



Introduction

This instruction manual explains use and maintenance of an AirSense 10 AutoSet machine. This is an auto-adjusting positive airway pressure (aCPAP) device that can be used to treat obstructive sleep apnea (OSA).

Components

AirSense 10 aCPAP
Integrated humidifier water tub
ClimateLine Air tubing
Filters
Power supply and power cord
SD Card
Masks based upon mask fit, size, and comfort

Sleep SMART Care Team Phone Number

470-655-6688





Use and Care of The PAP Device

Device Overview



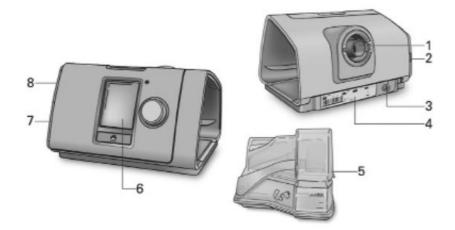








AirSense™ 10 At A Glance



1 Air outlet

2 Air filter cover

3 Power inlet

4 Serial number and device number

5 Water tub

6 Screen

7 Adapter cover

8 SD card cover

About the Control Panel

0

Start/Stop button



Dial

Press to start/stop therapy.

Press and hold for three seconds to enter power save mode.

Turn to navigate the menu and press to select an option. Turn to adjust a selected option and press to save your change.

2

Home button

Press to return to the Home screen.

Different icons may be displayed on the screen at different times including:

1

Ramp Time

Ju.

Wireless signal strength (green)

⊿ Auto)

Ramp Time Auto

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Wireless transfer not enabled (gray)

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Humidity

(d)

No wireless connection

SSS

Humidifier warming

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Airplane Mode

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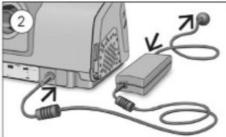
Humidifier cooling

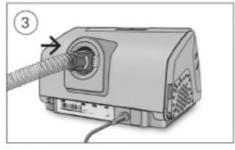




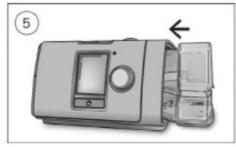
Setting Up The PAP Unit

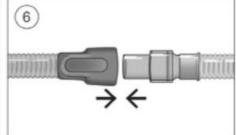












A CAUTION

Do not overfill the water tub as water may enter the device and air tubing.

- 1. Place the device on a stable level surface.
- 2. Plug the power connector into the rear of the device. Connect one end of the power cord into the power supply unit and the other end into the power outlet.
- 3. Connect the air tubing firmly to the air outlet located on the rear of the device.
- Open the water tub and fill it with distilled water up to the maximum water level mark. Do not fill the water tub with hot water.
- 5. Close the water tub and insert it into the side of the device.
- Connect the free end of the air tubing firmly onto the assembled mask.See the mask user guide for detailed information.

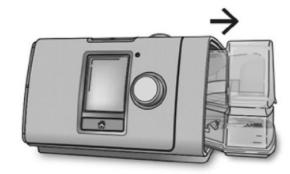
Recommended masks are available on www.resmed.com.





Filling the Water Tub

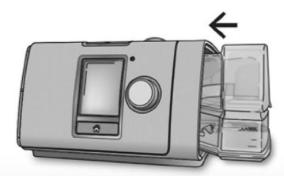
1. Remove the water tub.



Fill the water tub with distilled or deionized water up to the maximum water level.



3. Close the water tub and insert it into the side of the device.

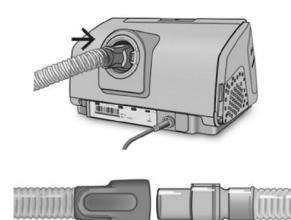






Setting Up the ClimateLine Air Tubing

- Align the ClimateLine Air tubing with the ClimateLine Air connection port. Push the ClimateLine tubing firmly onto the air outlet.
- 2. Connect the assembled mask system to the free end of the ClimateLine air tubing.



Adjusting to Therapy

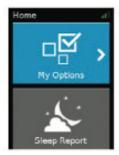
If the subjects are first-time users, they might need some time to get used to the therapy. This is not unusual as it takes most PAP users between one day and two weeks to adjust to the air pressure.

Overcoming symptoms by changing comfort settings

If subjects are having difficulties getting used to therapy, use the AirSense 10 comfort features to help them on their journey to better sleep.

- Dry or runny nose If they are getting a dry or runny nose, adjust the Humidity Level by turning it up.
- Droplets of water (condensation) If they are getting droplets of water on their nose, mask or air tubing, adjust the Humidity Level by turning it down.

To change the Humidity Level:



 Press the dial to enter My Options.



2. Turn the dial to highlight Humidity Level and then press to select it.



3. Turn the dial to adjust to your preferred setting.



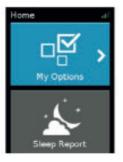
Press the dial to save the change.





- Trouble falling asleep If they have having trouble falling asleep with high pressure, turn on Auto Ramp or increase Ramp Time.
- Bloated feeling If they are experiencing a slightly bloated feeling from swallowing air, turn on Auto Ramp or increase Ramp Time
- Feeling of not getting enough air If they feel like they are not getting enough air, turn Ramp Time to Off.

To change the Ramp Time:









Climate Control

Humidity Level

The humidifier moistens the air and is designed to make therapy more comfortable. If they are getting a dry nose or mouth, turn up the humidity. If they are getting any moisture in the mask, turn down the humidity.

Users can set the Humidity Level to Off or between 1 and 8, where 1 is the lowest humidity setting and 8 is the highest humidity setting.

To adjust the Humidity Level:

- 1. In My Options, turn the dial to highlight Humidity Level and then press the dial.
- Turn the dial to adjust the humidity level and press the dial to save the change.









Getting Started

- 1. Make sure the power is connected.
- 2. Adjust the humidification level, if required.
- 3. Fit the mask as described in the mask user guide.
- 4. To start therapy, press the Start/Stop button or simply breathe into the mask. The Smart Start function will turn on the device. The green light indicates the device is off, and the blue light indicates it is on.
- 5. Lie down and arrange the air tubing so that it is free to move if they turn in their sleep.
- 6. To stop treatment at any time, press the Start/Stop button and remove the mask, or simply remove the mask. The Smart Stop function will turn off the device.

Using PAP at Bedtime

- Always fill the water tub with distilled water only.
- Put on the mask and start the device. Remember that the device will increase flow if it senses leak.
- Place the tubing above the headboard or between the pillow and the wall. Bringing it
 over the pillow in this manner may help keep it out of the way during sleep.

The SmartStart Feature

The aCPAP device has a comfort feature called SmartStart / Smart Stop that is enabled. This feature will start the device automatically when the subject breathes into the mask and then stop the device automatically when the subject removes the mask. If a subject does not like the SmartStart feature, it can be disabled by contacting the Sleep SMART Care Team.

Restarting PAP during the Sleep Cycle

- If it is necessary to interrupt use of PAP (to use the restroom, for example), stop the
 device.
- Subjects can either disconnect the tubing at the mask, and keep just the mask on, or take the mask off and then put it back on when they come back to bed.
- When they return to bed, they should push Start/Stop again or simply breathe into the
 mask. The device will restart using the same lower pressure it likely started with at the
 beginning of the night. As before, the machine will gradually ramp up the pressure until it
 reaches the targeted range.
- If subjects wake up in the middle of the night and the mask is to the side of the face, off
 of their face, or on the floor, just put it back on and return to sleep. People sometimes
 remove their PAP masks while they are asleep during the first few weeks of acclimation
 to treatment.





When They Wake Up

- Turn off the aCPAP unit by pushing the Start/Stop button on the device or by simply removing the mask. This will also turn off the humidifier.
- Disconnect the hose and take the water out. Be careful with the humidifier because the heating element may be hot.
- Clean the hose and water tub (see pages 12 and 13 in this manual).
- If they notice a small amount of flow coming from the device after turning it off, this is the system cooling off the humidifier. This is normal and automatically stops after 20 minutes.

The Five Most Important Aspects of PAP Treatment:

1. Type and Fit of the Mask

The most important piece of equipment in any aCPAP system is the mask. The mask is the one part of the aCPAP system that is in constant contact to the subject's face. An uncomfortable mask makes sleep difficult, if not impossible. A mask that does not fit properly can cause a leak, which leads to the aCPAP giving more pressure and adds to discomfort.

Here are some tips for a comfortable mask fit:

- Always adjust the straps while lying down. Gravity can affect the fit of the mask unless subjects sleep sitting up, don't adjust the mask sitting up.
- Some leak is normal, but if you can't get the leak to go away after repositioning and adjusting the straps while lying down - or if a leak interrupts his or her sleep - subjects should consider asking the Sleep SMART Care Team for another mask.
- It is completely normal to go through an adjustment period with a mask. If the mask causes discomfort or leaks, even after it has been adjusted it while lying down, the mask should be changed.
- Mask leak and facial breakouts can be alleviated with daily mask cleaning.
- Masks are made to be replaced. Subjects should get a new cushion for the mask every three (3) months.
- The Mask Fit Function (on the Setup menu of the aCPAP) is only for use while working with a clinician.

2. Pressure

The aCPAP adjusts itself to create enough pressure to keep the airway open. Here are some important tips for making the device more comfortable:





- The subject can always use the Start/Stop button on the top of the aCPAP. As the SmartStart feature will generally be enabled, the device will start automatically when the subject breathes into the mask.
- Never turn the device on until the mask is on the subject's face.
- It's important that the device be comfortable when it is put on. If the pressure from the
 device is too much or not enough when starting treatment, please call the Sleep SMART
 Care Team.
- If pressure wakes the subject up, try setting the Expiratory Pressure Relief (EPR). By default the EPR is set to 3.

3. Humidity

The flow of air from the aCPAP that goes across the nose, sinuses, mouth, throat, and upper airway can cause dryness. This can happen especially if the mouth is often open while the subject sleeps. The humidifier that comes with the aCPAP helps to reduce dryness. The user controls how much humidity they receive. Here are some tips for setting the humidity for maximal comfort:

- It is normal to have to adjust the humidity differently throughout the year.
- Without enough humidity, the body will cause the tissue in the nose and throat to become inflamed. If the subject wakes with a stuffy nose that goes away 2-3 hours into the day, they should try increasing their humidity.
- A typical mid-range starting setting for the humidity is 4, on a scale of 0 (off) to 8.
- Adjust the humidifier to their comfort. If they prefer a lower temperature and humidity, they should set their humidity low.
- If subjects need more help with setting the humidifier for comfort, or they think that dryness is occurring because they might be keeping their mouth open at night, encourage them to call the Sleep SMART Care Team.

4. Replacement of Supplies

The Sleep SMART Care Team is the best source of information. It is always a good idea to know when the supplies are due to be replaced or requested. Standard replacements will occur according to the schedule just below. However, the experience is different for each person, and sometimes parts need to be requested and replaced sooner. If not replaced periodically, headgear may stretch out and the aCPAP mask interface/pillows will get soft and floppy. They may begin to have leaks of pressure or humidity, which could lead to sub-optimal treatment, appearance of snoring, or daytime symptoms.

Standard replacement of supplies: filters should be replaced every month, nasal pillows and other mask interface seals every three (3) months. The mask, headgear, ClimateLine tubing, and water chamber should be replaced every six (6) months. These can be replaced more often





when occasionally necessary. Encourage subjects to call the Sleep SMART Care Team for filters, hoses, and replacement cushions or pillows when needed.

5. Proper Cleaning Techniques

It is recommended that the water chamber, mask cushion, and nasal pillows be cleaned daily. All other items should be cleaned weekly or more often including the hose. It is best to clean their supplies more often if the subject has been sick or if they have dust or mold allergies.

- 1. Water Chamber: Daily, empty the water chamber, rinse with distilled water, and let air-dry. In addition, once each week rinse water tub with 50% mixture of white vinegar and water.
 - Quick easy cleaning tip Get a Liter size water bottle with pull top. Fill half full with vinegar and top off with water. Leave this handy in the bathroom. Remove the water chamber from the humidifier and take the water chamber to the bathroom. Empty the remaining water from the water tub, squirt about ½ inch of mixture into the tub. Shake around to spread the mixture. Place the tub in the sink and turn on the hot water to rinse. Rinse and let chamber air dry. Once dried, the water tub is ready for sleep time use. Fill tub with distilled water for only one (1) night once they are ready for sleep.
- 2. Hose: Daily, rinse hose and hang with the ends down to dry. Weekly, fill hose with mixture as above. Slosh the mixture back and forth several times. To rinse, turn the tap on in the bathtub. Rinse for several minutes to eliminate vinegar smell and build-up.
 - Keep in mind, the tubing is corrugated. Clean and rinse thoroughly. The acidity of the vinegar will loosen the build-up. It is an all-natural cleaner with no harsh chemicals.
- 3. Filter: (Monthly) Take the filter out of the device to check it. If they notice dust build-up, change the filter out. Subjects will have spare filters in their aCPAP bag. Subjects should contact the Sleep SMART Care Team if more filters are needed.
- 4. Mask: (Daily) Clean the mask in the sink. Use Ivory Soap or baby shampoo to clean the cushion. They can also take the mask into the shower and clean it in the same way. Rinse well with cool water and hang to dry, with both openings of the tube hanging downwards on the towel rack in the bathroom.

Never use an alcohol-based product on the mask interface or nasal pillows. The alcohol will cause a quicker breakdown of the materials. CPAP supply cleaning wipes are available online.

Remember, we are here to help! Please follow these suggestions and the PAP treatment will benefit the subject and their health. If subjects have any questions or concerns, encourage them to contact the Sleep SMART Care Team at **470-655-6688**.





Troubleshooting

Issue	Possible Solution
Frequent Awakenings	Try to determine cause, and respond as listed below if any of these more specific problems are identified. Contact Sleep SMART Care Team.
Air leak from mask seal with nose or face	Tighten headgear that holds mask, within tolerated range; change from nasal pillows or full face mask (which tend to leak more especially with high pressures) to nasal triangle mask. Contact Sleep SMART Care Team.
Air leak through mouth	Add chin strap; if chin strap does not eliminate mouth leak, replace mask with a full face mask that covers the mouth (if no contraindication to full face mask).
Dry mouth / Nasal dryness	Add chin strap as these could suggest mouth leak; consider increase in humidifier setting. Contact Sleep SMART Care Team.
Mask uncomfortable	Adjust headgear to improve fit; loosen headgear just short of allowing leaks at edges of mask; change to different mask type or model. Contact Sleep SMART Care Team.
Nose stuffiness	Increase humidification; consider chinstrap as congestion can occur with mouth leak; consider full face mask (if no contraindication). Contact Sleep SMART Care Team.
Too much pressure	Determine if leak is a factor. Verify that Ramp is in Auto. Contact Sleep SMART Care Team.
Not getting enough air with PAP	Turn Ramp off. Turn EPR off, if it has been on. Contact Sleep SMART Care Team.
Difficulty exhaling	Verify EPR is ON and set to 3. Verify Ramp is ON. Contact Sleep SMART Care Team.
Air swallowing / Bloating (Aerophagia)	Verify EPR is ON and set to 3 Elevate the head by adding pillows. Contact Sleep SMART Care Team.
Facial Sensitivity / Desensitization	Consider switching to less obtrusive mask (e.g., nasal mask instead of a full face mask, or nasal pillows instead of nasal triangle mask). Contact Sleep SMART Care Team for desensitization techniques.
Condensation in mask/tubing	Increase tube temperature setting by 1-2 degrees, can consider lowering the humidifier setting, and contact Sleep SMART Care Team





Frequently Asked Questions by PAP Patients

Q: Why is air still blowing from the Automatic Positive Airway Pressure (aCPAP) machine after I turn it off?

A: The aCPAP machine will blow a small stream of air to cool the heating element. The aCPAP machine will turn itself off after 20 minutes.

Q: Do I have to use my aCPAP every day?

A: Yes, aCPAP therapy treats sleep apnea, it does not cure it. When you do not use your aCPAP therapy, you may have pauses in breathing (apneas) as you did before you started aCPAP. There may be times when you may not be able to use aCPAP therapy such as during a power outage or if your nose is stuffed up from a cold or flu. Please let the Sleep SMART Care Team know as soon as possible if ANYTHING interferes with your aCPAP use. You should try to use your aCPAP whenever you sleep - all night, and during any daytime naps.

Q: Will I suffocate if the electricity goes off during my normal sleeping time?

A: No. If you realize that power has been lost, you should take off the mask. A sudden loss of power may wake you up, but you will still be able to breathe without the device running. If you wake during a power outage, you can turn your alarm or radio on loud. When the electricity is restored, the radio will wake you. Then you can put your aCPAP back on.

Q: Why is my mouth dry when I wake up?

A: Your humidifier may be set too low. Every night increase the humidity level by 1 until your symptoms are gone. If this doesn't work, you may need a chin strap to help keep your mouth closed or other treatments to stop the problem. Contact the Sleep SMART Care Team if you continue to experience a dry mouth.

Q: How long before I feel a difference during my waking hours?

A: It depends on each individual; some people feel the effects after the very first time, and for some people it can take a few weeks. If you still feel sleepy despite seven or more hours of sleep with the aCPAP, contact the Sleep SMART Care Team to make sure the machine is working properly. Some people who use aCPAP effectively may still have symptoms of obstructive sleep apnea, such as daytime sleepiness. However, such people may still experience health benefits from avoiding the pauses in breathing during sleep.

Q: How often do I get a new mask?

A: The typical lifespan of a mask is at least six months. However, this can vary from one person to the next. If your mask or any other components become ineffective or seem damaged, contact the Sleep SMART Care Team for replacements.

Q: Why does the inside of my nose feel dry and tender after using the nasal pillows?

A: Some people have dryness or tenderness inside the nose during the first few weeks as they





get used to aCPAP. Using water-soluble gel or spray may help for some people. If the discomfort continues, contact the Sleep SMART Care Team. You may need a different mask.

Q: I don't think the humidifier is heating the water in the tub. What should I do?

A: Check the humidifier to make sure it is properly attached to the aCPAP device. Turn up the humidifier's humidity dial and turn on the aCPAP. Feel the heating plate for warmth, taking care not to burn yourself. You should not feel a lot of heat from the heating plate. It only needs to warm the water to work effectively. Also, there may still be water in the humidifier chamber at the end of your normal sleeping time. If the hot plate is cold to touch, then you may need a humidifier replacement. In this case, contact the Sleep SMART Care Team to exchange or repair the unit.

Q: I am having difficulty using this mask. I do not think this mask will work for me. What should I do?

A: You may need a different mask. Contact the Sleep SMART Care Team for another mask.

Q: I am having trouble using this mask. I sometimes wake up to find that I have taken off the mask in my sleep. Is this normal?

A: It is normal for this to happen while you get used to wearing the mask. As time goes on, it should happen less and less. You may wear a chin strap over the headgear to keep the mask in place. Or, you may need a different mask. Contact the Sleep SMART Care Team to discuss options.

Q: I feel like I cannot breathe properly while using the aCPAP device. It's difficult to exhale against the pressure or I cannot get comfortable with the pressure of the aCPAP device. A: It is normal to feel this way while you're awake. This sensation of breathing trouble will not happen once you fall asleep. With time and patience, most people become comfortable especially after falling asleep. If after several attempts, this does not improve, you may find a full face mask more comfortable if not contraindicated. We encourage you to continue your aCPAP therapy even if you are struggling a bit. Adjusting to aCPAP can take a few weeks in some cases, so don't give up. Contact the Sleep SMART Care Team if you continue to have trouble adjusting to therapy. They are here to help.





Appendix

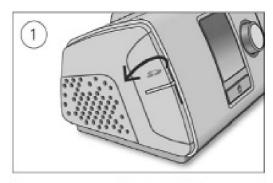
SD Card

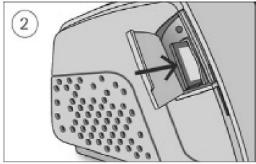
An SD memory card has been supplied to gather therapy data from the AirSense 10 device. Subjects should only remove the SD card when instructed to do so. They should disconnect the AirSense 10 device from the power outlet, remove the SD card, insert it in the protective folder and send it to FusionHealth.

Removing the SD Card

- 1. Open the SD card cover
- 2. Push the SD card to release it and remove the card.
- 3. Insert the card into the protective folder.
- 4. Send the protective folder back to the Sleep SMART Care Team, as instructed.

For more information on removing and inserting the SD card, refer to the AirSense 10 SD Card Protective Folder provided with the device. Please retain the AirSense 10 SD Card Protective Folder for future use.





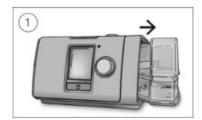
Maintenance Checklist

- Inspect the water tub and flip lid seal for wear and deterioration.
- Replace the water tub if any component is leaking or has become cracked, cloudy or pitted.
- Replace the flip lid seal if cracked or torn.
- Clean white powder deposits in the water tub by using a solution equal parts household white vinegar and water.





Disassembling the Water Tub



1. Remove the water tub from the side of the device.



2. Discard any excess water from the water tub.

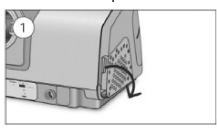
Reassembling and Filling the Water Tub

- 1. Place the tub lid back onto the base.
- 2. Clip all for side latches.
- 3. Fill the water tub with distilled or water up to the maximum water level mark.
- 4. Return the water to the AirSense 10 ensuring that it clicks into place.

Replacing the Air Filter

Replace the air filter every month.

- 1. Open the air filter cover and remove the old air filter. The air filter is not washable or reusable.
- 2. Place new air filter onto the air filter cover and then close it. Make sure the air filter is well fitted at all times to prevent water and dust from entering the device.









Glossary of Terms

Apnea - literally means "no breath"; the pausing of airflow at the nostrils and mouth for a least 10 seconds.

Apnea Index (AI) - total number of apnea events per hour.

Apnea-Hypopnea Index (AHI) - the number of apneas and hypopneas per hour of sleep, used more loosely in Sleep SMART to refer to the number of apneas and hypopneas per hour of recording by the Nox T3 sleep apnea testing device, which records breathing, but not sleep. In general: 5-15 suggests mild, - 16-30 moderately severe, and ≥ 30 severe obstructive sleep apnea.

Arousal — abrupt 3-15 second changes in brain wave activity from a "deeper" stage of sleep to a "lighter" stage without waking up.

Auto-Adjusting Positive Airway Pressure Device (aCPAP) — a type of PAP delivery system that monitors breathing and adjusts automatically by making appropriate changes in pressure. **Central Apnea** — absence of airflow without trying to breathe; apnea caused by irregularity in the brain's control of breathing.

Continuous Positive Airway Pressure (CPAP) — a device used to treat sleep apnea by sending positive airway pressure at one consistent pressure to keep the upper airway open. CPAP Setting — pressure needed to maintain an open upper airway in a sleep apnea patient treated with CPAP, expressed in centimeters of water (cm H20). The positive pressure can range from 4-20 cm H20. Different people require different pressures.

Excessive Daytime Sleepiness (EDS) — self report of difficulty staying awake, to a point that daytime activity or safety is affected, and often accompanied by repeated episodes of dozing off when the individual is not active.

Fatigue — a feeling of tiredness usually associated with decrease in performance.

Gastroesophageal Reflux Disease (GERD) — (acid reflux) flow of stomach acid into the esophagus that can disrupt sleep.

Home Sleep Apnea Test (HSAT) - an overnight test for obstructive sleep apnea. In contrast to a polysomnogram, an HSAT is generally unattended: performed in a patient's home; and focused on measures of breathing without monitoring of sleep and wake states. In Sleep SMART, the Nox T3 is an HSAT that is used in the hospital or rehabilitation unit rather than at home.

Hypertension — high blood pressure.

Hypopnea — period of diminished breathing, for at least 10 seconds during sleep. Hypopneas lead to drops in oxygen or arousals from sleep, and like apneas can be associated with snoring. **Hypoxemia** — a reduced level of oxygen in the blood.

Insomnia — difficulty falling asleep, difficulty staying asleep, and/or feeling unrefreshed from sleep even after adequate sleep time.

Mixed (Sleep) Apnea — an episode of cessation of breathing during sleep, for at least 10 seconds, with features of a central apnea followed by features that suggest obstructive apnea. **Obstructive Apnea** — a pause of airflow (at least 10 seconds) in the presence of continued effort to breathe; a pause of breathing during sleep due to a blockage in airflow.





Obstructive Hypopnea — an episode of partial closure of the airway during sleep, for at least 10 seconds resulting in reduced air exchange, blood oxygen drops, and/or brain arousals.

Polysomnogram — often called a "sleep study," this test is attended by a technologist, in a sleep laboratory. A polysomnogram is used by Sleep Medicine Physicians to diagnose and treat some sleep disorders. The test usually shows information such as brain waves, eye movements, muscle activity, heart rate, nasal and oral airflow, respiratory effort, snoring, body position, pulse oximetry, and other types of data.

Restlessness — frequent body movements or the patient perception of feeling like movement is necessary.

Sleep — a process marked by the absence of wakefulness, and restorative changes in metabolism and cellular function.

Sleep Apnea — pausing of breathing for 10 or more seconds during sleep.

Sleep Deprivation — lack of sufficient sleep.

Sleep Disorders — a broad range of illnesses, diseases, and syndromes from many causes, including dysfunctional sleep, abnormalities in physiological functions during sleep, abnormalities of the biological clock, and sleep disturbances that are caused by factors unrelated to the sleep process.

Sleep Hygiene — sleep habits, conditions and practices that affect the ability to obtain continuous and effective sleep. Good sleep hygiene typically includes a regular bedtime and wake time; sufficient time in bed to avoid sleepiness when awake; restriction of alcohol, tobacco, and caffeine in the period prior to bedtime; and exercise, nutrition, and environmental factors that lead to restful sleep.

Sleepiness — a sense of needing to sleep; difficulty remaining awake. Sleepiness is different from fatigue, tiredness, and lack of energy, though sleep disorders such as obstructive sleep apnea can be associated with any or all of these symptoms and patients sometimes use these terms interchangeably.

Snoring - noise produced by vibrations of the walls of the upper airway (throat) during sleep. Snoring occurs because a constricted upper airway leads to turbulent as opposed to smooth (laminar) air flow. Snoring is common but not universally present among patients who have obstructive sleep apnea. Not all patients who snore have obstructive sleep apnea.