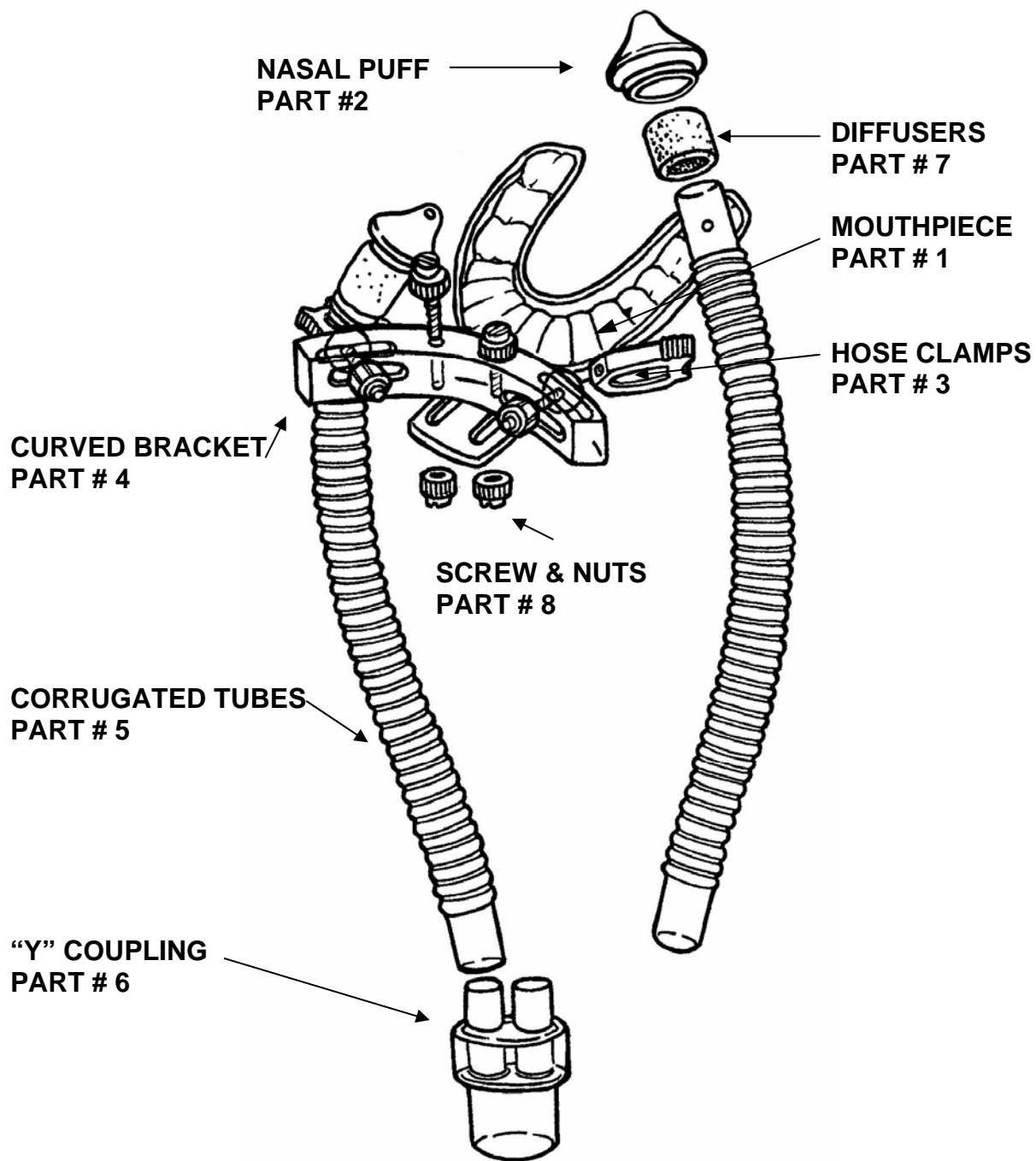


CPAP PRO®

NASAL INTERFACE INSTRUCTION MANUAL

Form 10560 - DCC 07-086 Rev. B



CPAP PRO® NASAL INTERFACE

INTENDED USE: The CPAP PRO is an accessory to a non-continuous ventilator (respiratory) intended for single patient use for adult patients prescribed continuous positive airway pressure (CPAP) or bi-level therapy.

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

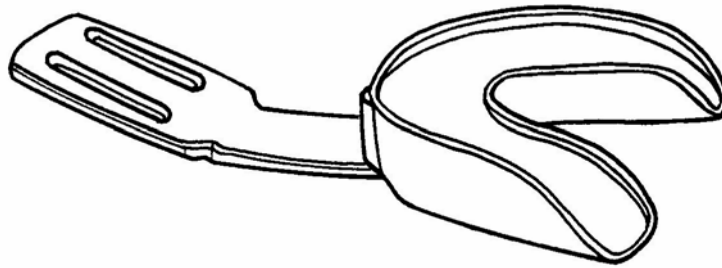
NOTE: The CPAP PRO does not contain latex materials. If you have ANY reaction to any part of the system, discontinue use and consult your sleep therapist or physician.

WARNING: CPAP PRO should be used only with CPAP or bi-level systems prescribed by your physician or respiratory therapist. It should not be used unless the CPAP or bi-level system is turned on and operating. The exhalation ports and diffusers should never be blocked.

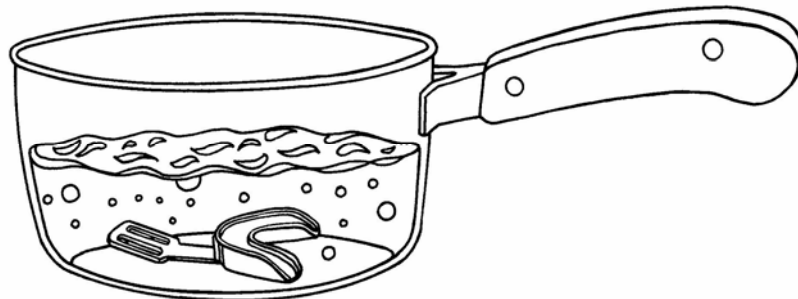
CUSTOM FORMING YOUR BOIL 'N BITE MOUTH PIECE

1. Prior to disassembling your CPAP PRO® make note of the assembly so that you can reassemble properly after forming the mouthpiece.
Please note that the two parallel tubes face towards your mouthpiece rather than outwards!

2. Unscrew the dental mouthpiece bracket, which is held in place by two white nylon screws.
Be sure to save the screws and nuts!

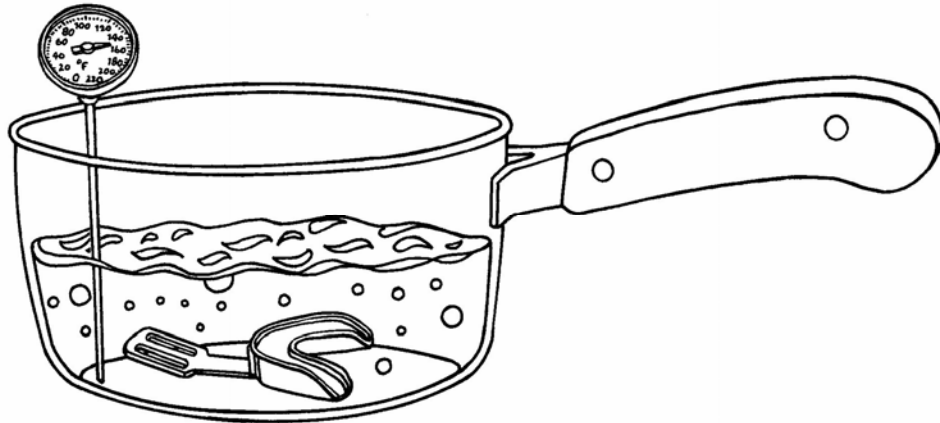


3. Place the mouthpiece in a small pot and add approximately two inches of water.

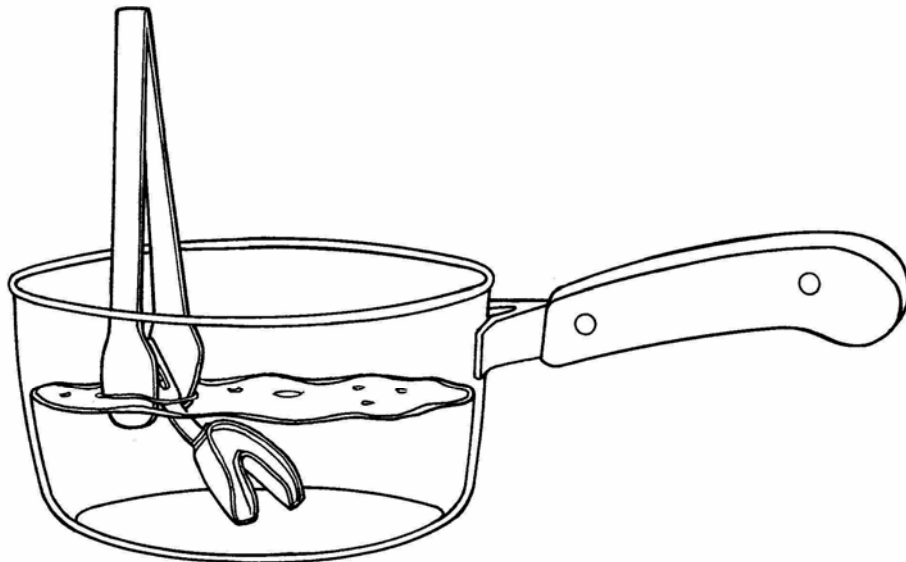


4. Heat the water and mouthpiece so that the water comes to a rolling boil.

5. Remove pot from heat.
6. Place thermometer tip in water to determine water temperature.

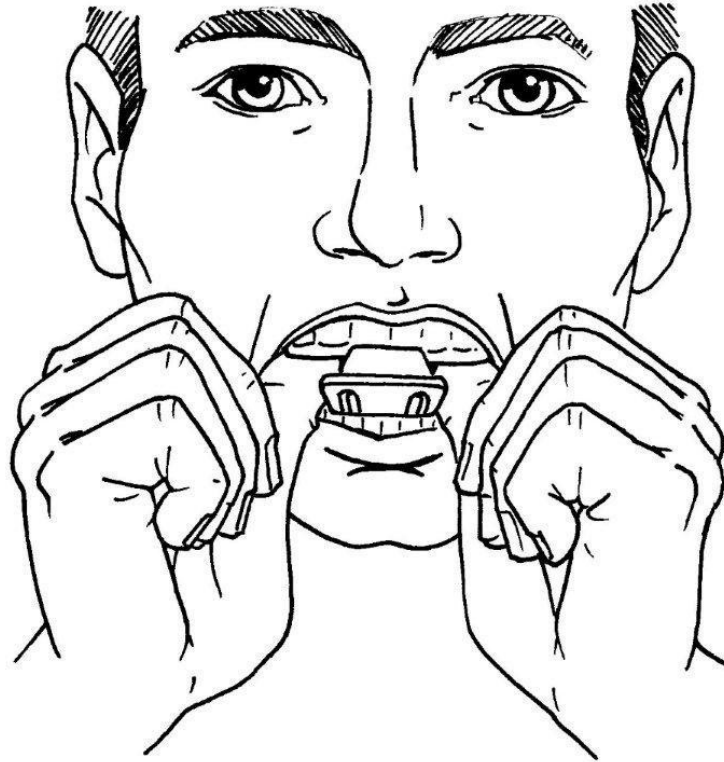


7. When the water cools and the thermometer reads 140-150 degrees, carefully remove the mouthpiece with tongs.



8. Shake off excess water.

9. **Make certain that the mouthpiece is not too hot to place in your mouth...** if you are sensitive to hot liquids or hot foods **consult with your physician prior to proceeding.** Using a mirror, quickly center the mouthpiece bracket directly under your nose and place the heated mouthpiece up against your upper teeth (with front teeth as far forward as possible in mouthpiece.)



10. With fingers and thumbs exert as much pressure as possible upwards to force your teeth firmly into impression material.
11. Your teeth should actually touch the bottom of the mouthpiece tray. Bite down firmly on the mouthpiece to form the impression.

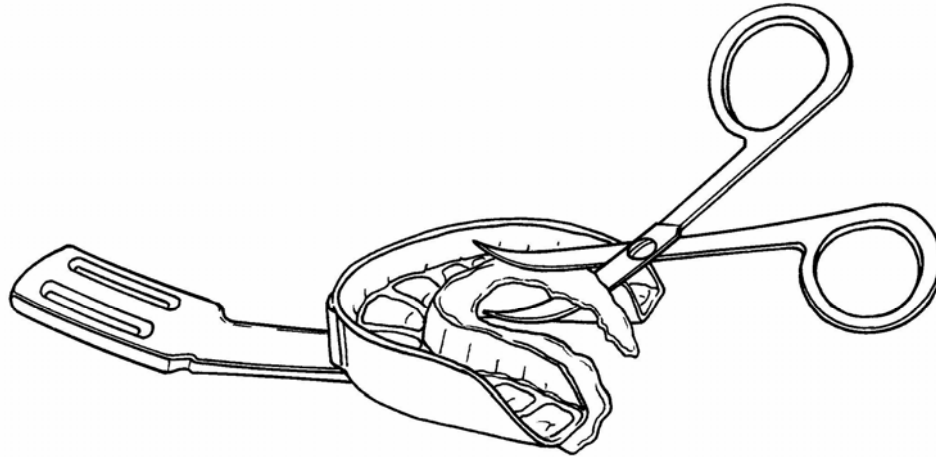
12. VERY IMPORTANT!

Do not remove the mouthpiece for approximately 5 minutes so that the filler material can cool down and solidify. If you remove too soon, you will not have a good impression of your upper teeth and the mouthpiece will not stay affixed to your upper teeth.

13. Gently remove the mouthpiece from your upper teeth.

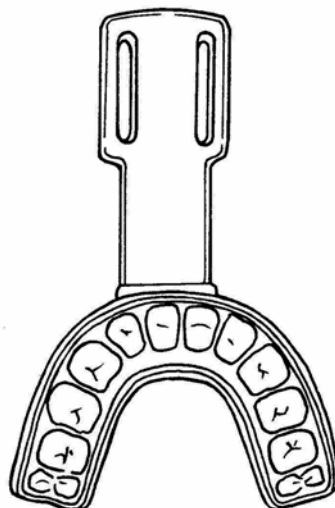
14. With a rounded scissors, while the mouthpiece is still warm, trim off the filler material. Save trimmed filler material to use if you need to re-form the mouthpiece.

IMPORTANT! Do not trim the filler material that extends out the back of the tray around the last tooth...simply flatten and smooth.



15. Let your mouthpiece reach room temperature and harden. You can speed the process by dipping in ice water.

16. Check the fit of your mouthpiece. It should press comfortably on to your upper teeth and stay in place. If it is too loose, you can reheat the mouthpiece, flatten out the filler material and redo the entire process.



17. Now that you have made your mouthpiece, we suggest that prior to reassembling your CPAP PRO®, you get use to having it in your mouth by wearing it while watching TV or reading the newspaper, etc. for a few hours daily.

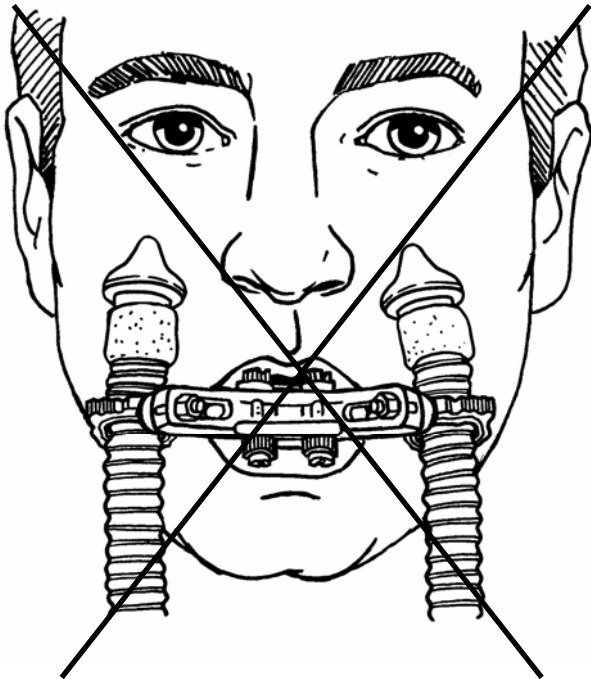
Initially, some patients accumulate an excess amount of saliva in their mouth. Once the body gets used to having this foreign object in the mouth, this problem will diminish.

18. Reconnect the mouthpiece to the curved bracket with the two parallel tubes towards facing the mouthpiece. (Refer to page 2)

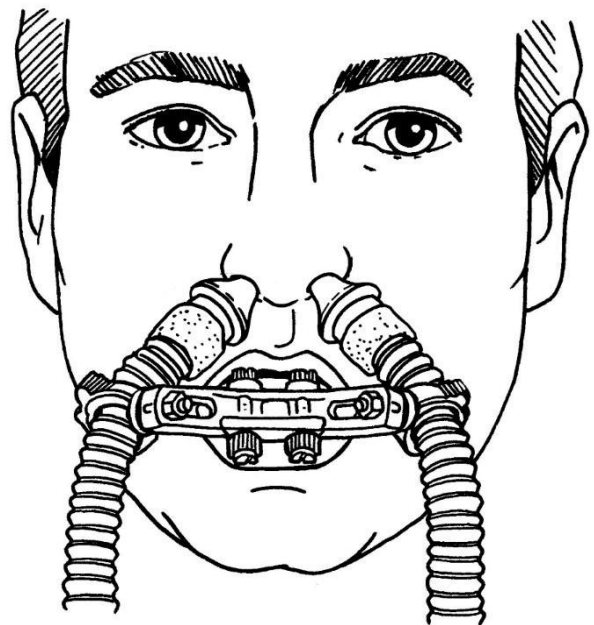
Adjusting Your CPAP PRO® For Personal Use

19. Open the two tube holder clamps (Part # 3 Hose Clamps) by sliding one end up and the other end downward. A sample hose clamp is enclosed for practice.
20. While looking into a mirror with the mouthpiece affixed to your upper 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.
21. When the nasal puffs are in the proper position with your nostrils, tightly squeeze the hose clamps to lock the corrugated tubes in position.
22. For most patients, having the two tube holder clamps in the extreme outward position of the curved bracket Part # 4 is the most comfortable position, however the hose clamps can be repositioned by sliding them inward if necessary.
23. PLEASE NOTE THAT IN ORDER TO KEEP THE NASAL PUFFS IN PLACE WITH THE NOSTRILS, WITHOUT THE NASAL PUFFS POPPING OUT, THE HOSE CLAMPS MUST BE POINTING TOWARDS ONE ANOTHER.

INCORRECT HOSE CLAMP ANGLE !!



CORRECT HOSE CLAMP ANGLE



24. Connect to CPAP machine and evaluate CPAP PRO® fitting. If there is excess leakage, the nasal puffs can be readjusted to apply more pressure to the nostrils. If the nasal puffs spring outwards from the nostrils, adjust the hose clamps to a more extreme vertical angle.

Additional Suggestions!

It will take several days or even weeks to get used to your CPAP PRO®...just as it does with other CPAP interfaces! Be patient and persevere!

Clean your CPAP PRO® daily in warm water and DAWN® or similar product.

Clean your mouthpiece daily with warm water and a dental cleanser such as Efferdent® or similar product.

Wash your face before bedtime to eliminate slipping and sliding of the nasal puffs. Do not use any creams or ointments on nostrils or nasal puffs.

Caution: At low CPAP pressures (4-5 cm/H₂O), the flow rate through the exhalation ports may be inadequate to clear all the exhaled gas from the tubing.

Some re-breathing may occur. If your pressure has been set this low, it is important for you to consult with your physician. Regardless of the CPAP product you are using, settings in this low range are not recommended.

Inspection and Replacement: Proper care and usage should result in long trouble free utilization of your CPAP PRO®. However, daily inspection and prompt replacement of any part showing wear or damage is required.

Upon receipt and before use, carefully inspect all parts and tubing for visual defects and signs of wear or damage.

Check the ends of the tubes and fittings for signs of cracks and splitting.

The tubing should be free of stains and discoloration.

Replace any parts of tubing if evidence of wear, cracking, staining or discoloration is noted.

Replacing Exhalation Diffusers Part #7

PLEASE NOTE!

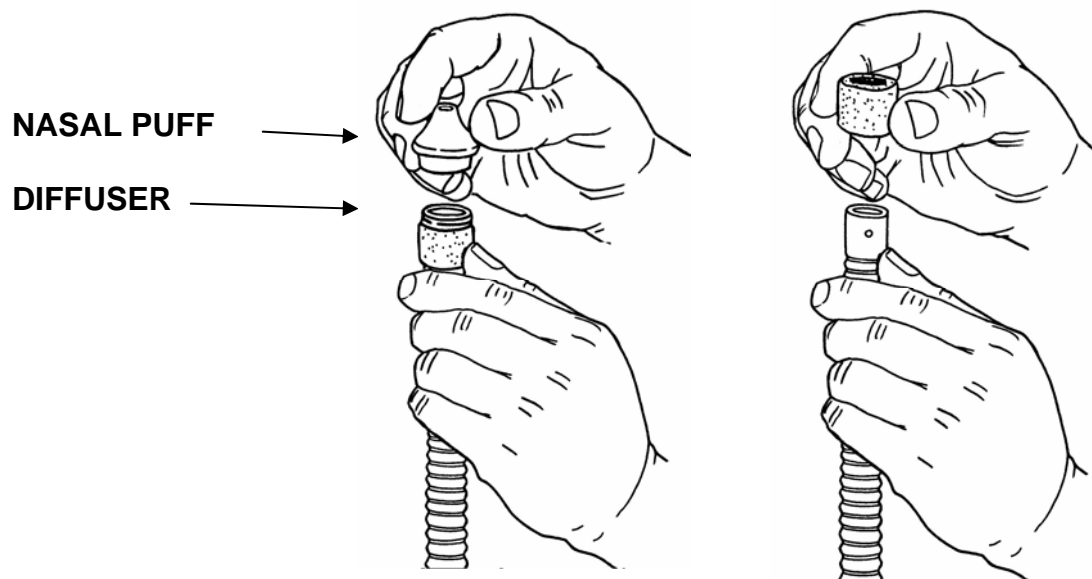
The CPAP PRO® nasal interface has been designed for maximum patient comfort and long term use. In order to avoid damage, it is essential that there be no undue strain, pulling or kinking of the respiratory corrugated tubing. Caution: when replacing Exhalation Diffusers do not pull on tubing, but grasp diffusers to remove tubing from nasal puffs as illustrated.

Diffusers must be kept clean and dry and should be replaced at least monthly. In order not to damage the corrugated tubes (part # 5), the nasal puff assembly should be gently removed from the tubes with pressure exerted **only on the nasal puff and on the diffuser... NOT THE TUBING!** Use a gentle rocking motion to separate the nasal puff tubing!

When removed slide new diffuser over exhalation hole and gently press nasal puff assembly into place.

SUGGESTION

Soaking the nasal puff, the diffuser and the tubing in warm water prior to separating is recommended.



User Information

Intended Use: The CPAP/PRO® CPAP interface is intended to treat adult obstructive sleep apnea (OSA).

Description: The CPAP/PRO® CPAP interface is a latex free comfortable device for the treatment of adult obstructive sleep apnea (OSA). Individual nasal tubes are combined with a specially made dental appliance or a heat molded mouth piece 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 exhaled back into the tubes while you are breathing.

Note: The device is supplied clean, for single patient use, reusable.

The table below provides information about the performance of the CPAP/PRO®. Your prescribing health practitioner will explain this information to you in detail if requested. Table 1 shows how much dead space (in ml or cc) is in each CPAP/PRO® 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
CPAP/PRO® CPAP	Less than 3.9 ml

Table 2

PRESSURE IN CM/H2O	CPAP/PRO® 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

Please take a few moments to review all of the instructions, warnings and cautions before using CPAP/PRO®.

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

Explanation of the Warning: CPAP machines are intended to be used with special nasal cannulas which have vent holes to allow continuous flow of air out of the tubes. When the CPAP machine is turned on and functioning properly, new air from the CPAP machine flushes the exhaled air out through the nasal cannula vent hole. However, when the CPAP machine is not operating, fresh air will not be provided through the nasal cannula, circumstances which lead to suffocation. This warning applies to most CPAP machines.



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