

Intended Use

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

Operating Instructions

The operating pressure range of the mask is 4-20cm H2O.

The transport and storage temperature range of the mask is -20 to 50°C (40 - 122°F).

The operating temperature of the mask is 5-40°C (40 - 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 are 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.

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.

- Discontinue use if reaction occurs to 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 by themselves.
- Use on adults only (>66lb/30kg).
- Shake loose hot water off seal before placing on face for fitting.
- Do not to misuse mask.
- Only use the mask with approved CPAP or Bi-Level machine that complies with ISO 17510-1 or ISO 14971.
- Use a humidifier if experiencing nasal congestion or dry airway.
- Do not store or transport the mask in temperatures outside of -20 to 50°C.
- Electrically conductive breathing tubes should not be used (does not apply to approved heated breathing tubes).
- 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.

User Instructions

Morf[®]
Nasal Mask



Airway Management Contacts

Manufacturer



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Fax: (214) 691-3151
Email: contactami@amisleep.com
Website: www.tapintosleep.com

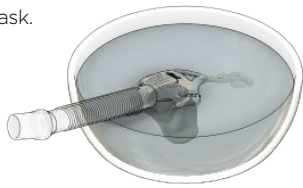
Fitting Your Mask

Fitting Your Seal

The first step to fitting your mask is to fit the seal to your face.

This process can be repeated using the same seal to adjust the fit as necessary. (Please read these instructions in full before starting to fit your seal.)

1. Remove the headgear from the mask.
2. Place boiling water into a bowl.
3. Holding the mask by the flexible tube, place the white mask Seal into the bowl for **60 seconds**. (ensure that the white Seal is entirely submerged and all white areas turn clear, including the upper lip region and ensure the tube is not placed in the hot water)
4. Shake any excess hot water off the Seal and wait **30 seconds** for the seal to cool.
5. **Lying on your back** place the Seal on your nose, with the tube pointing down.
6. Gently press the mask against your face so the mask touches your upper lip and the forehead support comes close to, or touches, your forehead.
7. Keep the mask still, while lying on your back for **5 minutes** while the Seal cools and sets to the shape of your face. Once it turns completely white everywhere it has set.
8. Remove the mask from your face and reconnect the headgear.



Fitting Your Nasal Mask

1. Place your mask on your face and adjust all four headgear straps to secure the mask on your face. This is best done lying down in your common sleeping position.
2. Connect your mask to your CPAP machine, turn the machine on and test the fit of your mask.
3. Adjust the headgear straps to prevent any air leaking between the mask and your face.
4. Increasing tension on the lower straps is the best way to eliminate leaks.

Trouble Shooting

Seal is uncomfortable or leaks

- If this cannot be eliminated by headgear adjustment you can reheat and refit the seal to get a better fit to your face.
- You can do this as many times as you like.
- You can even reheat only the part of the seal you want to refit.
- Try refitting the mask and ensure that you are lying on your back and do not move the mask during the 5 minute cooling period.
- When refitting your seal you may want to gently press on the region that was leaking or needs reshaping.
- You may find using a fabric mask liner such as RemZzz's® may improve the comfort and seal.

Mask movement

- If you find your mask moves and leaks please ensure that the forehead support is touching your forehead.
- You will need to reheat and fit the seal of the forehead support is not touching your forehead.

Wide nose

- If you have a wide nose you may want flare your nose during the seal fitting process to widen the mask Seal.
- Or widen the seal with your fingers before placing on your nose during the Seal fitting process
- Or place ear plugs in your nose during seal fitting to widen the seal.

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 Swivel Connector

Your Morf Nasal Mask may be disconnected from the main CPAP Tube by disassembling the Swivel Connector. It is easiest to assemble and disassemble the Swivel Connector at an angle.

Cleaning Your Mask

After each use:

1. Remove the headgear.
2. Place the Mask in lukewarm water that contains a mild soap. Note: Do not soak for more than 10 minutes.
3. Remove the mask components and rinse them thoroughly in fresh water, ensuring that all soap residue is removed.
4. Leave all parts to dry out of direct sunlight.

Weekly:

Hand wash the Headgear following the same procedure as above.

Warning:

Do not wash the mask in the dishwasher.

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

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

Disposal:

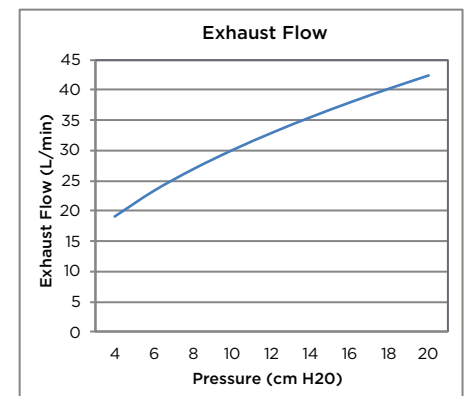
Your mask be disposed of in the general waste.

Technical Specifications

Bias Flow Data

Mask Pressure (cm H2O)	Vent Flow Rate (L/min)
4	19
6	23
8	27
10	30
12	33
14	36
16	38
18	40
20	42

Bias Flow Graph



Resistance to flow

Drop in pressure (through mask at given flow rate)

- At 50 L/min 0.14 cm H2O
- At 100 L/min 0.56 cm H2O

Materials

The Morf nasal mask is Silicone and Latex free.

Mask Dead Space

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

Sound

Sound Power Level 23.7 dBA

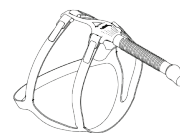
Sound Pressure Level 15.7 dBA

Service Life

Service life is dependent on the care, maintenance, intensity of usage and environmental conditions in which the mask is used in and stored.

Spare Parts

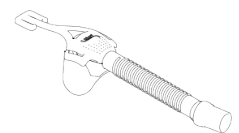
Morf Nasal Mask (Headgear)
Part Number 80000



Morf Headgear
Part Number 80002



Morf Nasal Mask (No Headgear)
Part Number 80001



Morf Swivel
Part Number 80003

