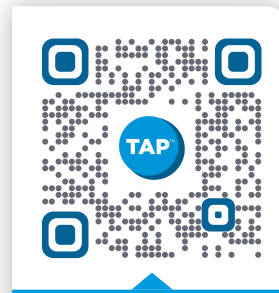


myTAP PAP Nasal Pillow Mask



Watch Video

Scan QR code for videos and more information on myTAP PAP.

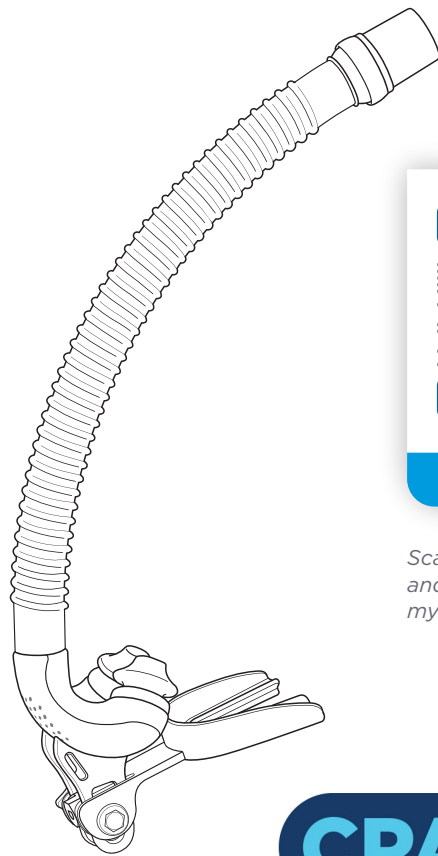


Figure A

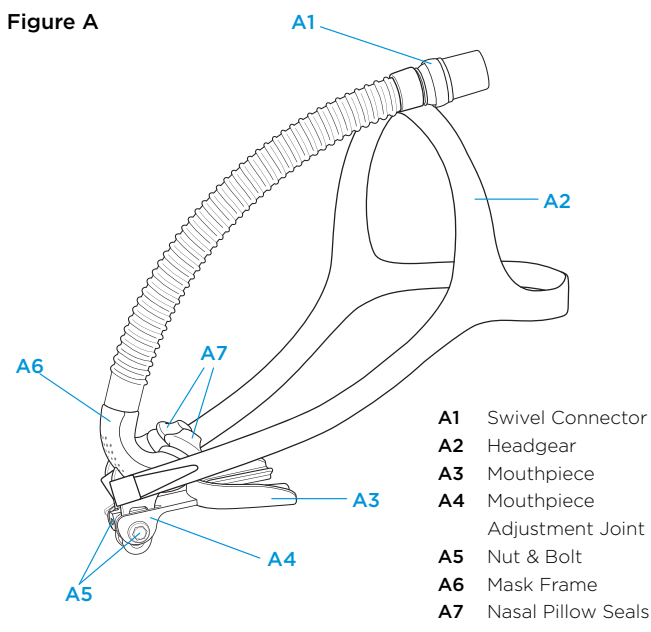


Figure B

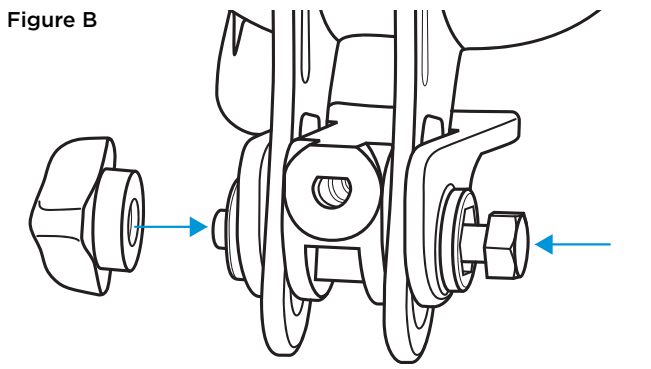


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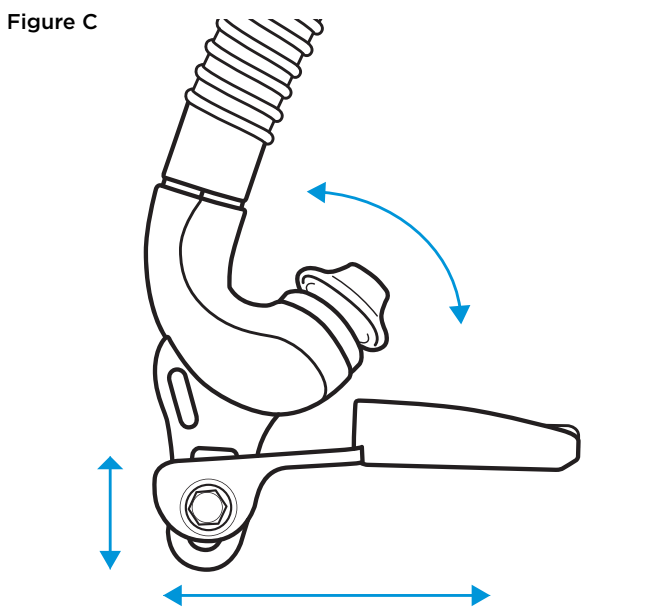


Figure D

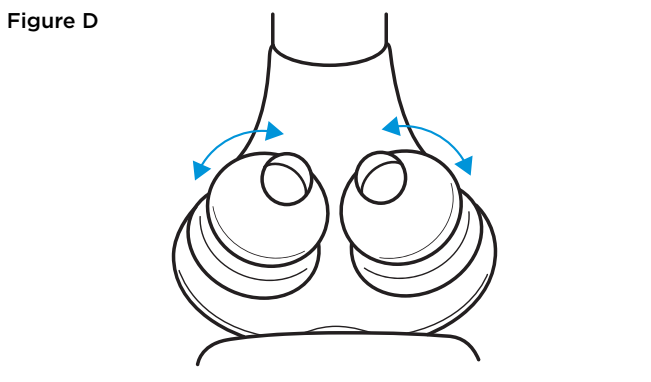


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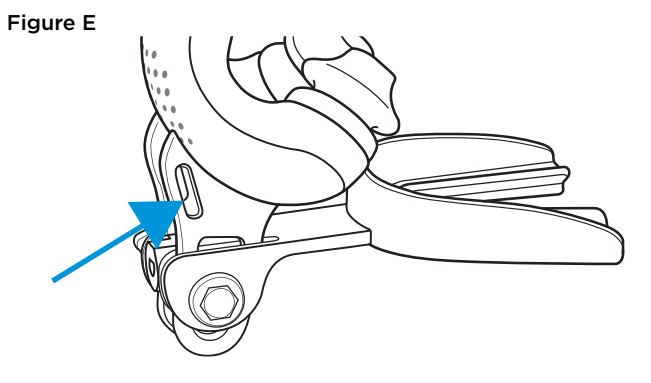


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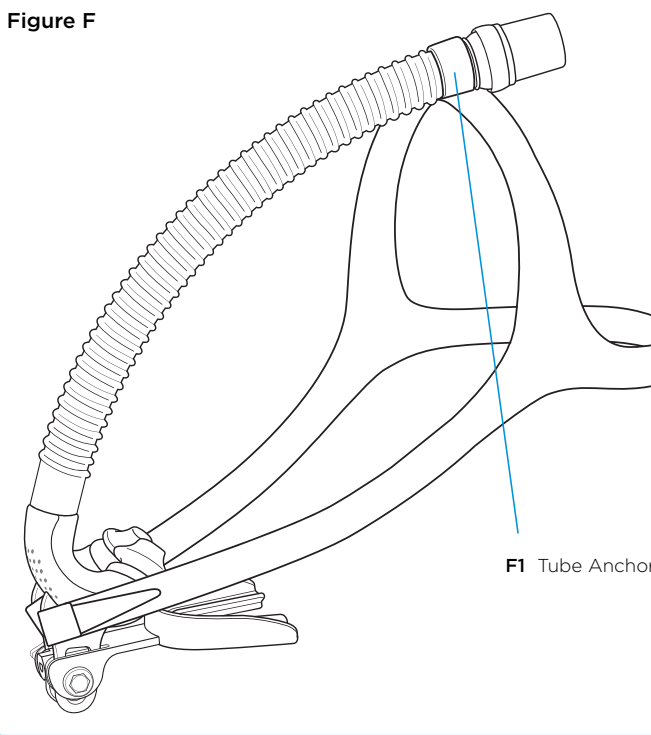
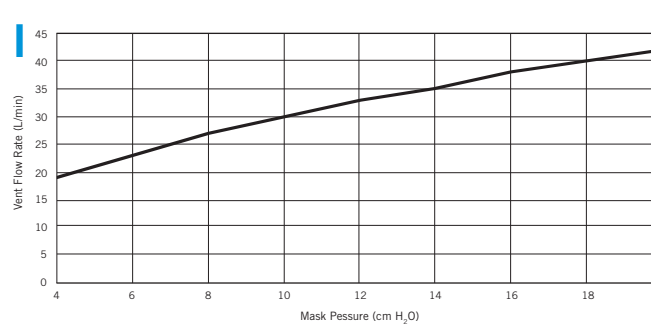


Figure H

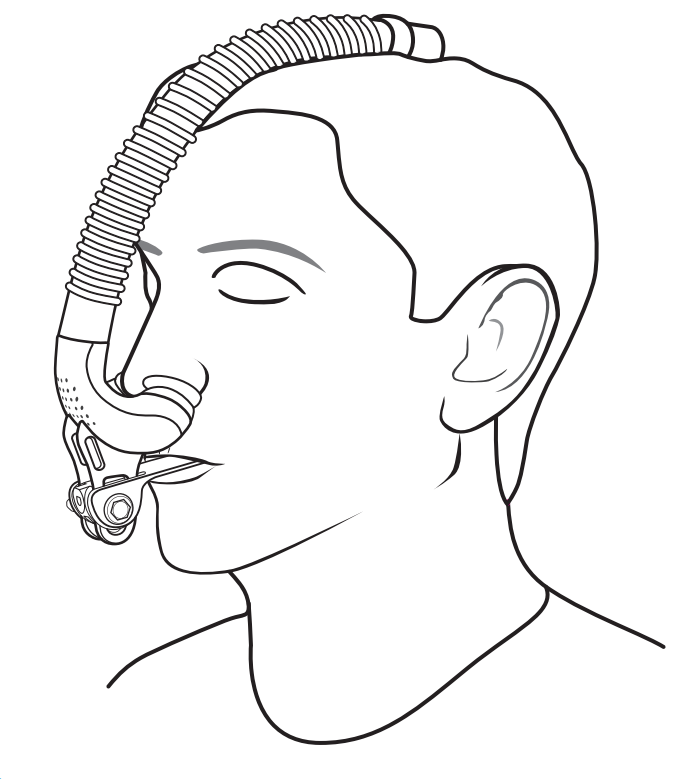


Airway Management Contacts

Manufacturer 4300 Alpha Rd, Suite 115
Farmers Branch, TX 75244
Tel: (866) 264-7667
Fax: (214) 691-3151
Email: contactami@amisleep.com
Website: www.tapintosleep.com

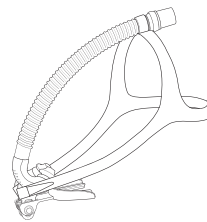
India Cell 91 99307 99107

Figure G

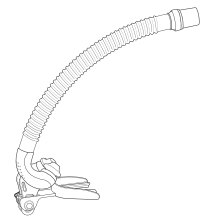


Spare Parts

myTAP PAP Nasal Pillow Mask With Headgear PAP-NP1-000
myTAP PAP Nasal Pillow Mask Without Headgear PAP-NP1-001



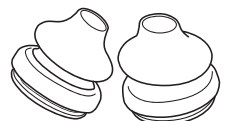
myTAP PAP Swivel Connector PAP-NP1-502



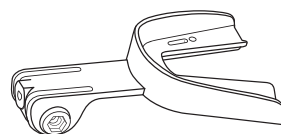
myTAP PAP Nasal Pillow Seal
Small: PAP-NP1-101
Medium: PAP-NP1-102
Large: PAP-NP1-103



myTAP PAP Upper Mouthpiece PAP-NP1-201



myTAP PAP Headgear PAP-NP1-300



myTAP PAP Nut and Bolt PAP-NP1-500

Intended Use

The myTAP PAP™ Nasal Pillow Mask is intended to be used by individuals who have been diagnosed by a physician as requiring CPAP or Bi-level ventilator treatment. The myTAP PAP Nasal Pillow Mask is intended for single patient adult (> 66 lb./30kg) use in the home, hospital or other clinical setting.

Operating Instructions

The operating pressure range of the mask is 4 to 20 cm H₂O. The transport and storage temperature range of the mask is -20°C to 50°C (-4°F to 122°F).

The operating temperature range of the mask is 5°C to 40°C (40°F to 104°F).

Before each use:

- Make sure the air path through the mask is clear.
- Inspect the vent holes. Do not use if blocked.
- Inspect the mask for damage. DO not use if there is any visible deterioration (tears, cracks, etc.), and seek replacement part(s).

Note: Failure to follow the operating instructions may compromise the performance and safety of the mask.

Dental Warnings

(See full list of warnings in the warning section)

Do NOT use if any of the following apply:

- You are under active treatment by a dentist or orthodontist.
- You have removable dentures or bridges.
- You have temporary crowns.
- You have loose teeth, loose crowns, or loose fillings.
- You have braces.
- You have less than 8 original upper teeth.
- You have not seen a dentist within the last 12 months.

If you are unsure, stop and seek advice from a dentist about the suitability of this mask for you.

Fitting Your Mouthpiece

The first step to fitting your mask is to fit your Mouthpiece (A3). It is the most important part of fitting your mask, and once done correctly will enable you to easily fit the rest of your mask.

This process can be repeated using the same Mouthpiece to adjust the fit as necessary.

Please read the instructions in full before starting to fit your mouthpiece.

1. Loosen the Nut (Figure A5). Remove the ThermAcryl™ Mouthpiece and set the Nut & Bolt aside.
2. Place the Mouthpiece over your upper teeth. Bite gently to check that your teeth fit within the flat surface of the tray. If not, you will need to narrow or widen the tray later in the fitting process.
3. Pour boiling water into a bowl. Then, submerge the Mouthpiece in the water for **one minute**. Remove the Mouthpiece with a pair of tongs, shake off the excess water and wait 20 seconds, allowing the Mouthpiece to cool.
4. Place the Mouthpiece over the upper teeth. **Be sure that the clear post is directly aligned with your nose.** You can do this by looking in a mirror or cupping your hands over your nose and Mouthpiece.
5. For the first **two minutes**, suck gently on the Mouthpiece while softly closing your mouth (do not bite down hard).
6. For an **additional two minutes**, open your mouth and breath normally with the Mouthpiece in place.
7. Place your fingers on the top edge of the Mouthpiece on both sides of the tray along your molars. Pull downward to remove the Mouthpiece.
8. You are now finished fitting the Mouthpiece. Set it aside with the Nut and Bolt. Next, you will fit the mask.

Helpful Fitting Tips:

- If the Mouthpiece is too loose or too tight, repeat the boiling and fitting process (this can be done as many times as needed). You can achieve a looser or tighter fit by sucking on the Mouthpiece less or more.
- **Note:** After the initial fitting, your Mouthpiece will continue to cool, shrink a small amount, and become firmer. It is recommended that the Mouthpiece be somewhat loose after the initial fitting. **After the first two minutes** of the Mouthpiece fitting process, you will be able to move the Mouthpiece Adjustment Joint (Figure A4) from side to side while the Mouthpiece is in your mouth to achieve a looser fit.
- If it is tight, when cold use your thumbs to spread (widen) the Mouthpiece.
- Your Mouthpiece should fit snugly and be comfortable to wear properly.
- If you have never worn a Mouthpiece, it may take a few days to become accustomed to it.

Fitting Your Nasal Pillow Mask

1. The myTAP PAP Nasal Pillow Mask comes with 3 sizes of Nasal Pillows. Hold the Mask Frame (Figure A6) with the Medium size Pillow against your nostrils to check for sizing. **You should use the largest size Pillow that you can, ensuring that the Pillow outlets fit comfortably into your nostrils.** If you are unsure, you can try the different sizes after you have completed the fitting process and have connected your mask to your CPAP machine.
2. Assemble the Mask Frame with the Mouthpiece.
3. Place the Bolt through the Adjustment Joint (Figure B) and loosely screw on the Plastic Nut. **Note: This can be assembled with the Plastic Nut on the left or right side.**
4. Place the Mouthpiece on your upper teeth.
5. Adjust the Mask Frame so the Pillows rest gently against your nostrils. The Mask Frame can move up and down, closer and further away from your nose and the angle can be changed (Figure C).
6. Holding the mask in place with one hand, firmly tighten the Plastic Nut to lock the Mask Frame in place.

Changing and Adjusting Your Pillows:

1. The angle of each Pillow may be adjusted individually to suit the angle of your nostrils. To do this, grab the Pillow at its base and rotate (Figure D).
2. To assemble a Pillow into the Mask Frame Assembly,
 - a. Gently squeeze the Pillow with your thumb and middle finger.
 - b. Guide the lower part of the Pillow into place.
 - c. Use your forefinger to push the upper part of the Pillow into place.
 - d. Then push down firmly against the base of the Pillow to secure it.
3. You may find it beneficial to use a different size Pillow for each nostril.

Use Life and Shelf Life

The myTAP PAP NPM has a minimum use life of 6 months. There is no claim made on shelf life, as the materials used are stable at the stated storage temperature range.

Condensation or Whistling

If you experience whistling sounds or excessive condensation in your mask, you may need to turn down your humidifier. Do this gradually, over a few nights, to avoid reducing the humidity too much.

Using Your Headgear

You may find it beneficial to use myTAP PAP Headgear (Figure A2) to help hold your mask in place and hold the Tube in position on top of your head. The Headgear connects to the Mask Frame in slots that are located above the Adjustment Joint (Figure A4). The Tube Anchor can be used to hold the Tube in place (Figure G).

Using Your Swivel Connector

Your myTAP PAP Nasal Pillow Mask may be disconnected from the main CPAP Tube by disassembling the Swivel Connector (Figure A1). It is easiest to assemble and disassemble the Swivel Connector at an angle (Figure F).

Cleaning Your Mask

After Each Use:

Rinse the Mouthpiece with cold water and let it dry out of direct sunlight.

Weekly:

Hand wash the Chin Strap and/or Headgear if used, following the same procedure as above.

Remove the Pillows from the Mask Frame Assembly and remove the Headgear.

Place the Pillows and Mask Frame in lukewarm water that contains a mild soap. Scrub Mouthpiece with a soft toothbrush.

Note: Do NOT soak for more than 10 minutes.

Remove the mask components and rinse them thoroughly in fresh water, ensuring that all soap residue is removed. Leave all parts to dry out of direct sunlight.

Warning:

Do NOT wash the mask in the dishwasher.

Do NOT clean the mask with products that contain chlorine, bleach, moisturizer, antiseptic, anti-bacterial agents or alcohol.

Do NOT wash your mask in hot water as this may change the fit of your Mouthpiece.

Note: Failure to follow the cleaning instructions may compromise the performance and safety of the mask.

Disposal

Your mask may be disposed of in the general waste.

Warnings

- US Federal Law restricts this device to sale by, or on order of, a physician.
- This mask should only be used with CPAP/Bi-level equipment recommended by your physician or respiratory therapist. A mask should not be used unless the CPAP/Bi-level device is turned on and operating properly. The vent holes of the mask should never be blocked.
- Explanation of warning: CPAP and Bi-level machines are intended to be used with special masks which have exhalation ports to allow continuous flow of air out of the mask. When the CPAP/Bi-level machine is turned on and functioning properly, new air from the CPAP/Bi-level machine flushes the exhaled air out through the exhalation ports. However, when the CPAP/Bi-level machine is not operating, enough fresh air will not be provided through the mask, and exhaled air may be re-breathed. Re-breathing of exhaled air for longer than several minutes can in some circumstances lead to suffocation.
- If oxygen is used with CPAP/Bi-level machine, the oxygen flow must be turned off when the CPAP/Bi-level machine is not operating.
- Explanation of warning: When the CPAP/Bi-level device is not in operation, and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within the CPAP/Bi-level machine enclosure. Oxygen accumulated in the CPAP/Bi-level machine enclosure will create a risk of fire.
- Do not use Polyvinyl Chloride (PVC) pressure and/or oxygen tubing. Use silicone tubing instead.
- Explanation of warning: Flexible PVC contains elements that can be detrimental to the materials of the mask, and may lead to cracking or breakage of mask components.
- Refit the Mouthpiece if too tight and discontinue use if discomfort persists.
- Discontinue use if a reaction is caused by any part of the mask and consult physician.
- Discontinue use if experiencing discomfort and consult physician.
- Mask is single patient use.
- Discontinue use of mask if damaged or cracked and seek replacement.
- Do not use mask if vomiting or feeling nauseous.
- Do not use mask if patient is unable to remove mask independently.
- If bite changes, wait to see if the bite returns to normal during the day. If bite changes continue or do not return to normal during the day, discontinue use and contact physician if changes continue.
- Use on adults only (>66lb/30kg).
- Shake loose hot water off Mouthpiece before placing in mouth.
- Do not misuse mask.
- In the event of muscle or jaw joint pain, discontinue use for a minimum of two days or until pain subsides and consult physician.
- Use a humidifier if experiencing nasal congestion or dry airway.
- Combinations with other medical products can alter the performance of the product, e.g. combinations with: humidifier for medical use, nebulizer, heat and moisture exchanger (HME), filters, CPAP, Bi-level positive airway pressure device, self-adjusting sleep apnea breathing therapy device, or additional oxygen supply.
- Electrically conductive breathing tubes should not be used (this warning does not apply to approved heated breathing tubes).
- Do not use if you are under active treatment by a dentist or orthodontist.
- Do not use if you have removable dentures or bridges.
- Do not use if you have temporary crowns.
- Do not use if you have loose teeth, loose crowns, or loose fillings.
- Do not use if you have braces.
- You must have at least 8 original upper teeth.
- You must have seen a dentist within the last 12 months.

Technical Specifications

Bias Flow Data

Mask Pressure (cm H ₂ O)	4	6	8	10	12	14	16	18	20
Vent Flow Rate (L/min)	19	23	27	30	33	35	38	40	42

Bias Flow Graph (Figure H)

Resistance to Flow Data

Drop in pressure (through mask at given flow rate)

- At 50 L/min 0.2 cm H₂O
- At 100 L/min 0.6 cm H₂O

Drop in pressure with Medium Seal in place

- At 50 L/min 0.6 cm H₂O
- At 100 L/min 2.1 cm H₂O

Mask Dead Space

- 95 mL (the physical dead space is the empty volume of the mask to the end of the swivel)

Sound

- The Sound Power Level of the mask is 25.7 dBA with uncertainty 1.96 dBA.
- The Sound Power Level of the mask is 17.8 dBA with uncertainty 1.96 dBA.