

# First Impressions

## Quarterly™

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## Studies Link Sleep Disorders and Cardiovascular Disease

Recent studies have shown that many patients with impaired cardiac function can also suffer from some form of sleep disordered breathing.<sup>1</sup> What's more, forms of sleep disordered breathing like Obstructive Sleep Apnea (OSA) may actually exacerbate cardiovascular disease.<sup>1,2</sup> Diagnosis and treatment of OSA with Continuous Positive Airway Pressure (CPAP) can result in improved cardiac function for patients leading to a decrease in morbidity and mortality of patients with both disorders.<sup>2</sup> These conclusions have been reached in a variety of recent studies\* conducted by both cardiac and sleep specialists.

Cardiovascular Disease and Sleep Disordered Breathing often arise in the same general patient population. They both occur predominately in men vs. women, people who are obese, people who have a history of smoking or alcohol abuse, and post-menopausal women. Because of the similarities in the impacted population, OSA often goes undiagnosed in patients with cardiac disorders.<sup>1</sup> As a result of the undiagnosed disorder, the patient's cardiac condition may worsen. Untreated OSA can contribute to the development of hypertension or high blood pressure, congestive heart failure, cardiac arrhythmias or stroke.

Normally, when a patient sleeps the cardiovascular system enters into a restorative phase. During non-REM (Rapid-Eye-Movement) sleep, which normally accounts for about 80% of sleep time, the heart rate goes down, cardiac output or blood ejected from the heart is reduced, and systemic blood pressure is reduced. The other 20% of sleep is known as REM sleep. This cycle occurs approximately every 90 minutes and increases in duration as the individual nears waking. During REM sleep, heart rate, blood flow and blood pressure rise similar to when the patient is awake. So, with 80% of sleep spent in a non-REM state, the normal patient's heart has ample time to rest.

*(Continued on page 5)*

## Educating Cardiologists/Marketing Your Business

Not surprisingly, cardiologists and other healthcare providers treating patients with chronic heart failure tend to focus on how the patient presents while awake. However, as Drs. T. Douglas Bradley and John S. Floras observe in the April 1, 2003 issue of *Circulation*, "this approach presupposes that any mechanisms that might contribute to the pathophysiology or progression of [heart failure] are quiescent during sleep."

For cardiovascular patients with simultaneous sleep apnea, sleep may be anything but quiet or inactive. The two conditions, occurring together, can lead to increased morbidity and mortality.

As a sleep specialist, you have an excellent opportunity to help physicians understand the prevalence, diagnosis and treatment of sleep-disordered breathing in patients with cardiovascular disease. In so doing, you'll be building your business in a market where OSA remains largely undiagnosed and untreated. Here are a few tips that can help.

- **Know your customers.** Your most important contact point for a

*(Continued on page 5)*

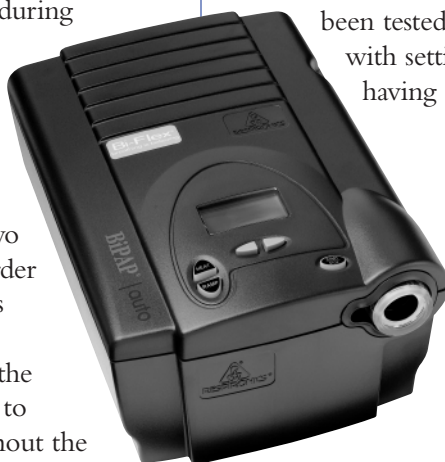


# Ask the Respironics Experts

**Q:** *When should I consider BiPAP® Auto (auto bi-level therapy) for my patients?*

**A:** Bilevel therapy is an established and effective therapy for non-tolerant CPAP users who are identified in the lab at time of titration<sup>1</sup> or for patients who have been identified as non-tolerant or non-responsive to CPAP therapy at home.<sup>2</sup> Since CPAP intolerance<sup>3</sup> may be associated with high mean airway pressure levels, bi-level can be an effective therapy option. Bi-level therapy reduces mean airway pressure during exhalation and provides an IPAP/EPAP differential that mimics a natural flow pattern. The result is more comfortable and tolerable therapy for OSA patients.

When switching a patient from CPAP to traditional bi-level you must identify and set two different pressure levels (IPAP and EPAP) in order for the patient to be effectively treated. With its auto adjusting algorithm, the BiPAP Auto can automatically identify and continuously adjust the required IPAP and EPAP pressures in response to changing breathing patterns that occur throughout the night and from night to night. BiPAP Auto provides effective Bi-level therapy for all OSA patients whether intolerance occurs in the sleep laboratory or at home.



Suggested protocols for starting therapy with the BiPAP Auto include: setting the EPAP at the minimum setting or according to protocol for auto CPAP, and set the maximum delta at 8 cm. By using a rescue protocol that is based on collaborative patient management, the homecare provider and physician can work together to achieve lasting positive outcomes for their non tolerant patient population.

The BiPAP Auto costs the same as our BiPAP® Pro 2 and can also be used as a traditional bi-level device. The device has been tested to safely and effectively treat OSA patients with settings from 4 cm H<sub>2</sub>O to 25cm H<sub>2</sub>O without having to set specific IPAP and EPAP levels.

<sup>1</sup> Szumstein, et. al., ATS abstract 1999

<sup>2</sup> Gay, et. al. Sleep 2005;28;A210

<sup>3</sup> Robinson, et.al. Sleep Disorders Medicine 2nd ed. 1999, 345

<sup>4</sup> Wylie and Grover. Automatic bi-level positive airway pressure delivery with flow-directed pressure modulation and expiratory pressure relief – an in-laboratory comparison with conventional bi-level positive airway pressure therapy. Respironics, Inc., 2005

*Answer provided by Respironics Experts Maura Weis, US Marketing Manager, CPAP/Humidifier; Sharon Baer, Manager, Medical Education and Brian Bunofsky, Global Product Manager, Bi-level.*



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## Upcoming Tradeshows and Events

### Preventive Cardiovascular Nurses Association (PCNA)

April 20 – 22, 2006  
Denver, CO

### FOCUS on Respiratory Care and Sleep Medicine Conference

April 20 – 22, 2006  
Nashville, TN

### American Thoracic Society (ATS)

May 21 – 23, 2006  
San Diego, CA

### Associated Professional Sleep Societies (APSS)

June 19 – 21, 2006  
Salt Lake City, UT

### American Association of Heart Failure Nurses (AAHFN)

June 22 – 24, 2006  
Miami, FL

# Reimbursement Review

## CPAP and RAD Devices Face Reimbursement Cuts Capped Rental Option to be Eliminated under Medicare

**By Beth Guevara**  
*Manager, Reimbursement Planning*

In a last-minute addition to the Deficit Reduction Act of 2005 (S.1932), Representative Bill Thomas (R-CA) proposed inclusion of a provision that ends capped rental under Medicare Part B for items such as CPAPs and Respiratory Assist Devices (RAD) and puts a 36-month limit on oxygen equipment payments.

The bill passed in the House on February 1, 2006 by a narrow margin of 216-214 after having passed in the Senate on December 21, 2005 by a vote of 51-50, with Dick Cheney being called back from overseas to cast the tie-breaking vote. The President signed the bill into law on February 8, 2006 and now the Centers for Medicare and Medicaid Services (CMS) will be responsible for interpreting it and writing the rules that will put it into practice.

What does all of this mean to the provider of durable medical equipment, including CPAP and RAD?

Currently, Medicare pays up to 15 months rental for these devices. After 15 months, the provider continues to hold title to the equipment and receives payment every 6 months (equivalent to one month rental) to perform any necessary maintenance and service to keep the device in proper working order.

Under the new law, for rental agreements beginning on or after January 1, 2006, Medicare will pay up to 13 months rental on CPAP and RAD devices and subsequently transfer title of the equipment to the patient. The 6-month maintenance and service payments which previously began at the 21st month of rental will be eliminated. However, the new legislation does allow for unspecified payment

for these services. The working details will be the responsibility of CMS to determine.

Although under the new law, providers will lose a minimum of two months of rental payments, the amount of each monthly rental payment will not change. Medical necessity guidelines and qualifying criteria will also remain unaffected.

However, patients will now be required to take on the burdensome responsibility of maintenance, service and repair for their equipment – something neither patients nor providers advocate.

For more information, including the text of the DME provision of S.1392, visit the American Association for Homecare website at [www.aahomecare.org](http://www.aahomecare.org).

## Respironics Resource Corner

Recent studies have shown a significant link between OSA and Cardiovascular Disease. As a clinician you have an excellent opportunity to help educate Cardiologists and PCP's on the importance of diagnosis and treatment of OSA. Below are a few materials provided by Respironics designed to help you to educate and increase awareness among your local physicians and their patients.

### Physician Education

**PN 1025950**

Sleep Apnea and Heart Failure Fact Sheet

### Clinical Studies

**PN 1007314**

Prospective study on the association between sleep disordered breathing and hypertension Peppard et. al, NEJM, Vol. 342: 1378 – 1384, 2000

**PN 1007315**

Health care utilization in males with OSA two years after diagnosis and treatment Bahammam et. al, Sleep, Vol. 22, No. 6, 1999

**PN 1028832**

Association between OSA and A-Fib Gami et. al, Circulation, Vol. 110, No 4, 2004

**PN 1028770**

10 year cardio outcomes in men with OSA Marin et. al, Lancet, Vol. 365, No 9464, 1046 – 1053, 2005

### Patient Education

**PN 1012593**

OSA Patient Education Brochure and Holder General OSA awareness, symptom recognition and consequences. Comes with 50 brochures and one acrylic tabletop display to hold the brochures. For use in the physician office, healthfairs and other educational venues.

**PN 1011261**

OSA Patient Education Poster General OSA awareness, symptom recognition and consequences. For use in the physician office, healthfairs and other educational venues.

**PN 1006106**

OSA Quick Fact Sheet General OSA awareness, symptom recognition and consequences. For use in the physician office, healthfairs and other educational venues.

**PN 1021542**

Inside OSA Video – Information for Sleep Apnea Patients (DVD) (also available in VHS) A four segment educational video about OSA. Segment 1: Sleep Disordered Breathing Segment 2: Evaluating Sleep Segment 3: Treatment with PAP Therapy Segment 4: Living with PAP Therapy

# Mask Fitting Tips

Finding a good mask fit is key to helping patients stick to their OSA therapy. It is important to make a good first impression on patients when introducing them to their OSA mask. To find the best mask fit for your patient, try the following suggestions:

- Let new patients become familiar with the mask before fitting.
- A tight fit is not the best fit. Pulling the headgear too tight can often cause air leaks.
- Use the StabilitySelector™ to help correct leaks (see Figure 1). Adjust in the opposite direction of a leak.
- All leaks do not have to be corrected. If the leak is not in the eyes or is not disturbing sleep, most therapy devices will compensate to deliver the appropriate therapy.
- Always make final fitting adjustments while the patient is lying down and receiving prescribed therapy.
- To help maintain fit from day-to-day, instruct patient to use the quick clips for mask removal. Or, for masks without quick clips, use a permanent marker to mark the proper tab placements on the headgear.

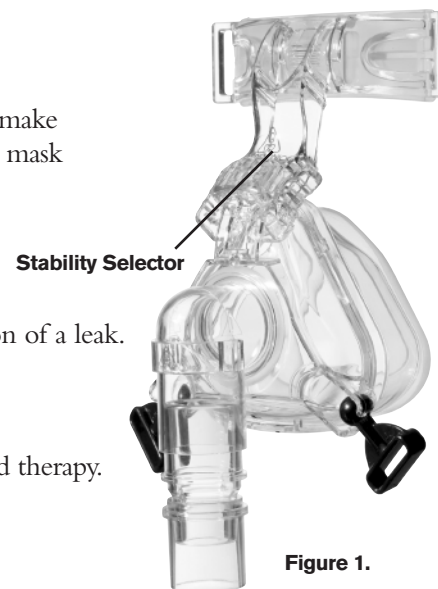


Figure 1.

## Ask the Respirionics Experts

*Q: Which masks are labeled 'Multiple Patient Use Reusable' and how can I get your validated sterilization/disinfection instructions?*

*A:* Respirionics has validated several masks to meet the stringent FDA guidelines for “Multiple Patient Use Reusable” labeling. The masks include: ComfortGel™, ComfortFull™ 2, ComfortSelect™, ComfortClassic™, ComfortLite™, Profile™ Lite, Simplicity™, and the Total™ Face Mask.

In order for an interface product to be considered Multiple Patient Use Reusable, efficacy testing must meet a “high level disinfection” FDA standard. Each of the agents/processes published in our *Guide to Cleaning and Disinfecting Respirionics Masks* meet the FDA standard (approved agents/processes vary by mask type)\*.

To order the *Guide to Cleaning and Disinfecting Respirionics Masks* (PN 1011138), call customer service 1-800-345-6443. You can also order separate disinfecting instructions for other Respirionics masks that are not mentioned above.

\* Other disinfecting agents/processes are available on the market. We cannot recommend them since we either have not performed efficacy testing, the agent failed efficacy testing on the specific product and/or the agent was found to damage the mask within a few cycles.

*Answer provided by Respirionics Expert, Laurie Scott, US Marketing Manager, Patient Interface.*

## Sleep Tech Tips

*After completing a titration cycle, remove the mask from the patient and give him or her five to ten minutes to re-acclimate to room air. After the short break, reintroduce PAP pressure to the patient. This time the pressure should be set to the pressure most likely to be prescribed by the physician. This will allow the patient to experience what therapy will be like at home.*

*I find it very helpful to complete this exercise with patients. Often, patients' therapy expectations are not realistic – they may only remember feeling the starting pressure of 4 to 5 cm H<sub>2</sub>O. In reality, most patients are prescribed 8 - 12 cm H<sub>2</sub>O and the feeling is very different. By reinforcing the feeling of actual therapy pressure, you will help the homecare provider have an easier time re-introducing PAP therapy to the patient in the home.*

*Joyce Black, CRT, RPSGT  
Pittsburgh, PA*

We have dedicated the “Sleep Tech Tips” section to helpful hints that you would like to share with your peers.\* If you have discovered ways to improve diagnostic procedures, to make your patients more comfortable during their sleep study, or to increase patient compliance, email them to us at [marketingcommunications@respiroics.com](mailto:marketingcommunications@respiroics.com). Please put “Sleep Tech Tips” in the subject line and be sure to include your name, title, the name of your facility and phone number. If we use your tip, we will send you a small gift of appreciation.

\* By submitting your tips you are granting Respirionics the right to publish and use your information in any way Respirionics deems appropriate, without obligation beyond the free gift mentioned here.

## Studies Link Sleep Disorders and Cardiovascular Disease

(Continued from page 1)

In a patient with sleep apnea, the normal restful pattern is disturbed. As the patient enters sleep (both non-REM or REM sleep), their airway becomes unstable and either partially or completely collapses. The collapse of the airway and reduction in airflow cause the patient to have a decrease in their oxygen level and rise in their carbon dioxide level. The patient's brain senses the decrease in the oxygen level and in turn sends a signal through the nervous system to awaken the patient to breathe. At the same time, that signal will also increase the patient's heart rate and blood pressure. As a result, the patient awakens, reestablishes their airway and begins to breathe normally again. But the patient's cardiac system has been stimulated adversely. As the patient relaxes, their breathing pattern will return to normal, then sleep occurs again. As sleep occurs, the cycle of airway collapse and cardiac stimulation will start again.

Rather than having a normal therapeutic effect, sleep time only magnifies the stress that is already a problem in the patient with cardiovascular disease. In fact, there is a whole range of chemical and physiological changes that can take place in patients suffering from apnea-disturbed sleep. For instance, recurring apnea-induced hypoxia can disrupt normal rhythms and damage heart tissues, which may already be weakened by heart disease. In addition, although there does not appear to be any direct cause/effect evidence, there is reason to believe repeated hypoxia and post-apneic reoxygenation of tissues can lead to the generation of reactive oxygen species and adhesion molecules associated with vascular effects like atherosclerosis.<sup>2</sup>

### Benefits of CPAP

If OSA is so detrimental to patients with cardiovascular disease, it would seem logical that therapies such as CPAP, which is the most common treatment for OSA, would be beneficial. Clinical trials have

demonstrated this outcome. Various studies have shown that with the application of CPAP to a patient with OSA, patients had an improvement in heart function, lower blood pressure, less cardiac arrhythmias and a decrease in morbidity and mortality associated with OSA. In two recently released studies, identifying a patient with OSA and treating them with CPAP significantly reduced their odds of developing fatal or non fatal cardiovascular events.<sup>5,6</sup>

Researchers have characterized the effects of CPAP as being similar to that of beta-blockade treatment, but they are achieved non-pharmacologically by reducing oxygen demand and increasing oxygen supply and attenuating sympathetic nervous system outflow.

Dr. Shahrokh Javaheri, Medical Director, Sleepcare Diagnostics, Cincinnati, OH, has written extensively on this subject. He sums up the situation in a 2005 paper he published with Dr. Laura Wexler in *Current Treatment Options in Cardiovascular Medicine*. "Although long-term controlled trials of the effect of treatment of sleep apnea on mortality in patients with heart failure are still pending," he says, "treatment of sleep apnea, both obstructive and central, does result in a decrease in sympathetic activity and an improvement in systolic function, which are known surrogates of mortality. Therefore, diagnosis and treatment of sleep-related breathing disorders may increase survival of patients with heart failure."

\* The information in this article was drawn from several sources, including:

<sup>1</sup> Javaheri, S., Wexler L.: **Prevalence and Treatment of Breathing Disorders During Sleep in Patients with Heart Failure.** *Current Treatment Options in Cardiovascular Medicine*, 2005, 7:295-306.

<sup>2</sup> Bradley, T.D., Floras, J.S.: **Sleep Apnea and Heart Failure Part I: Obstructive Sleep Apnea.** *Circulation*, 2003, 107:1671-1678.

<sup>3</sup> Somers, V.K., **Sleep Apnea and Heart Disease.** *Sleep Matters Magazine*, Summer, 2004.

<sup>4</sup> Trupp, R.J., et.al., **Prevalence of Sleep Disordered Breathing in Heart Failure Program.** *Congestive Heart Failure*, 2004, 10:217-220.

<sup>5</sup> Marin, J. et. al. **Long Term Cardiovascular Outcomes in Men with Obstructive Sleep Apnea-hypopnea with or without treatment with Continuous Positive Airway Pressure; an observational study.** *Lancet*, 2005; 365; 1046-1053.

<sup>6</sup> Campos-Rodriquez, F. et. al. **Mortality in Obstructive Sleep Apnea-Hypopnea Patients Treated with Postive Airway Pressure,** *Chest*, 2005; 128;624-633

## Educating Cardiologists/ Marketing Your Business

(Continued from page 1)

patient with heart disease will be the primary care doctor, cardiologist, heart failure nurse or the patient themselves.

- **Become known as the local expert.** Become a trusted resource for physicians and patients. Keep them up-to-date on the latest research and technology available.\*
- **Stress your success.** Provide doctors with reports on the successes you've had with other patients. Schedule a 'lunch and learn' session where you provide education but also personalize it with the results of other cases.
- **Get the word out.** Contact local newspapers with story ideas about the relationship between sleep-disordered breathing and heart failure. Get involved in community organizations, health fairs and other educational venues.\*

More than half of all patients with impaired cardiac function suffer from sleep-related breathing disorders. By helping patients and physicians understand their treatment options, you can build you business.

\* Respironics provides material to help you educate physicians and patients. Check out the Resource Corner on page 3 of this newsletter.

# Study Shows Association Between SDB and Stroke

By Sharon Baer, Manager, Medical Education

## Title and Author:

### Association of Sleep Disordered Breathing and the Occurrence of Stroke

Arzt, M.,<sup>1</sup> Young, T.,<sup>2</sup> Finn, L.,<sup>2</sup> Skatrud, J.B.,<sup>3</sup> Bradley, T.D.<sup>1</sup>

<sup>1</sup> Center for Sleep Medicine and Circadian Biology, University of Toronto, Toronto, Ontario

<sup>2</sup> Department of Population Health Sciences, University of Wisconsin School of Medicine, Madison, Wisconsin

<sup>3</sup> Department of Medicine, University of Wisconsin School of Medicine, Madison, Wisconsin

## Journal

*American Journal of Respiratory and Critical Care Medicine*, 2005. (172) 1447-1451.

## Brief Summary of Study

The study is a cross-sectional analysis of 1,475 subjects and longitudinal analysis of 1189 subjects from the general population. All participants underwent an overnight polysomnography to identify sleep disordered breathing and data concerning risk factors for stroke or a history of physician diagnosed stroke and were obtained at baseline, 4, 8 and 12 years after enrollment.

## Results

The results of the study were analyzed by looking at the prevalence of stroke within the population and the incidence of stroke within the population after adjusting for confounding factors such as hypertension, diabetes, age, sex, and body mass index.

When assessing **prevalence of stroke with the Wisconsin cohort**, patients with an AHI >20 had a 4 times greater risk (CI 95%) for developing a stroke compared to those without SDB (AHI <5).

| <b>Model 1A</b><br>Includes: AHI >20, Age, sex, BMI, weekly alcohol use and smoking history | <b>Model 2A</b><br>Includes: all in 1A plus history of hypertension | <b>Model 3A</b><br>Includes: all in 2A plus diabetes history |
|---|---|--|
| <b>Odds ratio:</b> 4.33<br>(1.32-14.24)   | <b>Odds ratio:</b> 3.87<br>(1.19-12.63)                             | <b>Odds ratio:</b> 3.83<br>(1.17-12.56)                      |
| <b>P value:</b> 0.02  | <b>P value:</b> 0.02  | <b>P value:</b> 0.03   |

When assessing **incidence of stroke with the Wisconsin cohort**, patients with AHI >20 had 4.3 % increased incidence (CI 95%) of developing a stroke over the next 4 years when compared to those with an AHI <5.

| <b>Model 1A</b><br>AHI >20, Unadjusted  | <b>Model 2A</b><br>AHI >20, Adjusted for age and sex | <b>Model 3A</b><br>AHI >20, Adjusted for age, sex and BMI |
|---|--|---|
| <b>Odds ratio:</b> 4.31<br>(1.31-14.25) | <b>Odds ratio:</b> 4.48<br>(1.31-15.33)              | <b>Odds Ratio:</b> 3.08<br>(0.74-12.81)                   |
| <b>P value:</b> 0.02                    | <b>P value:</b> 0.02                                 | <b>P value:</b> 0.12                                      |

## Conclusions

This latest data from the Wisconsin cohort demonstrates a significant association between SDB and stroke. This is the first evidence of a significant relationship between SDB assessed objectively in lab by polysomnography and prevalence of stroke in the general population (even after adjustment for known confounding factors). When adjusting for AHI ≥ 20, the prevalence of stroke was shown to be greater than reported in previous studies. This paper provides longitudinal data that demonstrated patients with an AHI ≥ 20 had a significantly higher probability of having a stroke within the next 4 years, independent of confounding factors.

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## New Product Introduction

### **ComfortFull™ 2 Full Face Mask**

The ComfortFull 2 is newly designed to help deliver OSA therapy more comfortably. Its dual-flap cushion is more forgiving for broader noses and features a soft, polished outer layer that provides a more reliable seal. The mask's combined faceplate and cushion design makes the ComfortFull 2 lightweight and easy to clean. And, its new entrainment valve split washer allows better swiveling while ensuring a secure connection.

ComfortFull 2 also features a new easier-to-use StabilitySelector™ which enables the wearer to adjust the mask to find the best angle, seal and fit.

The removable forehead support and pad automatically adjust to the angle of the wearer's forehead for an even more precise fit.

