

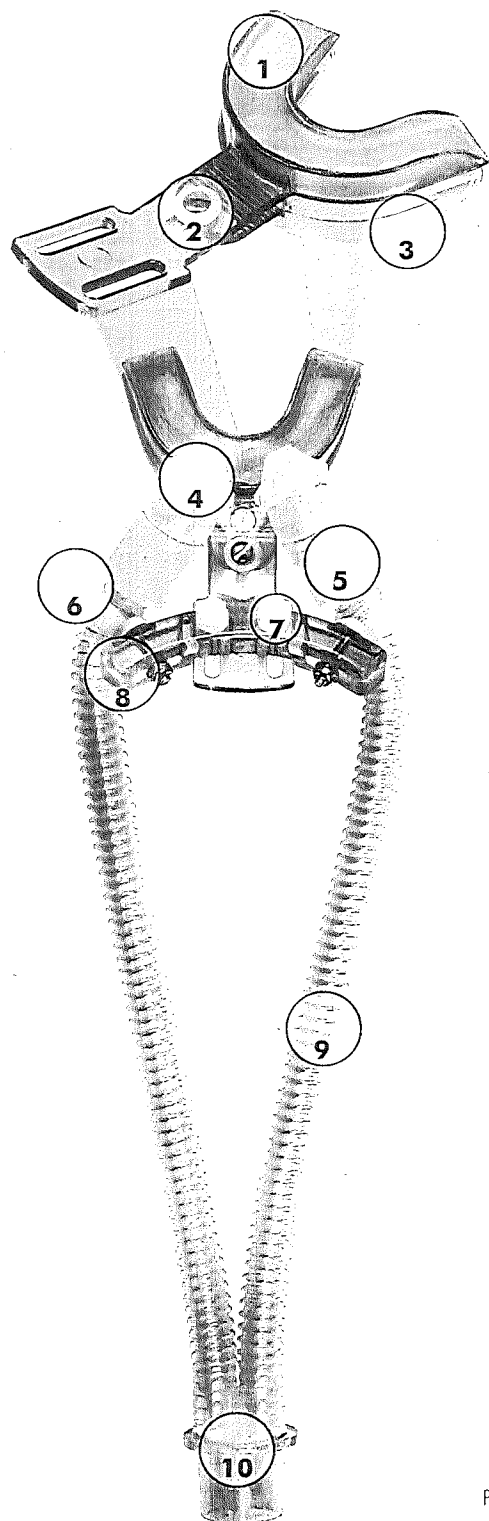
APNEAPAP

CPAP + MANDIBULAR ADVANCEMENT



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PATIENT INFORMATION
NASAL INTERFACE CARE AND CLEANING GUIDE



1. UPPER ARCH (Mouthpiece)
2. SCREW AND WASHER
3. LOWER ARCH (Mouthpiece)
4. NASAL PUFF
5. EXHALATION DIFFUSER
6. HOSE CLAMP
7. NYLON SCREW & NUT
8. CURVED BRACKET
9. CORRUGATED TUBES
10. "Y"-COUPLING

PLEASE READ THIS INFORMATION CAREFULLY!

INTENDED USE: The ApneaPAP™ (CPAP + Mandibular Advancement) interface is intended to treat exclusively adult sleep apnea patients that have been diagnosed by a qualified physician; and have been provided with a "PAP" machine for the nightly treatment of sleep apnea.

CAUTION: In the USA, federal law restricts this device to sale by, or on order of a physician, respiratory therapist, or dentist.

NOTE: The ApneaPAP™ does not contain latex materials. Inform your patient to immediately discontinue use if there is ANY reaction to any part of the system.

WARNING: ApneaPAP™ should be used only with systems prescribed by a physician, dentist, or respiratory therapist. It should not be used unless the air-supply system is turned on and operating. The exhalation ports and diffusers should never be blocked.

As part of this transaction, we would like to make certain that you and our company, Stevenson Industries, Inc. are in complete agreement with the terms of this sale. No warranties are made or implied that ApneaPAP™ is more suitable for the treatment of sleep apnea in comparison to CPAP masks, mandibular advancement, and/or other nasal devices that you may or may not have utilized, since the comfort level of each CPAP breathing device is a matter of personal individual preference and cannot be predicted prior to actual use by the patient.

If there are any serious problems whatsoever concerning the condition of a patient's teeth, gums, or mouth such as, but not limited to loose fillings, removable bridges, dentures, sore gum problems, or any other physiological problems such as TMJ or sensitivity to hot liquids or foods you should not utilize ApneaPAP™ without a consultation and/or examination to determine if ApneaPAP™ can safely be used.

CUSTOM FORMING THE MANDIBULAR ADVANCEMENT DEVICE

Note the relationship of assembled ApneaPAP™ mandibular advancement bracket affixed to cpap nasal interface device for proper reassembly upon completion of preparing the mouthpieces.

1. Disassemble the upper and lower arch members by removing screw and associated hardware.
2. Place the UPPER arch in a vessel and add enough water to cover.
Note: Do not prepare both arches at the same time as they may affix to one another.
3. Using a microwave or heat source, heat the water and arch so that the water comes to a rolling boil. The Elvax filler material will become clear indicating the arch is ready for the impression.
4. Remove the arch and allow it to cool to approximately **140F** or to a safe temperature for insertion into the patient's mouth.
5. Carefully center upper arch shell under patient's nostrils. With both thumbs, press hard shell firmly up against patient's teeth working from posterior forward with uniform pressure.
6. Leave in place for a minimum of 5 minutes for material to cool and set. **Do not remove the mouthpiece until after 5 minutes have passed so that the filler material can cool down and solidify. If you remove it too soon, you will not have a good impression of the patient's teeth and the mouthpiece will not stay affixed to the teeth.**
7. Remove arch. While filler material is still warm trim away excess or protruding material with scissors. It may be necessary to dip appliance into lukewarm water for an instant to soften material for this procedure.
8. Place arch in a bath of ice/cold water and allow to set for 2 minutes.
9. Repeat steps 4 - 8 but this time for the BOTTOM arch and the BOTTOM teeth impression.
10. Reassemble the TOP and BOTTOM arches together using the small screw and washer and attach the arches to the CPAP unit using the white nylon nuts and screws.

AFTER FORMING INSTRUCTIONS

1. Provide the patient with ApneaPAP™ care instructions and schedule a follow up visit.
2. Instruct the patient to discontinue use if soreness or pain in the teeth or jaw are experienced.
3. Instruct the patient on adjusting the mandibular advancement device.
4. Instruct the patient that there should be no advancement during the first week.
5. Following the first week the device can be advance for jaw positioning.
6. The patient should understand that the first two weeks will be a period of adaptation to the appliance. In most instances the patient will notice a significant improvement during the first week; however it may take 4-6 weeks to obtain the maximum benefit.

MANDIBULAR ADVANCEMENT

Each slot advances: 1.44mm (.056")

*Remove white nylon washer for maximum advancement.

SWIVEL CONNECTOR

The Swivel Connector (not shown) attaches to the Y-Coupling. The Swivel Connector assists in connecting the ApneaPAP™ to CPAP tubing and helps prevent kinks in the CPAP hose. This allows for additional comfort by increasing the ability to toss and turn trouble free.

CLEANING INSTRUCTIONS!

Daily: Wash the ApneaPAP™ with warm, soapy water. Do not use soaps with added scents. We recommend plain dishwashing liquid soap or baby shampoo. Rinse well and allow to air dry out of direct sunlight.

Nasal Puffs: Clean air outlet tips of Nasal Puffs with rubbing alcohol. Do not use rubbing alcohol on any other components.

Mouthpiece: Clean nightly. It is not necessary to disassemble the ApneaPAP™ to clean the mouthpiece. To clean the mouthpiece use a cool water dental cleanser such as ActiPro™.

Weekly: Separate and hand wash the components in warm, soapy water. Do not use soaps with added scents. Rinse the components well and allow them to air dry out of direct sunlight.

! CAUTION: It is essential that after cleaning, the Nasal Puffs and the Corrugated Tubing are both perfectly dry. If not, the Nasal Puffs may slip off the tubing!

! CAUTION: Do not use solutions containing vinegar, bleach, chlorine, aromatics, moisturizers, antibacterial agents, or scented oils to clean any part of the system. These solutions may cause damage and reduce the life of the product. Do not expose any part of the system or tubing to direct sunlight as it may deteriorate the product.

USER INFORMATION

Intended Use: The ApneaPAP™ CPAP interface is intended to treat adult obstructive sleep apnea (OSA).

Description: The ApneaPAP™ CPAP interface is a latex-free comfortable device for the treatment of adult obstructive sleep apnea (OSA). Individual nasal tubes are combined with a user formed heat molded mouthpiece or an optional, specially made dental appliance, depending on what your health care practitioner determines is best for your situation. Both types will seal effectively against each of your nostrils with the supplied soft synthetic nasal inserts. The seal is not airtight, however. The system allows for the escape of some air, as leakage helps eliminate trapped stagnant air that is exhaled back into the tubes while you are breathing.

Note: The device is for single patient use.

The table below provides information about the performance of the ApneaPAP™. Table 1 shows how much dead space (in ml or cc) is in each ApneaPAP™ tube. Vent leak rate (in liters per minute) is provided in Table 2. Leak rate is the amount of air that will flow through the vent holes. Vent leak rate is important as it helps to flush out the dead space air. The Table also shows how much "dead space" is contained in each nasal tube (the part between the tip of the nasal insert and the small vent holes in the tube).

Table 1

DEVICE

APPROXIMATE DEAD SPACE

ApneaPAP™ CPAP	less than 3.9ml
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Table 2

PRESSURE IN CM/H₂O

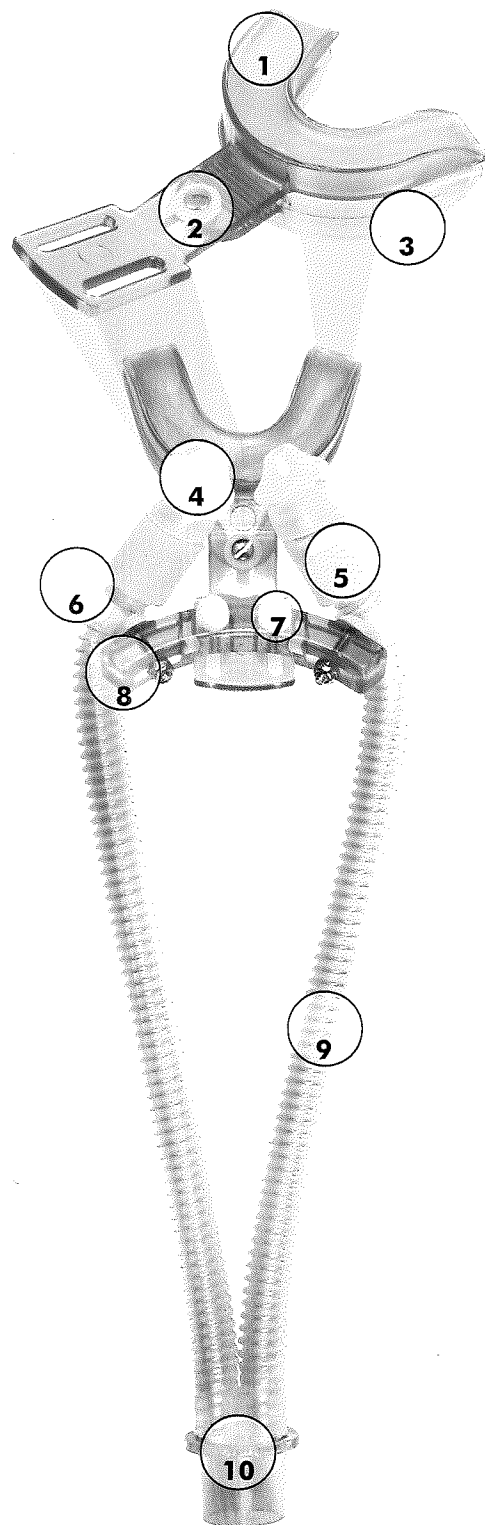
ApneaPAP™ VENT LEAK IN L/MIN

4.00	11.75
6.00	16.60
10.00	19.27
15.00	28.57
18.00	31.25

Mandibular Advancement: each slot advances 1.44mm (.056")

*Remove white nylon washer for maximum advancement.

! WARNING: The ApneaPAP™ nasal cannula and connectors should only be used with CPAP systems recommended by your physician, dentist, respiratory therapist or health care practitioner. A nasal cannula should not be used unless the CPAP system is turned on and operating properly.



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Patented. Additional Patents Pending.

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It may take several days or even weeks to get used to the ApneaPAP™, just as it does with other CPAP interfaces. Patience and perserverance is key!

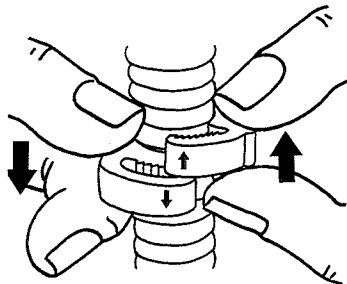
ADJUSTING THE APNEAPAP™

! CAUTION: The corrugated respiratory tubes are designed for maximum patient comfort and many months of use. Do not damage these tubes by pulling or kinking them!

1. Open the tube holder clamps (Hose Clamps) by sliding one end upward and the other end downward.

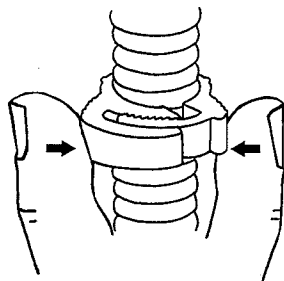
TO OPEN CLAMP:

SLIDE ONE END UP AND THE OTHER END DOWN



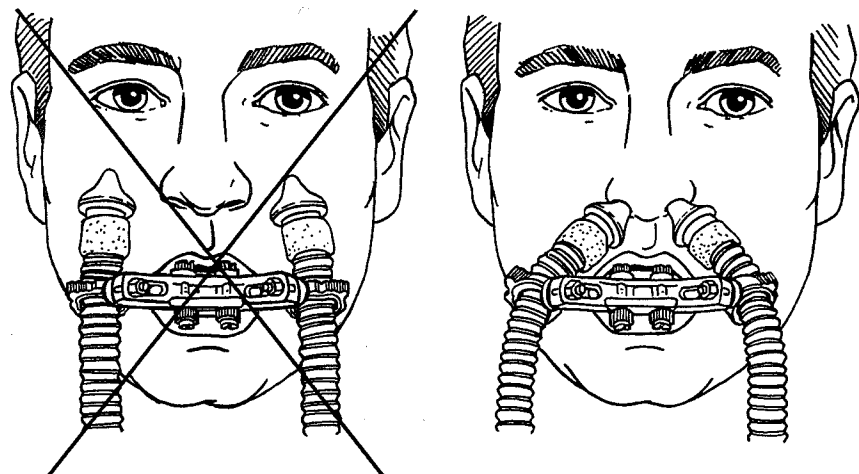
TO CLOSE CLAMP:

SQUEEZE TIGHTLY



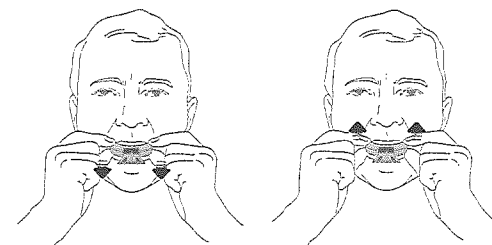
2. With the mouthpiece affixed to the patient's teeth, gently slide the two corrugated tubes upward or downward to press the Nasal Puffs against the nostrils to form a good seal to prevent leakage.

3. When the Nasal Puffs are in the proper position with the nostrils, squeeze the Hose Clamps to lock the Corrugated Tubes into position. **PLEASE NOTE THAT IN ORDER TO KEEP THE NASAL PUFFS IN PLACE WITH THE NOSTRILS, THE HOSE CLAMPS MUST BE POINTING TOWARDS ONE ANOTHER.**



REMOVING THE DENTAL DEVICE

To remove the dental device from your teeth grasp the device and pull directly down and then up while opening mouth. **DO NOT pull forward.**



CLEANING INSTRUCTIONS!

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Nasal Puffs: Clean air outlet tips of Nasal Puffs with rubbing alcohol. Do not use rubbing alcohol on any other components.

Mouthpiece: Clean nightly. It is not necessary to disassemble the ApneaPAP™ to clean the mouthpiece. To clean the mouthpiece simply fill a cup with warm water and dip the mouthpiece into it. For better cleaning use a dental cleanser such as ActiPro™.

Weekly: Separate and hand wash the components in warm, soapy water. Do not use soaps with added scents. Rinse the components well and allow them to air dry out of direct sunlight.

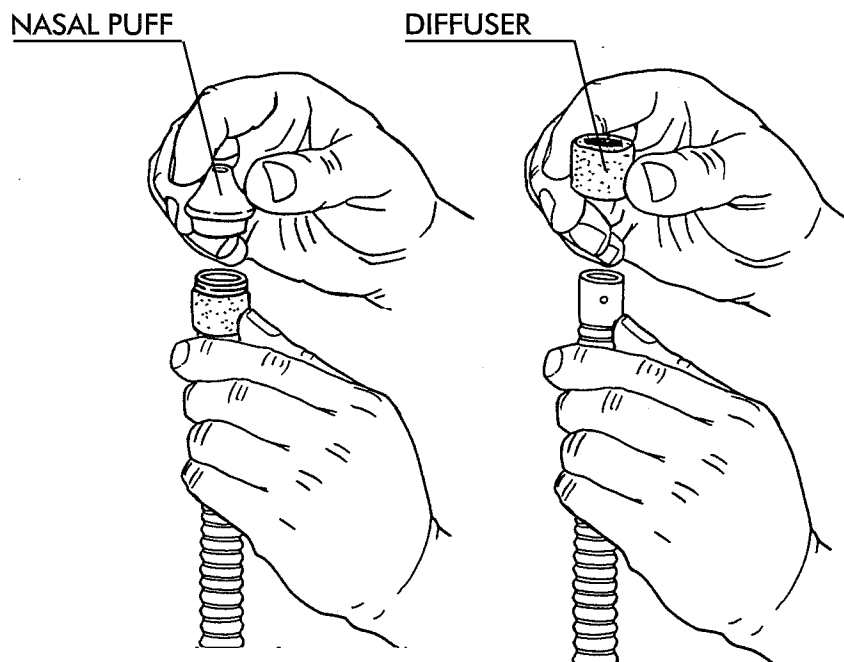
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REPLACING EXHALATION DIFFUSERS

! CAUTION: when replacing Exhalation Diffusers, do not pull on tubing; grasp diffusers to remove tubing from Nasal Puffs as illustrated below!

! NOTE: Soaking the tubing in warm water prior to separating the Nasal Puffs from the tubing will make it much easier to separate the components.

In order not to damage the Corrugated Tubes, the Nasal Puff assembly should be gently removed from the Corrugated Tubing for green foam diffuser replacement by using a gentle rocking motion to separate the Nasal Puff from the tubing. With pressure exerted only on the Nasal Puff and on the diffuser – **NOT THE TUBING!**



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