

## **Overcoming CPAP Compliance Obstacles: Comfort is Key. Patient retention solutions and revenue generators for the Sleep Therapy Industry**

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### **Good quality sleep is a valuable thing!**

Millions of people all over the world have been diagnosed with Obstructive Sleep Apnea, (OSA), a condition that is caused by a blockage of the airway when the soft tissue in the back of the throat collapses and closes during sleep. A Wall Street Journal article from February, 2010 put the number of people known (diagnosed) to have OSA at 18 million and the total number of people who actually have OSA at close to 30 million.<sup>1</sup> The most commonly prescribed treatment is CPAP (Continuous Positive Airway Pressure) Therapy. While this is a highly effective method of treating OSA, success is often limited by failure of the patient to comply with the prescribed CPAP Therapy program. Among the many barriers to compliance, perhaps the most compelling is the mask interface. An article from Chest (2007) reports that common problems with CPAP therapy include air leaks or discomfort from masks, discomfort with pressure, nasal irritation, dry mouth and/or throat, and even local tissue injury to the face and nasal bridge from mask cushions.<sup>2</sup> This paper will discuss how sleep issues impact home care providers and will delve into specifics regarding CPAP therapy, non-compliance factors and possible solutions.

### **How do sleep issues impact home care providers?**

Sleep-related breathing issues are becoming more known by the public. With this increased awareness, more patients discuss this with their health care provider and are being tested. With the increase in testing the numbers being diagnosed with OSA continue to grow. Many co-morbid conditions are inter-related with OSA, including diabetes, cardiovascular disease, insomnia, and obesity. With the increasing age of the population these conditions are beginning to appear. The co-morbid conditions (along with complaints of snoring or excessive daytime sleepiness) increase suspicion that OSA may be present. Approval for home-testing for OSA by the CMS has increased the number of people with this diagnosis.<sup>3</sup> The bottom-line is this: sleep diagnosis are going to continue to grow and this will be accompanied by more prescriptions for new CPAP and BiPAP start-ups and a continuing, growing need for replacement parts and service.

A survey from Respiratory Management done in the spring of 2009 with 235 respondents reported growth in their sleep business of between 6 to 10% looking back to the previous 12 months.<sup>4</sup> The results of another a survey of home medical equipment providers (HME) conducted in fall 2009 and published in 2010 reflects the expected growth in their patient volume for those with sleep-related breathing disorders (SBD). From the 226 responding HME providers, growth in SBD has increased at a median of 2.5% over the past 6 months and was expected to increase an additional 2.5% during the next 12 months. In companies with one location, this translated into 53 new patients each year along with 113 existing patients. For companies with 2 to 4 locations, this translated into 245 new patients each year along with 576 existing patients. Over the next three years, 36% of the respondents expected a slight increase in patient volumes, compared to 21% looking for moderate growth and 12% expecting significant growth.<sup>5</sup>

## **The issue: Patients stop using PAP therapy**

A major problem with positive airway pressure treatment is non-compliance: patients stop using their device and stop getting the prescribed therapy. Experts say that from 46% to 83% of adults and children with OSA are not using their positive airway pressure therapy as prescribed.<sup>6,7</sup> In deciding to not use this therapy, patients continue down the path of poor quality sleep, 26.2% of the which carries many detrimental health issues and increasing co-morbid problems. Moreover, CMS reimbursement for the device stops if compliance is not proven and the provider suffers a loss in revenue. Compliance is defined as using the device for a minimum of 4 hours a night, 7 nights a week across a 30 day span during the first 90 days. In questions asking about the CMS policy from a 2009 survey about the sleep market, 26.2% of the respondents said that getting patients to use the device for the required time was their biggest challenge. This was followed by physician cooperation (20.7%), getting patients to have a follow-up visit (18.8%), and getting data from the device/patient in a timely manner (13.1%).<sup>4</sup> Many private insurers are also checking on compliance and stopping payment if the patient is not faithfully using the device. All newer PAP devices have built-in data management components that records usage and most can distinguish between the therapy actually being used (reflected in variations in flow and pressure as the person breathes... often shown on a “leak” report) versus just being turned on and blowing into the air. This information is stored on a sim card or internal memory and can be downloaded into a computer to generate a report.<sup>6,8</sup> Compliant patients who “settle-in” with using the PAP device on a consistent basis have very little need for the services of the HME provider through the reimbursement period other than the request to replace a mask. The therapy is surprisingly simple, the devices are very reliable, and once the patient becomes accustomed to using the therapy and the benefits begin to appear, they are motivated to continue and have very little complaints. A compliant patient who regularly uses their CPAP through the 90 day period and beyond will generate reimbursement income for the home care provider for years to come.

## **Discomfort: The primary problem of non-compliance**

Many factors can affect non-compliance. Many of these are related to discomfort stemming from a variety of sources. Here are some factors that can be the reasons for reduced compliance for using CPAP, and discomfort is part of every one of these factors.<sup>9</sup>

- Nasal irritation, nasal congestion, rhinorrhea (runny nose)
- Dry mouth
- Pressure build-up in the ears (this is much like the sensation of riding an elevator up many floors or when flying)
- Claustrophobia
- Uncomfortable mask, poor fitting mask
- Nasal pressure sores
- Eye irritation
- Skin creases
- Air leak (often causing a forceful blowing sensation on the skin and creating noise)

Attempts to increase compliance often involve making several changes or employing several strategies. Adding heated humidity, changing the interface (trying different nasal masks, oronasal mask

or nasal pillows), changing delivery devices (trying different models or brands of CPAP/BiPAP), and adjusting and or changing the headgear are part of the troubleshooting process. In the Respiratory Management survey conducted in the spring of 2009, 89.6% of the respondents said their patients wanted a more comfortable mask. This far outstrips the patients looking for newer technology, more education, advice on coping with sleep apnea, or features added to the PAP devices such as built-in alarm clocks; all of these items ranked at less than 3% each in the survey.<sup>4</sup> Some CPAP devices use a pressure ramp mode that build up the positive airway pressure over a few minutes to allow the patient to “ease into” having the PAP applied. Other devices use an auto-tritrating mode to adjust the PAP to higher or lower pressure levels based on changes in the patient’s condition. The auto-tritrating devices monitor variables such as snoring, airflow reduction, flow versus time profile, or impedance to look for continuing ventilation (or the lack of ventilation) to gradually increase or decrease the pressure. Topical nasal sprays may be used to reduce irritation and congestion<sup>10, 11</sup> Misalignment of the nasal mask, oronasal mask or nasal pillows (where the interface is offset, sitting at an angle, or tilted) is often the cause for eye irritation, skin creases, and air leaks. Patients may fall asleep with everything in good working order but upon readjusting their position, they cause the mask or nasal pillows to shift and problems arise.

### A simple approach to addressing non-compliance

As described above, many changes or adjustments are called into play to try and address non-compliance. Many of the problems with nasal masks, oronasal masks, and nasal pillows are associated with the patient’s preferred sleeping position (back, side, or stomach) and the contact between the interface and the bed pillow. For those who prefer to sleep on their back, sometimes their bed pillow tends to rotate the head downward with the chin toward the chest which causes a misalignment of the mask and loss of a good seal ... and a leak appears. For those who prefer to sleep on their side, the mask is pushed out of place by contact with their bed pillow or the mask is pressed into the face, causing discomfort, pressure sores, leaks, and facial creases. For those who prefer to sleep on their stomach, wearing the CPAP interface often presents such problems that they are forced to adopt another sleeping position.

A survey sponsored by Contour Products was sent to 2,692 people with diagnosed OSA being treated with CPAP.<sup>12</sup> 560 people responded and of these, 75.5% stated that they primarily slept on their side, 18.3% slept on their back, 4.5% slept on their stomach, and 1.6% did not specify a position. When asked how long they had been using CPAP therapy, 71% responded greater than 12 months, and 13% responded between 6 and 12 months. The remaining 16% had been using CPAP for 6 months or less.

Below is the response to the question, “Do you change positions a lot during the night?” and is divided into groups by which sleeping position is primary.

Position(number)	Yes (change position often)	No (don’t change position)	Sometimes	N/R
Side (423)	54%	15 %	31%	<1 %
Back (103)	42%	12 %	45 %	<1%
Stomach (25)	68%	8%	24%	0
No response (9)	44%	0%	22%	33%

N/R - no response

Since the contact between the patient interface and the bed pillow seems to cause many of the problems with compliance, effect improvements in the design of the bed pillow may improve compliance. Incorporating pockets specifically designed for CPAP masks into the bed pillow would accommodate the interface and tubing and reduce the contact between the mask and the bed pillow. The pillow should provide a cool surface (too warm could contribute to the patient's general feeling of discomfort). Additionally, it should be comfortable for the support of the head and align the spine and head. It should not be too tall and not too short, plus it should not be oversized (a large "footprint") which could interfere with the mask or other PAP interface pieces, or intrude into the sleeping partner's space. Finally, it should be affordable.

The patented Contour CPAP Pillow (Contour Products, Charlotte, NC) uniquely addresses all of these issues and brings a solution to each. The unique design has cut-outs or pockets on both sides of the pillow that eliminate contact between the pillow and the mask/hose for those who sleep on their sides. Patients who prefer sleeping on their stomach can angle the head to one side, allowing the mask to fall into the pocket. This pillow, which has interference-free zones on either side, prevents leaks, pressure sores, facial creases, misalignment, and discomfort. Regardless of the interface design or the headgear, the CPAP Pillow improves comfort to the patient using PAP. It works with all interfaces (nasal pillows, nasal masks, and oronasal masks) and increases the patient's compliance with using their CPAP or BiPAP therapy. The design includes consideration for circulation and decreases possible heat build-up. It has a firm surface that aligns the head and spine, and has a suitable "footprint" so that the CPAP user and the sleeping partner can both be comfortable. The cost is reasonable and offers little to no barrier for the patient to purchase.

A survey<sup>12</sup> sent to 2,692 CPAP Pillow users took place in January 2011. Of this population, 560 responses were received (response rate of 20.8%). Of those who had the longest time using CPAP (some 396 said they had used CPAP greater than 12 months), 231 of them (58.3%) had been using the CPAP pillow for more than 6 months. When asked if the CPAP pillow improved the patient's comfort while wearing CPAP, 84% of the 560 respondents agreed. When asked if the CPAP pillow improved their ability to use their CPAP therapy, 82% of the respondents agreed

Key findings of the survey of CPAP Pillow users:

- 77% said it improves CPAP therapy compliance
- 67% said it increases the number of hours they used their CPAP therapy
- 85% said it reduces mask shifting and leaks
- 83% said it allows for more comfortably sleeping on the side

Another survey<sup>13</sup> taken in Feb. 2011 of 605 sleep medicine professionals had responses from 91 (15% response rate). 87% stated that the CPAP pillow increased the number of nights their patients were using CPAP therapy. The following list of items reflects the strength of the positive responses regarding the CPAP Pillow:

- Improves CPAP therapy compliance: 95%
- Increases the hours of CPAP use nightly: 95%
- Helps overcome obstacles to CPAP compliance: 91%

- Improves comfort while using CPAP therapy: 97%
- Reduces mask shifting and leaks: 98%
- Reduces the need to over-tighten mask straps: 90%

Overall, the results of both the end user and sleep medicine professional survey show a strong correlation between the use of the Contour CPAP Pillow, comfort and compliance. The pillow offers a simple yet effective solution to a compelling problem that has plagued the sleep community for many years.

## **Conclusion**

Proving compliance in the first 90 days opens the door for CMS (and many private insurers) to provide reimbursement. Successful completion of the 13-month period with acceptable compliance generates profit to the home care provider. Ongoing use of the PAP device justifies reimbursable replacement masks on a prescribed schedule. Over the course of several years with multiple patients, this can translate into a substantial revenue stream and a much higher patient base growth rate for the provider. Moreover, the patients get the health benefits found in getting consistent, good nights of adequate sleep.

Diagnosis of OSA and other sleep disorders are expected to increase steadily for years to come as the population ages and public awareness of this problem spreads. Likewise, use of CPAP and BiPAP devices to treat these problems will grow and this will impact the home care equipment market.

Reimbursement is strongly tied to patient compliance with the PAP therapy and despite much effort in improving compliance, this is a continuing and costly problem. Many strategies are available to try and improve compliance, including changing the mask interface, using a ramp feature on the CPAP device, adding heated humidity, adjusting the straps, or changing the CPAP device altogether. The CPAP Pillow addresses the discomfort problems that plague many of the non-compliant patients and is an effective tool for increasing CPAP use for all patients who need this valuable therapy. By improving compliance with using CPAP, the home care business can impact their bottom-line while increasing the health of the OSA population.

About the author:

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**Attachment A:****What is the difference? CPAP versus BiPAP**

Continuous Positive Airway Pressure (CPAP) has only one prescribed setting for positive pressure. Bi-level Positive Airway Pressure (BiPAP) has two prescribed settings; a low pressure setting which is reached during exhalation (called EPAP for expiratory positive airway pressure) and a high pressure setting which is reached during inspiration (IPAP). In either case (CPAP or BiPAP) the prescribed pressures are described in centimeters of water (cm H<sub>2</sub>O). For example, CPAP may be prescribed from a physician as “Use CPAP nightly at 10 cmH<sub>2</sub>O”. An example of a BiPAP prescription would be, “Use BiPAP nightly at 16/5 cmH<sub>2</sub>O” with the IPAP set at 16 cmH<sub>2</sub>O and the EPAP set at 5 cmH<sub>2</sub>O. For the patient to receive treatment for OSA using CPAP or BiPAP, he or she wears an interface (a nasal mask, a full face mask, or nasal pillows) which is connected to the device by a large-bore hose. The mask or nasal pillows are held in place by headgear – usually straps with hook-and-look fasteners. One strap goes around the back of the head at the level of the temple and the other is lower, going around the base of the skull and coming forward just under the ears. Both straps connect to the interface and the fit is adjusted by the hook-and-loop fasteners.

## **Attachment B: Defining problems with sleep and breathing**

Sleep-disordered breathing is the term used to describe all forms of breathing problems that link to sleep. Sleep-disordered breathing encompasses central sleep apnea (CSA), obstructive sleep apnea (OSA) and sleep hypopnea (and some cases will involve a mixture of two or even three of these problems). Central sleep apnea (CSA) is an uncommon problem relative to the other two (CSA is estimated to involve <5% of the patients referred to a sleep clinic). In CSA, there is a lack of drive to breathe and all effort to breathe stops for a time, so there is no airflow, and no chest or abdomen movement during this period of apnea.<sup>14</sup> Obstructive sleep apnea (OSA) occurs when the upper airway relaxes, the tongue falls back into the throat and the airway is blocked. Often this is preceded by snoring.<sup>15</sup> When the airway is blocked, efforts to breathe continue (seen in continued chest and abdomen movement) but no airflow occurs. If the event lasts greater than 10 seconds, it is officially called “apnea”. Hypopnea is another problem that often occurs during sleep. The definition for hypopnea is more complicated but essentially it means a decrease in airflow or chest movement by 30% or more plus a decrease of 4% or more in pulse oximeter reading of saturation.<sup>16</sup> Since OSA and hypopnea are the most common sleep-disordered breathing problems, we will look closer into these problems.

When OSA or hypopnea occurs, the patient’s deep sleep is often interrupted and they move into a lighter level of sleep (or sometimes they may wake-up). This interruption in the normal pattern of sleep levels is called an arousal and the overall effect is referred to as sleep fragmentation. Adding together the number of apnea events plus the number of hypopnea events that include respiratory-related arousals gives us obstructive events. The number of obstructive events per hour is called the Respiratory Disturbance Index (RDI) or the Apnea-Hypopnea Index (AHI). Obstructive sleep apnea is officially defined under two circumstances. First, OSA is present if the patient has at least 5 events per hour of sleep (with an event being apnea, hypopnea, or an arousal related to respiratory effort) combined with symptoms... this is a Respiratory Disturbance Index (RDI) of 5. Second, OSA is present if the patient has more than 15 events per hour regardless of symptoms. To describe severity, OSA is considered to be mild if the RDI is  $\geq 5$  and  $< 15$  per hour of sleep, moderate if the RDI is  $\geq 15$  and  $\leq 30$  per hour of sleep, and severe if the RDI is  $> 30$  per hour of sleep.<sup>17</sup>

## **Contour CPAP Pillow Improves Compliance 560 Users Surveyed January, 2011**

*The objective of the survey was to determine the impact that the pillow has on the customer's CPAP therapy experience.*

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Key Findings: The Contour CPAP Pillow...

Improves CPAP therapy compliance - 77%.

Increases number of hours CPAP therapy is used nightly - 67%.

Increases number of nights CPAP therapy is used - 61%.

Reduces mask shifting and leaks - 85%.

Improves comfort while using CPAP therapy - 84%.

Reduces facial pressure from the mask - 84%.

Allows comfortable side sleeping with CPAP therapy - 83%.

Improves the ability to use CPAP therapy equipment - 82%.

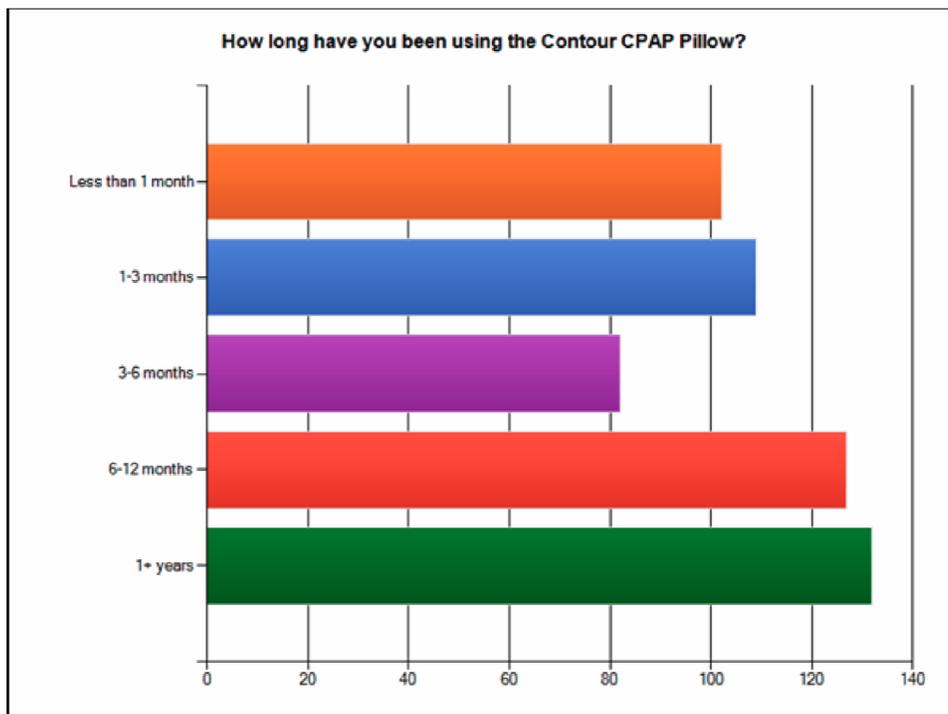
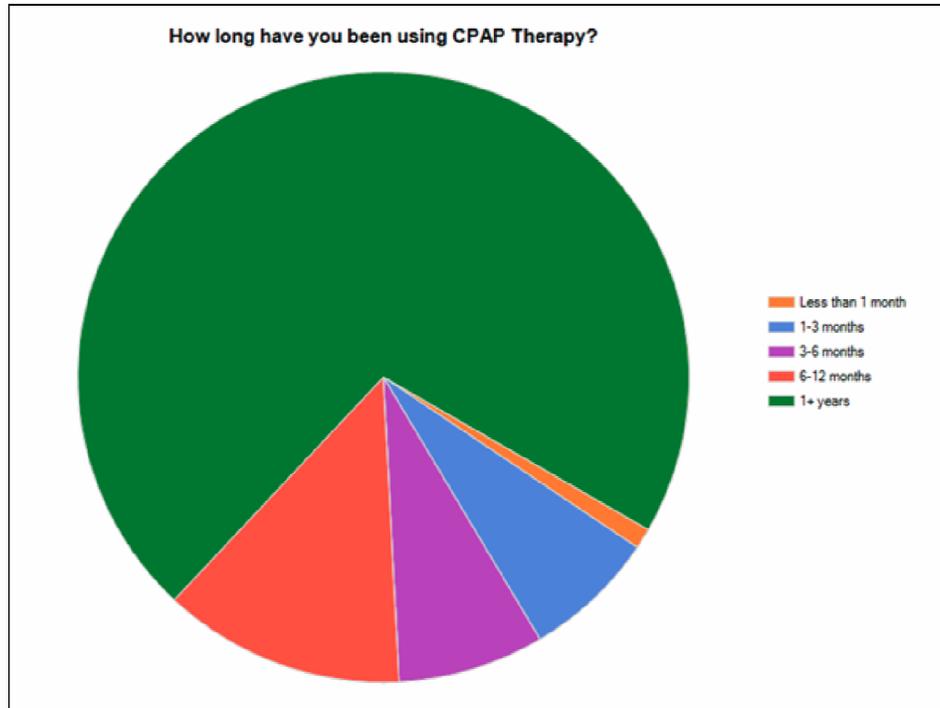
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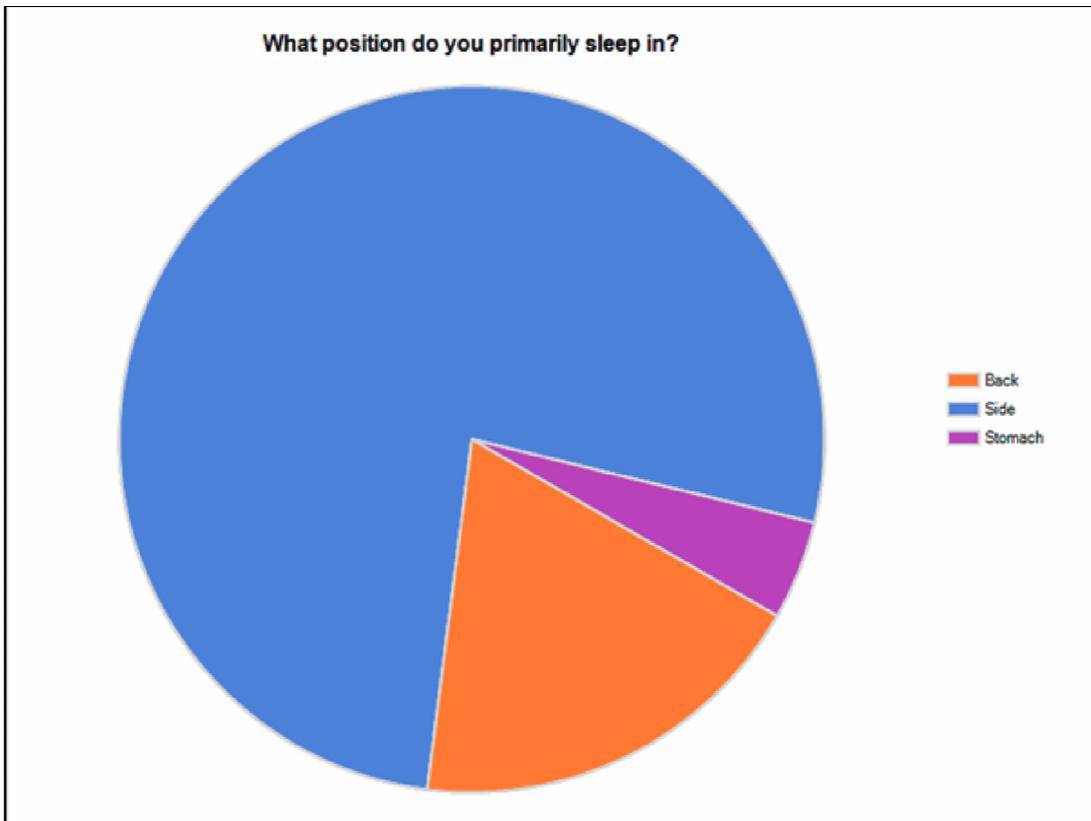
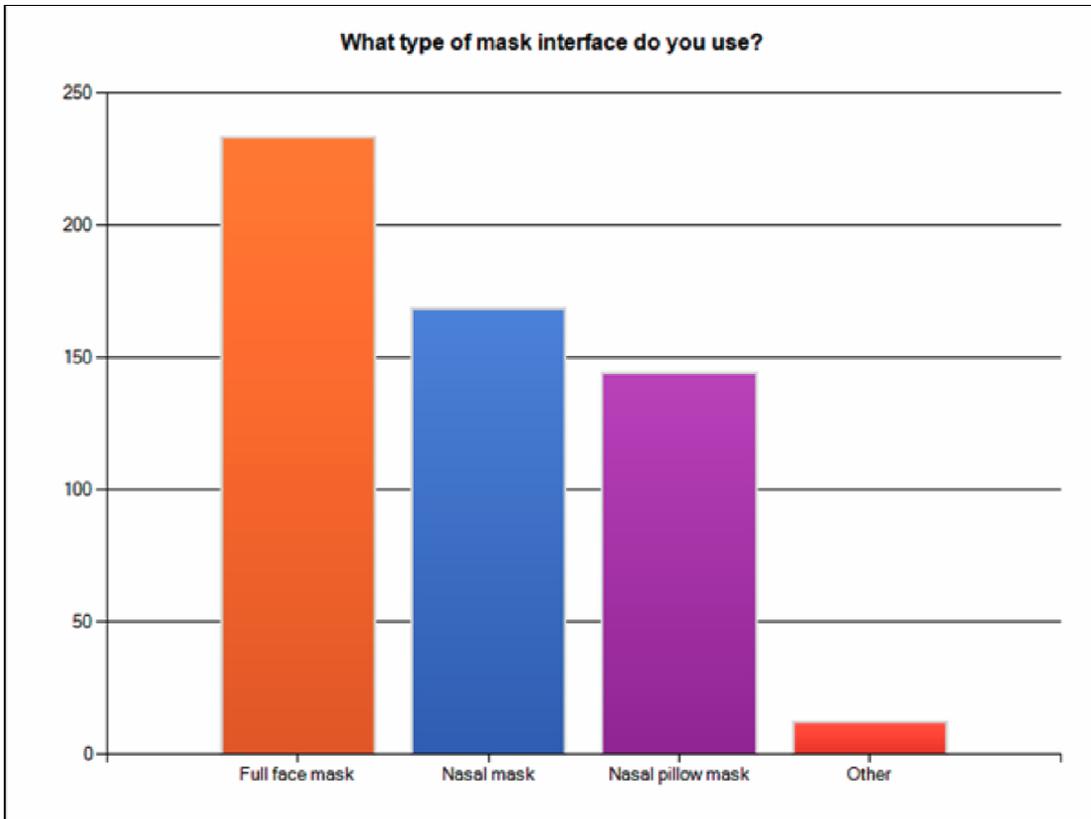
**2,692 Contour CPAP Pillow users were surveyed January, 2011  
Over 20% replied, (N = 560).**

The majority of respondents are side sleepers, (77%), and have been using CPAP therapy equipment for over one year, while the amount of time they have used the pillow ranged from less than 1 month to over one year, (71%). Nearly half of the respondents use a full face mask interface, (42%) and the rest were split between nasal masks and nasal pillows. About half (52%) responded that they change sleep positions frequently.

**Detailed information about the survey participants is charted below:**

The survey participants are direct customers of Contour Products. They are end users of CPAP therapy equipment who purchased the Contour CPAP Pillow from our e-commerce website, [www.contourliving.com](http://www.contourliving.com).





## **Contour CPAP Pillow Improves Compliance 91 Sleep Medicine Professionals Surveyed Feb., 2011**

*The objective of the survey was to determine, from the clinician's perspective, the impact that the pillow has on the CPAP therapy patients' ability to remain compliant with their treatment program.*

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Key Findings: The Contour CPAP Pillow...

Improves CPAP therapy compliance - 95%.

Increases number of hours CPAP therapy is used nightly - 95%.

Increases number of nights CPAP therapy is used - 87%.

Improves patient acceptance of CPAP therapy - 95%.

Helps patients overcome obstacles to CPAP compliance - 91%

Improves comfort while using CPAP therapy - 97%.

Reduces mask shifting and leaks - 98%.

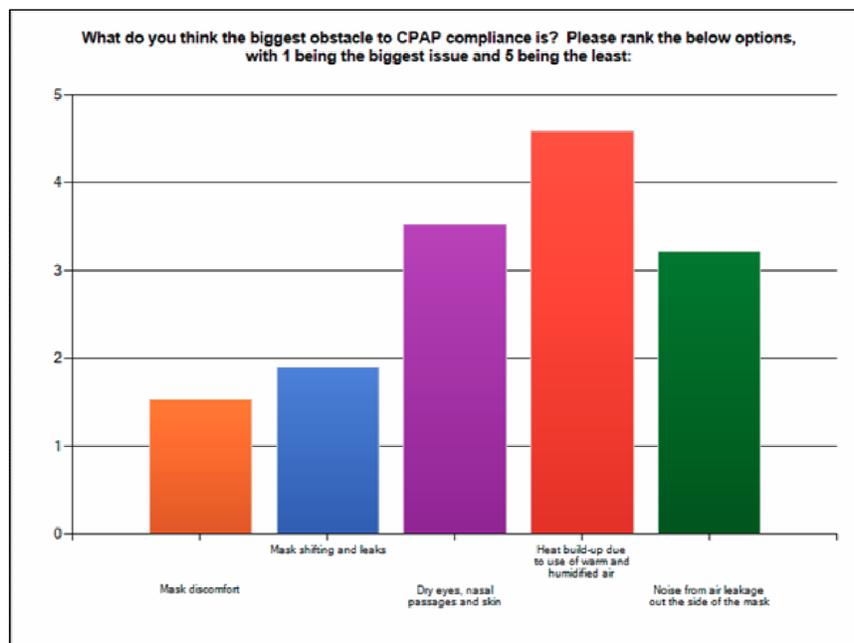
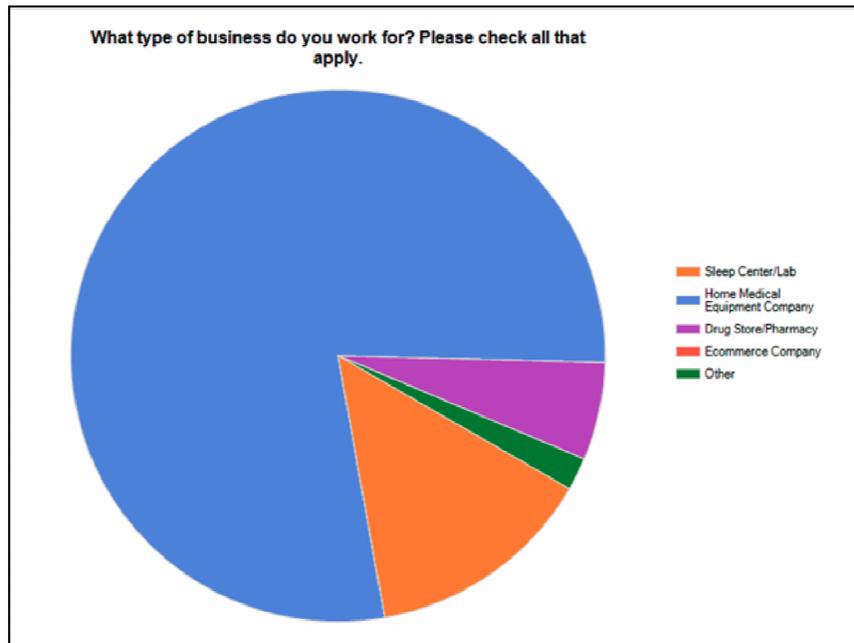
Reduces the need to over-tighten mask straps - 90%.

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**605 Sleep Medicine Professionals were surveyed February, 2011  
Over 15% replied, (N = 91).**

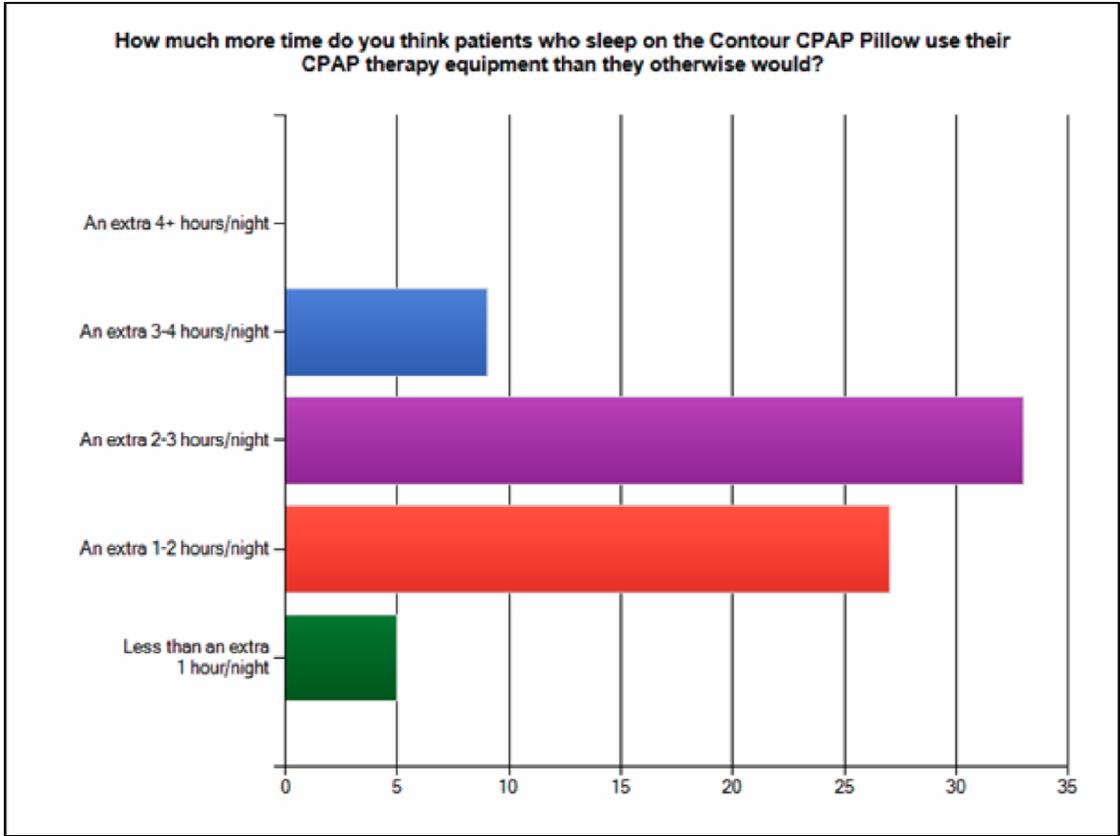
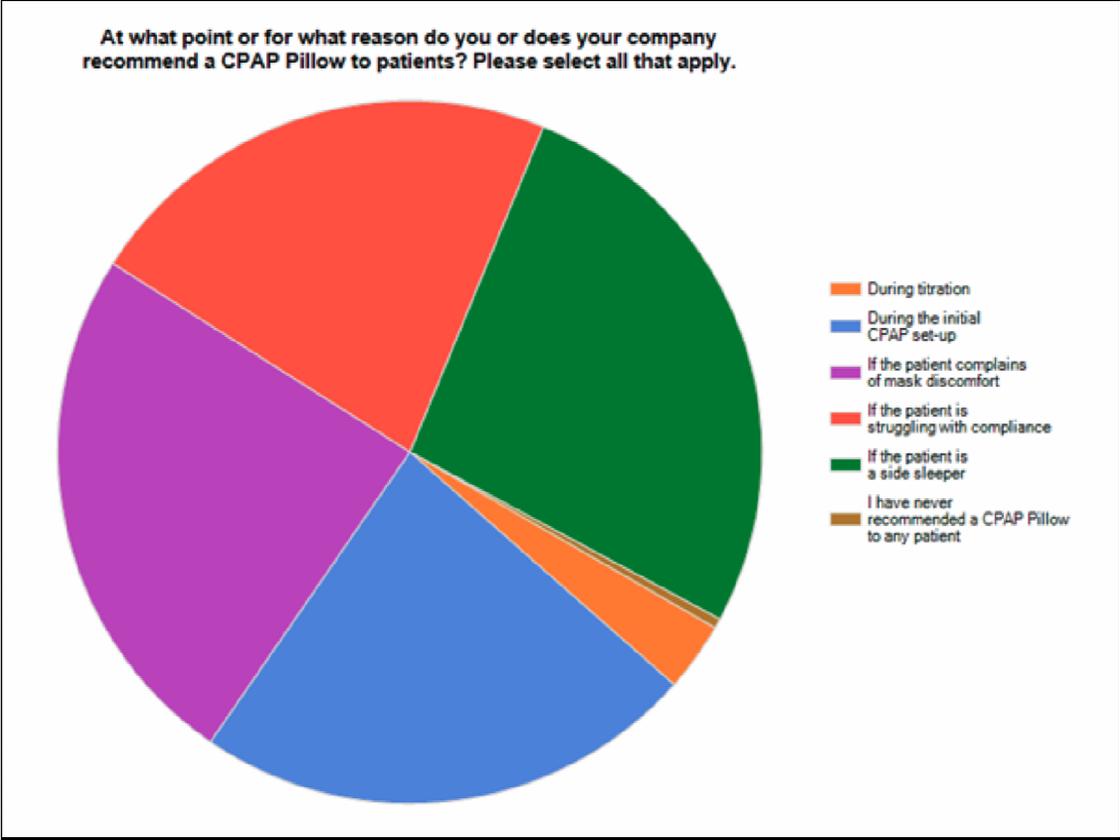
Survey participants were pulled from the Contour Products customer database. The majority of respondents, 87%, work for DME Companies, with 15% working at a sleep center/lab. About 86% work directly with CPAP patients. Nearly half of the respondents, (49%) are RTs, RRTs, RPSGTs and 35% serve in a director/manager capacity. 8% of respondents came from the executive level. The balance were MDs, CPAP specialists and sleep technologists.

**Detailed information about the survey participants is charted below:**



In addition to the obstacles charted, 34% stated that therapy intolerance is an issue, while 14% felt that self-consciousness plays a significant role and 5% said that a lack of education is an obstacle to CPAP compliance.

***Note: 91% of respondents indicated that the Contour CPAP Pillow helps patients overcome these cited obstacles.***



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