td>
<td>.2</td>
<td>.0</td>
<td>6.4</td>
<td></td>
</tr>
<tr>
<td>BiPAP autoSV Advanced – System One</td>
<td>.7</td>
<td>.8</td>
<td>.4</td>
<td>.0</td>
<td>3.1</td>
<td></td>
</tr>
<tr>
<td><strong>OAI</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPAP</td>
<td>13.6</td>
<td>9.6</td>
<td>10.1</td>
<td>5.0</td>
<td>36.4</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>BiPAP autoSV Advanced</td>
<td>1.4</td>
<td>2.3</td>
<td>1.0</td>
<td>.0</td>
<td>9.0</td>
<td></td>
</tr>
<tr>
<td>BiPAP autoSV Advanced – System One</td>
<td>.8</td>
<td>.6</td>
<td>.7</td>
<td>.0</td>
<td>2.1</td>
<td></td>
</tr>
</tbody>
</table>

*Overall p-values per the Friedman Test
Discussion
The efficacy of ASV technology has been demonstrated previously. In one study involving 10 patients with coexisting CSA/CSR treatment with ASV effectively suppressed CSA/CSR better than CPAP(7). Patients in that study were all males with a slightly lower BMI of 28.1 ± 1 Kg/m². The AHI on CPAP was 22±4 and was reduced to 4±1 with the first generation ASV device. Another study demonstrated that BiPAP autoSV was effective in treating SDB acutely and over a six week period(8). A group of ten male patients with a BMI of 26.9 ± 10 kg/m² with a mean age of 69 ± 10 were treated with the BiPAP autoSV Advanced for a six-week period. There was a significant reduction in AHI (diagnostic AHI 48.9 ± 20.6, initial treatment 8.9 ± 62 and 8.7 ± 7.4 after six weeks) and CAI (33.1 ± 10.8, 6.5 ± 4.9, and 6.1 ± 5.9). Further, servo-ventilation has been shown in two long-term studies in patients with CSR to be more effective in improving adherence compared to CPAP(9,10). In the present study, the BiPAP autoSV Advanced – System One device reduced the severity of sleep-disordered breathing in subjects with CSA when compared to CPAP and trended to perform better than the predecessor device, the BiPAP autoSV Advanced.

With both ASV devices there were clinically and statistically significant reductions in AHI, CAI and OAI, compared to the CPAP titration night. Both the BiPAP autoSV Advanced and BiPAP autoSV Advanced – System One produced mean AHI values that were significantly lower than those with CPAP (Table 5; p = 0.009 and 0.004 respectively). The BiPAP autoSV Advanced and BiPAP autoSV Advanced – System One also significantly reduced the CAI (p = 0.023 and 0.006, respectively) and significantly reduced the OAI (p = 0.003 and 0.006). There was not a significant difference in AHI, CAI, and OAI values between the two ASV devices.

The new BiPAP autoSV Advanced – System One operates by adjusting motor speed to control pressure. These data indicate that change in pressure control did not impact the performance of the device. In fact, the BiPAP autoSV Advanced – System One achieved these outcomes with a maximum pressure limit of 25 cm H2O. The previous device was capable of delivering up to 30 cm H2O.

Conclusion
BiPAP autoSV Advanced – System One has been shown to effectively treat this group of subjects with CSA. These data indicate that both ASV devices provide therapeutic benefit to patients diagnosed with CSA.

Bibliography
8. Michael Arzt, MD; Roland Wensel, MD PhD; Sylvia Montalvan, MD, et al. Effects of Dynamic Bilevel Positive Airway Pressure Support on Central Sleep Apnea in Men with Heart Failure. 2007 CHEST 1-22.
Helpful Hints
By Beth Guevara
Philips Respironics

Helpful hints for filing

BiPAP autoSV Advanced–System One
Sleep Therapy System

For patients with central or complex sleep apnea and periodic breathing
HCPCS Code E0470 and E0471

Overview

The following information describes the Durable Medical Equipment Medicare Administrative Contractors’ (DME MAC) medical policies for respiratory assist devices related to central and complex apnea and periodic breathing. Information was obtained from the DMEPOS supplier manuals and local coverage decisions from each region. This guide is for illustrative purposes only; it is not meant to be used as legal or reimbursement guidance. For specific instructions, please reference your supplier manual, or contact your DME MAC medical director or provider helpline.

If at any time the patient discontinues use of E0470 or E0471, the supplier is expected to ascertain the RAD device and discontinue billing for the equipment and related accessories and supplies.

The treating physician must fully document in the patient’s medical record, the symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc.

General coverage guidelines

The treating physician must be one who is qualified, by virtue of experience and training in noninvasive respiratory assistance, to order and monitor the use of respiratory assist devices.

For the consideration of coverage, polysomnographic studies must be performed in a sleep study laboratory, and not in a home or in a mobile facility. The laboratory must also comply with all applicable state regulatory requirements. Arterial blood gas, sleep oximetry and polysomnographic studies may not be performed by a DME supplier. This prohibition does not extend to results of studies conducted by hospitals certified to do such tests.
Central sleep apnea or complex sleep apnea

Note: All coverage criteria below, including those outlined in the CSA and CompSA definitions, must be met for coverage.

**Criterion A**
The diagnosis of central sleep apnea (CSA) or complex sleep apnea (CompSA).

and

**Criterion B**
Significant improvement of the sleep-associated hypoventilation with the use of an E0470 or E0471 device on the settings that will be prescribed for initial use at home, while breathing the patient’s usual FIO₂.

If all above criteria are met, either an E0470 or E0471 device will be covered for the first three months of therapy.

Coverage beyond the first three months requires, no sooner than 61 days after initiating use of the device:

- A re-evaluation of the patient by the treating physician
- A signed, dated statement from the treating physician declaring that the patient is compliantly using the device for an average of 4 hours per 24 hour period (download not required) and benefiting from its use

If the above criteria is not met, continued coverage of an E0470 or an E0471 device and related accessories will be denied as not medically necessary.

Medicare national average allowables for E0470 and E0471:

<table>
<thead>
<tr>
<th>HCPCS code</th>
<th>Allowable Rental per month*</th>
<th>Total allowed</th>
<th>Medicare payment (80%) (20%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0470 BiPAP Auto</td>
<td>$220.85</td>
<td>$662.55</td>
<td>$530.04</td>
</tr>
<tr>
<td>BiPAP Plus</td>
<td>$165.64</td>
<td>$1,656.40</td>
<td>$1,325.12</td>
</tr>
<tr>
<td>Totals</td>
<td></td>
<td>$2,318.95</td>
<td>$1,855.16</td>
</tr>
<tr>
<td>E0471 BiPAP S/T</td>
<td>$541.86</td>
<td>$1,625.58</td>
<td>$1,300.46</td>
</tr>
<tr>
<td>BiPAP autoSV Advanced</td>
<td>$406.40</td>
<td>$4,064.00</td>
<td>$3,251.20</td>
</tr>
<tr>
<td>Totals</td>
<td></td>
<td>$5,689.58</td>
<td>$4,551.66</td>
</tr>
</tbody>
</table>

* Allowable per month is based on 2011 DMEPOS fee schedule national average excluding non-continental areas that are not subject to the ceilings and floors.

† Rental months 4-13 subject to 75% of allowed amount; Medicare pays 80% of that amount while the beneficiaries pay the remaining 20%.

Central sleep apnea (CSA) is defined as:

1. An apnea hypopnea index (AHI) > 5; and
2. Central apneas/hypopneas > 50% of the total apneas/hypopneas; and
3. Central apneas or hypopneas ≥ 5 times per hour; and
4. Symptoms of either excessive sleepiness or disrupted sleep.

Complex sleep apnea (CompSA) is a form of central apnea specifically identified by the persistence or emergence of central apneas or hypopneas upon exposure to CPAP or an E0470 device when obstructive events have disappeared. These patients have predominately obstructive or mixed apneas during the diagnostic sleep study occurring at greater than or equal to five times per hour. With use of a CPAP or E0470, they show a pattern of apneas and hypopneas that meets the definition of CSA described above.

Relevant ICD-9-CM diagnosis code

<table>
<thead>
<tr>
<th>ICD-9 code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>327.21</td>
<td>Primary central sleep apnea</td>
</tr>
<tr>
<td>327.22</td>
<td>High-altitude periodic breathing</td>
</tr>
<tr>
<td>327.27</td>
<td>Central sleep apnea in conditions specified elsewhere</td>
</tr>
<tr>
<td>327.29</td>
<td>Other organic sleep apnea</td>
</tr>
<tr>
<td>786.04</td>
<td>Cheyne-Stokes respiration (Central sleep apnea due to Cheyne-Stokes breathing pattern)*</td>
</tr>
</tbody>
</table>

*There is no ICD-9 code for complex sleep apnea. Document presence of any central sleep apnea using code above.

BiPAP autoSV Advanced is cleared for the treatment of periodic breathing, such as Cheyne-Stokes respiration.
**Clinical applications guide**

Reimbursement Customer service Website
Information & fee schedules 1-800-345-6443; listen to the instructions www.philips.com/respironics
Educational materials & questions and follow prompts to select the insurance reimbursement information option

*Please note that a -KX modifier is necessary to include when billing E0470 and E0471. The -KX modifier also should be added when billing accessories used with E0470 and E0471.

This information is for illustrative purposes only. You should not consider this to be either legal or reimbursement advice. Given the rapid and constant change in public and private reimbursement, Philips Healthcare cannot guarantee its comprehensiveness, accuracy, or timeliness. Philips urges you to seek your own counsel and experts for guidance related to reimbursement, including coverage, coding, and payment.

**For more information from Philips Respironics concerning**

<table>
<thead>
<tr>
<th>HCPCS code</th>
<th>Description</th>
<th>Payment category/maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0470 BiPAP Auto and BiPAP Plus</td>
<td>Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device).</td>
<td>Capped rental • Rental payment can be made for up to 13 months of continuous use.</td>
</tr>
<tr>
<td>E0471 BiPAP S/T and BiPAP autoSV Advanced</td>
<td>Respiratory assist device, bi-level pressure capability, with backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device).</td>
<td>Capped rental • Rental payment can be made for up to 13 months of continuous use.</td>
</tr>
</tbody>
</table>

**Accessories**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>A4604</td>
<td>Tubing with integrated heating element for use with positive airway pressure device</td>
<td>1 per 3 months</td>
</tr>
<tr>
<td>A7030</td>
<td>Full face mask used with positive airway pressure device, each</td>
<td>1 per 3 months</td>
</tr>
<tr>
<td>A7031</td>
<td>Face mask interface, replacement for full face mask, each</td>
<td>1 per 1 month</td>
</tr>
<tr>
<td>A7032</td>
<td>Cushion for use on nasal mask interface, replacement only, each</td>
<td>2 per 1 month</td>
</tr>
<tr>
<td>A7033</td>
<td>Pillow for use on nasal cannula type interface, replacement only, pair</td>
<td>2 per 1 month</td>
</tr>
<tr>
<td>A7034</td>
<td>Nasal interface (mask or cannula type) used with positive airway pressure device, with or without headstrap</td>
<td>1 per 3 months</td>
</tr>
<tr>
<td>A7035</td>
<td>Headgear</td>
<td>1 per 6 months</td>
</tr>
<tr>
<td>A7036</td>
<td>Chin strap</td>
<td>1 per 6 months</td>
</tr>
<tr>
<td>A7037</td>
<td>Tubing</td>
<td>1 per 3 months</td>
</tr>
<tr>
<td>A7038</td>
<td>Filter, disposable</td>
<td>2 per 1 month</td>
</tr>
<tr>
<td>A7039</td>
<td>Filter, nondisposable</td>
<td>1 per 6 months</td>
</tr>
<tr>
<td>A7045</td>
<td>Exhalation port with or without swivel, replacement only</td>
<td>Not specified in current DME MAC policy</td>
</tr>
<tr>
<td>A7046</td>
<td>Water chamber for humidifier, replacement each</td>
<td>1 per 6 months</td>
</tr>
<tr>
<td>A9279</td>
<td>Monitoring feature/device, stand-alone or integrated, any type. Includes all accessories, components and electronics, not otherwise classified.</td>
<td>No current fee schedule allowance</td>
</tr>
<tr>
<td>E0561</td>
<td>Humidifier, nonheated</td>
<td>N/A purchase</td>
</tr>
<tr>
<td>E0562</td>
<td>Humidifier, heated</td>
<td>N/A purchase</td>
</tr>
</tbody>
</table>

*Please note that a -KX modifier is necessary to include when billing E0470 and E0471. The -KX modifier also should be added when billing accessories used with E0470 and E0471. This information is for illustrative purposes only. You should not consider this to be either legal or reimbursement advice. Given the rapid and constant change in public and private reimbursement, Philips Healthcare cannot guarantee its comprehensiveness, accuracy, or timeliness. Philips urges you to seek your own counsel and experts for guidance related to reimbursement, including coverage, coding, and payment.

For more information from Philips Respironics concerning

<table>
<thead>
<tr>
<th>Reimbursement</th>
<th>Customer service</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information &amp; fee schedules</td>
<td>1-800-345-6443; listen to the instructions and follow prompts to select the insurance reimbursement information option</td>
<td><a href="http://www.philips.com/respironics">www.philips.com/respironics</a> (coding, coverage and payment)</td>
</tr>
</tbody>
</table>
Encore guide

1. Long-term usage
2. Long-term trends
3. Short-term trends
4. Waveform reports
5. Summary
6. Tips and suggestions
The first number represents time duration of total compliance. The second number represents total blower hours.

Number of hours of use below preset threshold.

Blower on but patient not compliant.

Blower on and patient compliant.
### Long-term usage

**Compliance Information**

5/19/2009 – 5/25/09

- **Auto Servo Ventilation**
- **Avg Humidifier 3.1, Last Setting: 3.0**
- **Avg Flex 1.0, Last Setting: 1.0**

**Displays the average humidifier and Flex value and the last setting.**

**Compliance threshold** (here 4 hours) but can be set differently using the Encore software preferences settings.

**Daily compliance**
- Displays the hours of usage per day
- Irregular pattern may indicate issues such as patient discomfort

- **Average PS per night**
  \[ \text{PS} = \text{IPAP} - \text{EPAP} \]

- **90% EPAP**: Patient spent 90% of the night at or below this expiratory pressure

- **Residual AHI per night**

- **Residual AHI averaged over the total period**

- **Average AHI: 8.9**

**Displays**
- Days of usage
- Average pressure support (Pressure Support (cmH2O))
- Hours of usage
- Pressure (cmH2O)
- AHI

**Long-term usage**

- Displays the average humidifier and Flex value and the last setting.
- Compliance threshold (here 4 hours) but can be set differently using the Encore software preferences settings.
- Daily compliance
  - Displays the hours of usage per day
  - Irregular pattern may indicate issues such as patient discomfort

- **Average Pressure Support (PS) per night**
  \[ \text{PS} = \text{IPAP} - \text{EPAP} \]

- **90% EPAP**: Patient spent 90% of the night at or below this expiratory pressure

- **Residual AHI per night**

- **Residual AHI averaged over the total period**

- **Average AHI: 8.9**
Long-term trends will allow you to evaluate how patient therapy progressed.

### Diagram 1: Long-term trends

- Average pressure support (PS) per night
- Percentage of Periodic Breathing
- CAI: clear airway apnea index (opened upper airways)
- OAI: obstructed airway apnea index (closed upper airways)
- Total AHI = CAI + OAI + HI
- HI: hypopnea index
- Flow limitation index
- Vibratory snoring index
- Percentage of time in large leaks

### Diagram 2: Other parameters

- Percentage of patient-triggered breaths (here 90.4%): indicates if patient is breathing spontaneously (high percentage) or relying on the backup rate (low percentage)
- Spontaneous breathing frequency
- Minute ventilation: volume of air inspired into or expired out of the lungs in 1 min. It is expressed as:
  Tidal volume $\times$ breathing frequency
  Example: $500$ ml (Tidal volume) $\times$ 12 bpm $= 6$ l/min
Short-term trend analysis is a ‘close-up’ look at one night vs. the long term trends.

- All values in the column are averaged over total period
- See detail in illustration below
- Percentage of patient spontaneous breaths (here 99.2%)
- Percentage of Periodic Breathing
- Residual respiratory events during the night are split into categories
- Mask fit indicator: green = good fitting, black = large leak period
- Patient breathing rate
- Device backup rate
- Minute ventilation

Maximum pressure setting: this is the maximum IPAP (the pressure will never go above this value)
IPAP Range = IPAP pressure changes during a 2-min. window
IPAP = Average IPAP over a 2-min. window
EPAP = Average EPAP over a 2-min. window
Minimum EPAP: this is the minimum EPAP setting (the pressure will never go below this value)

The blue area shows IPAP range during a 2-min. window
Here IPAP went from 5 cmH₂O to 15 cmH₂O
Sample of daily trends

Example: Important leaks

Patient switched off 3 times probably due to discomfort induced by large leaks (as illustrated below)

Large leaks periods are displayed in the ‘Mask fit indicator’

⇒ Check patient interface
Our detailed Patient Flow and Event report found with the BiPAP autoSV Advanced allows you to view on a weekly basis every breath your patient takes and how the BiPAP autoSV Advanced responded.

The blue line is an indication of the patient’s flow waveform.

Below the patient waveform line, the red line documents the pressure delivered to the patient. The dots indicate a change in EPAP pressure (either increase or decrease).

Colored indicator flags are available to indicate events that are identified by the device.
Summary

Compliance Summary – All Data

**Compliance Statistics**

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Range</td>
<td>22/09/2009 – 18/10/2009 (27 days)</td>
</tr>
<tr>
<td>Days with Device Usage</td>
<td>24 days</td>
</tr>
<tr>
<td>Days without Device Usage</td>
<td>3 days</td>
</tr>
<tr>
<td>Percent Days with Device Usage</td>
<td>88.9%</td>
</tr>
<tr>
<td>Cumulative Usage</td>
<td>5 days 12 hrs. 35 mins. 36 secs.</td>
</tr>
<tr>
<td>Maximum Usage (1 Day)</td>
<td>9 hrs. 11 mins. 28 secs.</td>
</tr>
<tr>
<td>Average Usage (All Days)</td>
<td>4 hrs. 54 mins. 39 secs.</td>
</tr>
<tr>
<td>Average Usage (Days Used)</td>
<td>5 hrs. 31 mins. 29 secs.</td>
</tr>
<tr>
<td>Minimum Usage (1 Day)</td>
<td>5 mins. 54 secs.</td>
</tr>
<tr>
<td>Percent of days with Usage &gt;= 4 hours</td>
<td>70.4%</td>
</tr>
<tr>
<td>Percent of days with Usage &lt;= 4 hours</td>
<td>29.6%</td>
</tr>
<tr>
<td>Total Blower Hours</td>
<td>5 days 12hrs. 49 mins. 10 secs.</td>
</tr>
</tbody>
</table>

**BiPAP autoSV Advanced Summary**

- Average Device EPAP Pressure <= 90% of Time: 6.0 cm H2O
- Average Percent of Night in Periodic Breathing: 0.1%
- Average Time in Large Leak Per Day: 2 secs.
- Average Breath Rate: 16.6 bpm
- Average Minute Vent: 7.3

**Settings**

- Min. EPAP: 4.0
- Max. EPAP: 10.0
- Min. Pressure Support: 0.0
- Max. Pressure Support: 10.0
- Max. Pressure: 25.0
- Min. Pressure Support: Auto
- Flex Setting: 2.0

Summary of all compliance data

- Patient usage is very good
- Percentage of the night the patient has a periodic breathing waveform pattern

Reminder of all therapy settings
6 Tips and suggestions

Tips and suggestions:

• Always pay attention to diagnostic night before setting/checking an Encore report.
• Choose the patient interface that suits your patient – there is no efficient therapy without a good mask fit!
• Clinical follow-up.

Usages:

BiPAP autoSV Advanced–System One is intended to provide noninvasive ventilation support to treat:

• Adult patients with obstructive sleep apnea
• Respiratory insufficiency caused by central and/or mixed apneas and periodic breathing.

It is to be used in hospital, or home.