

PAP SET-UP CHECKLIST and PLAN OF SERVICE

Customer Name: _____ Phone: _____ Date: _____

CPAP / BIPAP Pressure: _____ Machine type: _____

Mask: _____ Size: _____

INSTALLATION

- ___ How to turn the flow generator ON
- ___ How to attach headgear, mask, and tubing
- ___ How to position mask and headgear
- ___ Demonstrate proper connection and operation of PAP unit
- ___ Oxygen Bleed-in @ _____ LPM
- ___ Informed on the importance of turning the PAP device on prior to introducing oxygen flow and disconnecting the Oxygen prior to turning the PAP unit off.
- ___ Customer provided return demonstration on safe and proper use of equipment and adjustment of interface

CARE AND CLEANING

- ___ Explain cleaning procedure for mask, headgear, and tubing.
- ___ Explain the supplies have a limited life and replacement schedule
- ___ Explain cleaning procedure of flow generator.
- ___ Explain cleaning procedure of intake filter.
- ___ Refer to manufacturer's manual/guide for specific device and mask instructions.
- ___ Customer understands cleaning devices are not recommended by the manufacturer. (ie. ozone / uv cleaners)
Make sure to read and follow the instructions if one is purchased.

SAFETY CHECKLIST

- ___ Explain procedure if skin irritation, ear/sinus infection, develops after PAP use.
- ___ This is not a life-sustaining device. In the event of a life-threatening problem, seek medical attention immediately.
- ___ PAP pressure verified against physician order and customer notified not to change pressures.
- ___ Education that masks with magnet headgear clips are contraindicated for patients and their household members, caregivers and bed partners that may be in close vicinity to patients using the masks, that have implanted devices or other health conditions that may have contraindications to use. (See contraindication list in mfr instructions.)

FOLLOW-UP AND REORDERING

- ___ Customer understands masks, headgear, tubing and filter replacement procedure.
- ___ Customer has received the CareLinc Welcome Packet / Advanced Directives
- ___ Explanation given to customer concerning plan of service and future follow-up procedures, including support calls from u-sleep and possible replenishment calls.
- ___ Customer has received the manufacturers operators manual and warranty information
- ___ Discussed the MyAir program and helped them download the app while in the setup appointment.

INSURANCE COVERAGE REQUIREMENTS

- ___ Customer has 90 days to meet insurance requirements (4 hours a night for 70% of 30 consecutive nights).
- ___ Insurance / Physician may require a follow-up office visit between 31-90 days after set-up
- ___ Customer will be responsible for deductible and copays per their insurance. **Note: Different models/styles of PAP machines may be issued based on physician recommendation, clinical condition, device availability and/or other considerations.*

Follow-Up Date: _____ Physician: _____ Location: _____

Comments: _____

Customer Signature: _____ Date: _____

Email Address: _____

Clinical Signature: _____ Date: _____

*complete and turn in with CareLinc paperwork

Account #: _____

Positive airway pressure (PAP) therapy is the first line of treatment for obstructive sleep apnea. PAP therapy keeps your airway open during the night by gently providing a constant stream of air through a mask you wear while you sleep. This eliminates the breathing pauses caused by sleep apnea, so you should no longer snore or make choking noises in your sleep. You should be able to sleep through the night without your body waking up from a lack of oxygen.

When you use PAP each night, you will likely feel more alert during the daytime. Your mood may improve and you may have improved memory. PAP prevents or reduces the effects of serious health problems linked to sleep apnea, such as heart disease and stroke. Your partner may even sleep better because you should stop snoring.

PAP therapy includes a device, flexible tubing, and a mask. Most devices are small, lightweight, and relatively quiet. You can keep the PAP machine on your nightstand or at the side of your bed.

No matter what type of mask you use, it is important that it fits well and is comfortable. The mask must create a seal in order to keep your airway open through the night. A good mask seal will prevent air leaks and maintain the right level of air pressure to stent open your airway.

Your sleep doctor will determine the amount of air pressure needed for PAP to treat your sleep apnea. The doctor may recommend a PAP titration study to calibrate your air pressure setting. Most PAP units also come with a timed pressure “ramp” setting. This starts the airflow at a very low level, so you can fall asleep comfortably. The setting then slowly raises the pressure while you sleep until it reaches the right level to treat your sleep apnea.

PAP is a lifestyle change. It works best when used every night, for the entire time you are sleeping. You also should use PAP when you are napping. Just one night without the treatment can have a negative impact on your blood pressure. The more you use PAP, the better you will feel. Proper PAP operation requires the user to follow specific manufacturer instructions as outlined in the patient instructions manual.

Types of PAP therapy - There are several forms of positive airway pressure (PAP) therapy. All forms of PAP therapy work by keeping your airway open as you sleep by providing a stream of air through a mask that you wear:

CPAP- Continuous positive airway pressure is one constant level of pressure.

APAP (Auto CPAP)- Auto titrating positive airway pressure therapy automatically raises or lowers your air pressure as needed during the night.

BIPAP-Bilevel positive airway pressure devices have two alternating levels of pressure. When you inhale, the pressure rises. The pressure decreases as you exhale. If you do not tolerate CPAP or APAP, your sleep doctor may recommend BIPAP. Your doctor also may recommend using BIPAP if you have complex forms of sleep apnea.

Types of Masks

Nasal mask-covers only your nose, this is most common type of mask used.

Nasal pillows- uses soft silicone cushions that fit directly in your nostrils. Helps with air leaks or if you don't like the feeling of a mask over your nose and face.

Full face mask- fits over both your nose and mouth. This type is used if you are a mouth breather or have leak

issues with a nasal mask. Helpful to prevent dry throat/nose if you are a mouth breather.

Nasal cradle-a nasal mask that rests under the nose, similar to a nasal pillow but does not rest inside the nostrils.

Other Accessories

Chin strap-used if you are a mouth breather and are unable to tolerate a full face mask. It gently puts pressure on your chin to help your mouth stay closed. This may help prevent mouth breathing.

Humidifiers-help reduce side effects from PAP and make it easier for you to breathe through your mask. Some people may have nasal irritation or drainage from using PAP. A humidifier can reduce these side effects by providing heated moisture to the air coming from the PAP unit. All PAP units come with a humidifier.

Heated tubing- this helps water from accumulating in your tubing and helps deliver proper temperature and humidity. Helps prevent the side effect of dryness.

PAP THERAPY

PAP - Side Effects

PAP therapy has relatively minor side effects. Most of these problems can be fixed through simple adjustments:

Strap marks or skin sores typically occur due to a poor mask fit. By readjusting or switching the type of mask that you use, you can eliminate these symptoms. You also should adjust your mask straps to make sure they are not too tight. **Dry nose and sore throat** can be reduced by adjusting the heated humidifier attached to your PAP unit. **Nasal congestion, runny nose, or sneezing** can be alleviated by using a saline nasal spray or by taking an over-the-counter nasal decongestant. In severe cases, your doctor may prescribe a stronger decongestant for you. Please contact CareLinc for help with side effects.

Additional PAP Information

As with all medical equipment devices, there are do's and don'ts you should be familiar with. When using electrical products, especially when children are present, basic safety precautions should always be followed. Ensure you read all instructions before operating any electrical device.

In the information you may read important safety related issues will be identified with the terms such as **DANGER, WARNING, CAUTION** or **NOTE**.

A “**DANGER**” marking indicates the existence of urgent safety information for hazards that might cause serious injury or death. **DANGER** information associated with your PAP unit is intended to reduce the risk of electrical shock and include:

- Do not use while bathing; do not place or store your PAP unit where it can fall or be pulled into a tub or sink.
- Do not place in or drop your PAP unit into water or other liquids;
- Do not reach for your PAP unit if it has fallen into water or other liquid until the unit has been unplugged or otherwise de-energized.

A “**WARNING**” marking indicates the existence of important safety information for hazards that might cause serious injury.

- Close supervision is necessary when your CPAP unit is used near children or disabled individuals.
- Use your PAP unit only for its intended purpose.
- Never operate your PAP unit if it:
 - has damaged power cord or plug
 - has been dropped or otherwise damaged
 - is not working properly
 - has been dropped into water or other liquid
- Keep the power cord away from heated surfaces.
- Your PAP device is not intended for invasive applications.
- Your PAP device is not intended for life support.
- All patient settings must be determined via appropriate diagnostic testing and monitoring. These settings are only to be adjusted by authorized personnel in accordance with a physician's prescription.

A “**CAUTION**” marking indicates the existence of information for preventing damage to the piece of equipment. A “**NOTE**” marking indicates information to which you should pay special attention.

- Don't block the air flow openings on the unit. Air must flow freely around the unit for the system to work properly. Make sure bedding, curtains, or other items are not blocking air flow openings or vents.
- Do not add anything other than distilled water to the humidifier chamber (tap water, well water, essential oils, medications, etc.)
- Do not use an ozone cleaner that puts ozone into the PAP device to avoid potential damage to the device or a voiding of the warranty.

Basic Steps for Using a PAP Device

1. Connect one end of the circuit tubing to the air outlet port on unit.
2. Connect the appropriate connectors to the free end of the tubing.
3. Put on your mask, adjusting it for a proper fit and connect it to the fitting installed on the free end of the tubing.
4. Ensure the power cord is properly attached to the unit and on an appropriate power source.
5. As appropriate, energized the unit.
6. Relax. Keep your mouth closed and take slow relaxed breaths through your nose.

PAP CLEANING & MAINTENANCE

Supply Cleaning Instructions

DAILY: It is recommended on a daily basis to wipe your mask off with a damp cloth to get rid of the oils from your skin. You should rinse out your humidifier and refill it with distilled water.

WEEKLY: It is recommended that once a week that you wash your mask and headgear in warm water with mild dishwashing detergent in a clean container or basin. **DO NOT** use bleach, alcohol, cleaning solutions containing alcohol, or any strong household cleaners containing conditioners or moisturizers. Rinse thoroughly. Air dry. Make sure mask is dry before use. If using, **DO NOT** submerge the memory foam cushion of your mask into the warm soapy water (example: Airtouch memory foam, and Flexifit Masks). It is recommended that you wipe off the foam cushion with a damp cloth. Your humidifier and tubing should be washed out with soap and water once a week in the same manner.

MONTHLY: Once a month it is recommended that you soak your mask, tubing, and humidifier in one part distilled white vinegar and two parts water for thirty minutes, rinse well, and then follow the weekly cleaning instructions for your mask.

Machine Maintenance

Cleaning and replacing filters – most units come with a fine, disposable filter designed to filter out pollen and household dust. This filter should be checked and replaced monthly at minimum or when discolored/dirty.

If your unit is equipped with coarse, reusable filter, check this filter monthly and wash monthly, replacing with a new one every 6 months.

Ensure every effort to take good care of your PAP unit. Avoid smoking near the unit.

Cleaning:

***Caution:** Unplug the unit before cleaning.

1. Using a cloth slightly dampened with water and a mild detergent, wipe the outside of unit.
2. Let the unit completely dry before plugging it in and returning it to normal operations.

Tips for PAP therapy

It may take some time for you to become comfortable using PAP therapy. Follow these tips to improve your quality of sleep with PAP:

- **Begin using your PAP device for short periods of time during the day while you watch TV or read.**
This will help you get used to wearing your mask. It will feel more natural when you are trying to fall asleep.
- **Make your PAP device part of your bedtime routine.**
Use your PAP device every night and for every nap. Using PAP less often reduces its health benefits and makes it more difficult for your body to adjust to the therapy.
- **Make small adjustments to increase your level of comfort.**
Adjust your mask straps and headgear until you get the fit right. You also can try using a special bed pillow that is shaped for a PAP mask and tubing.
- **Make sure your mask is a good fit. The most common problems with PAP therapy occur when the mask does not fit properly, or the supplies are old and worn out.**
If the mask is too big, the straps holding it to your face will need to be pulled tightly. This may irritate your skin or lead to sores as the straps rub against your face. A mask that is too small will not seal properly and air will leak out through the edges. The air may blow into your eyes. If you are having either problem, you may need a different mask or headgear or to replace the supplies with new ones.
- **If the pressure feels too high as you are trying to fall asleep, use the “ramp” mode on your PAP unit.**
The ramp mode will start your device on a low pressure setting and gradually increase the pressure over time. You should be able to fall asleep before the air pressure reaches its proper level.
- **Use a saline nasal spray to ease mild nasal congestion.**
Nasal congestion can be a problem with PAP treatment. A nasal spray or decongestant can help with nasal or sinus congestion.
- **Coughing**
You may experience a cough when you start PAP therapy. This may be caused by post-nasal drip from nasal congestion. If it is a dry cough, it may be from not enough moisture. Having a heated humidifier should help with this. If you have a chronic cough that is worsened with PAP therapy, then please discuss with your physician.
- **Use/adjust your humidifier if you have a dry mouth, throat or nose.**
All PAP devices have a heated humidifier. It ensures that you are breathing warm, moist air through your mask. If you are having issues and do not know how to use or adjust your settings, please call.
- **Schedule a regular time to clean your equipment.**
Clean your mask, tubing and headgear once a week as instructed in this packet. Put this time in your schedule so that you don't forget to do it.
- **If you are having problems remembering to use your PAP every night, find someone to help.**
Consider joining a support group or asking someone you trust to hold you accountable for using your PAP device.

If these adjustments do not work, talk to your local clinical staff at CareLinc Medical. If you have medical concerns, contact the staff at your sleep center or your physician.

The staff at your local sleep center are prepared to help you adjust to PAP therapy. You may need a different type of mask or machine, or you may need an adjustment to your air pressure setting. Some people also benefit from cognitive-behavioral therapy (CBT). CBT can help you identify and overcome fears or concerns that may be preventing you from getting a good night's sleep with PAP.

Ozone vs. Ultraviolet PAP Supply Cleaners-

Are both methods safe? Is one method safer than another?

Devices claiming to clean, disinfect or sanitize continuous positive airway pressure (PAP) devices or accessories (such as masks, tubing, headgear) using ozone gas or ultraviolet (UV) light **are not approved for this use by the FDA in the U.S.**, and as such, their safety and effectiveness for use with CPAP devices and accessories is unknown.

OZONE	Ultraviolet (UV)
Fast, Powerful Oxidizer- Ozone is a gas that can be used to kill harmful bacteria. However, for ozone to be effective in killing harmful bacteria, it must be present at a concentration far greater than what is considered safe for humans. Although products claiming to clean, disinfect or sanitize CPAP devices that use ozone gas claim that they are designed to keep ozone gas inside the machine and its accessories, leaks can occur at tubing connections, filters or through containers used to house CPAP accessories.	Exposure Concerns- UV light is a powerful sanitizer that is only effective on the surface that it touches, meaning any shadows might impede the effectiveness of the UV light cleaning process. If the UV light fails to penetrate all components of CPAP devices and accessories or if they aren't processed for a sufficient amount of time, some pieces may be left un-sanitized. This would lead to health, safety and performance issues.
Possible Ozone Leakage- The FDA explains that in order for ozone to be effective in killing bacteria, it must be present at a high concentration that is unsafe for humans. Although ozone CPAP cleaners claim that they are designed to keep ozone gas inside the machine and its accessories, it is possible for a leakage to occur at tubing connections, filters or through the container. When leaks occur, ozone gas may be released into the room at unsafe levels, especially if the room is small or not well ventilated.	Variable UV Exposure- Direct exposure to UV light may cause injury depending on its wavelength, intensity and exposure time. Additionally, the UV light may not be able to penetrate all components of CPAP devices and accessories, like the plastic tubing, masks and connectors, which could lead to inadequately disinfected components that may be unsafe for people to reuse. If CPAP components are exposed to insufficiently strong UV light or processed for an insufficient amount of time, the CPAP components could be inadequately disinfected leading to safety and performance issues.
Health Risks- If the CPAP machine or accessories are used without first allowing fresh air to circulate through the entire CPAP system to remove any remaining ozone gas, this could lead to someone inhaling ozone gas, which could cause breathing problems. Exposure to high levels of ozone gas can worsen a patients' existing chronic respiratory symptoms or stimulate decreased lung function.	Health Risks The FDA has received no reports of injury from UV light. UV light-based products could cause burns, eye damage or increase the risk of skin cancer due to over exposure. The FDA has not received any adverse event reports for UV light products claiming to clean, disinfect or sanitize CPAP devices and accessories.
Efficient- Ozone is a more powerful oxidizer than ultraviolet, providing a faster reaction. Ozone CPAP cleaners require over an hour of product downtime before use.	Eco-friendly- Ultraviolet sterilization is an eco-friendly, non-toxic way to effectively eliminate bacteria and other microorganisms. Since the mid-20th century, hospitals, labs, schools, food processing plants and other crowded spaces have been using UV light disinfection.
While the FDA is currently working with manufacturers to evaluate the effectiveness of ozone sanitizers, third-party laboratory testing has shown that ozone is 99.99% effective at destroying harmful microorganisms.	
To ensure the safe and effective cleaning of CPAP devices and accessories, the FDA recommends that consumers and health care providers follow the cleaning instructions provided by the CPAP manufacturer. These directions normally include regular cleaning with soap and water.	

References:

AASM American Academy of Sleep Medicine

FDA Food & Drug Administration, 2/27/2020- FDA Reminds Patients that Devices Claiming to Clean, Disinfect or Sanitize CPAP Machines Using Ozone Gas or UV CPAP supplies- by Curt del Principe June 28, 2021

NEJM Journal Watch: FDA Warns Against Cleaning CPAP Machines with Ozone or UV Light
Cpapselect.com

Sleep Apnea Facts and Figures

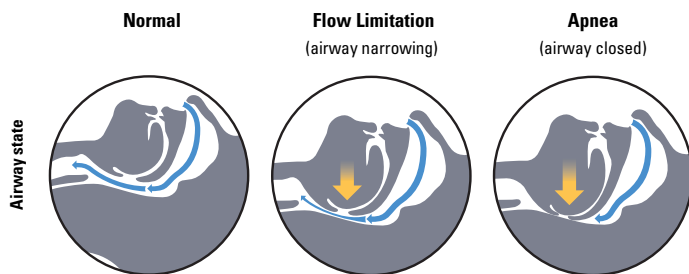
What is sleep-disordered breathing (SDB)?

SDB describes a number of breathing disorders that occur during sleep

- Obstructive sleep apnea (OSA)
- Central sleep apnea (CSA)
- Nocturnal hypoventilation
- Cheyne–Stokes respiration (CSR)

What is obstructive sleep apnea (OSA)?

- A partial or complete collapse of the upper airway caused by relaxation of the muscles controlling the soft palate and tongue
- Person experiences apneas, hypopneas and flow limitation
 - Apnea: A cessation of airflow for ≥ 10 seconds
 - Hypopnea: A decrease in airflow lasting ≥ 10 seconds with a 30% oxygen reduction in airflow and with at least a 4% oxygen desaturation from baseline
 - Flow limitation: Narrowing of the upper airway and an indication of an impending upper airway closure



Signs and Symptoms of Sleep Apnea

- Lack of energy
- Morning headaches
- Frequent nocturnal urination
- Depression
- Large neck size
- Excessive daytime sleepiness
- Nighttime gasping, choking or coughing
- Gastroesophageal reflux (GE reflux)
- Irregular breathing during sleep (eg, snoring)

Classification of sleep apnea

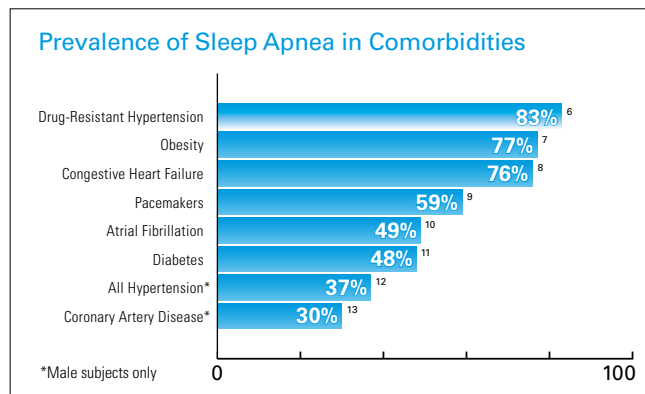
Apnea–hypopnea index (AHI)

- Number of apneas and/or hypopneas per hour of sleep (or study time)
- Reflects the severity of sleep apnea

AHI: < 5	Normal range
AHI: 5 to < 15	Mild sleep apnea
AHI: 15 to < 30	Moderate sleep apnea
AHI: ≥ 30	Severe sleep apnea

Prevalence of sleep apnea

- Approximately 42 million American adults have SDB¹
- An estimated 26% of adults have at least mild SDB²
- 9% of middle-aged women and 25% of middle-aged men suffer from OSA³
- Prevalence is similar to asthma (20 million) and diabetes (23.6 million) of US population⁴
- 75% of severe SDB cases remain undiagnosed⁵



Increased risk factors for sleep apnea

- Male gender
- Obesity (BMI >30)
- Diagnosis of hypertension
- Excessive use of alcohol or sedatives
- Upper airway or facial abnormalities
- Smoking
- Family history of OSA
- Large neck circumference (>17" men; >16" women)
- Endocrine and metabolic disorders

Sleep Apnea Facts and Figures

Hypertension links

- Studies have shown that sleep apnea is an independent risk factor for hypertension
- 30–83% of patients with hypertension have sleep apnea^{6,12}
- 43% of patients with mild OSA and 69% of patients with severe OSA have hypertension⁵
- AHA guidelines on drug-resistant hypertension have shown treatment of sleep apnea with continuous positive airway pressure (CPAP) likely to improve blood pressure control



Stroke risk

- 65% of stroke patients have SDB¹⁴
- Up to 70% of patients in rehabilitation therapy following stroke have significant SDB (AHI >10)¹⁵

Health care costs (Economic consequences of untreated SDB)

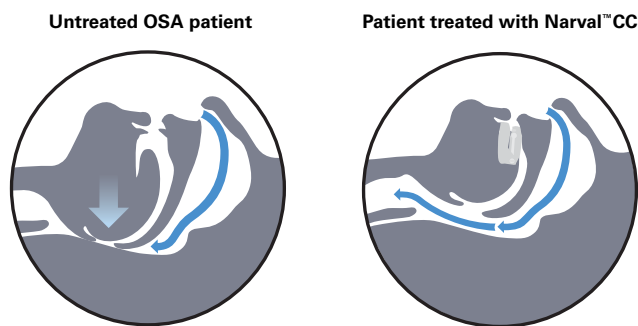
- Undiagnosed patients used \$200,000 more in the two-year period prior to diagnosis than matched controls¹⁶
- Prior to sleep apnea diagnosis, patients utilized 23–50% more medical resources¹⁷
- Total economic cost of sleepiness = approximately \$43–56 billion¹⁸
- Undiagnosed moderate to severe sleep apnea in middle-aged adults may cause \$3.4 billion in additional medical costs in the US¹⁹

Traffic accidents

- People with moderate to severe sleep apnea have an up to 15-fold increase of being involved in a traffic accident²⁴
- People with sleep apnea are at twice the risk of having a traffic accident²⁵
- Treating all US drivers suffering from sleep apnea would save \$11.1 billion in collision costs and save 980 lives annually²⁶

Treatment of OSA with MRD

- A mandibular repositioning device (MRD) is a custom-made, adjustable oral appliance (available from a dentist) that maintains the lower jaw in a forward position during sleep. This mechanical protrusion widens the space behind the tongue and reduces the vibration and physical obstruction to breathing and the tendency to snore.
- MRD treatment offers significant improvement of sleep apnea symptoms including sleepiness, quality of life, systolic or diastolic blood pressure and cognitive performance²⁰
- MRDs offer an equally efficacious alternative in mild to moderate OSA patients who are not compliant or refuse CPAP therapy²¹
- MRDs are indicated as primary treatment for patients with mild to moderate OSA²²
- Mandibular advancement can increase upper airway capacity by 50–75% with maximum mandibular protrusion²³
- OSA is a chronic condition; MRD or CPAP treatment must be used nightly



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