**Fitting Your Mask**

Refer to the mask assembly diagram:

1. Attach Headgear by connecting one of the clips (A) and pulling all the way over the Silicone Seal.
2. If you experience any discomfort, refer to the mask assembly diagram. (A)
3. If you find that there is a high level of mask leak in the tube, decrease the comfort by one setting at a time until no mask leak occurs. (B)
4. If you are still experiencing dryness, it could be due to a small air leak out of the nose. Nasal Plugs (C) will restrict this leak and help to retain some moisture in your mouth. (C)
5. If you are experiencing a dry mouth and not using the SleepStyle™ 600 Series CPAP system, try the following:
   - Increase the humidity on your machine.
   - Use nasal plugs for at least the first two weeks.

**Fitting Tips**

1. If the mask leaks around the teeth, tighten the SnapFlap™ Cover (D) by rotating the Dial (E).
2. If possible, try using the large Silicone Seal, which is included in your Oracle™ Oral Mask box.
3. It is recommended to use the Headgear with your Oracle™ Oral Mask for optimum comfort and performance. However, if preferred, it is optional to discontinue use of Headgear.
4. To reposition clip, simply pull on the Easy-Release Cord (F).
5. If discontinue use of Headgear, simply remove by unlocking both clips from SnapFlap™ Cover.

**Using Your Mask**

Oral CPAP/Bi-Level bypasses the nasal airway and requires optimum humidity. For best results, use with Fisher & Paykel Healthcare SleepStyle™ 600 Series CPAP system with Thermasmart™ Technology at the following settings:

- Comfort setting, 3
- Climate setting

Heated Humidification MUST be used in conjunction with the Oracle™ Oral Mask.

1. Ensure water chamber is filled.
2. Breathe through your mouth only.
3. Use nasal plugs, at least the first two weeks.

**Dial Settings**

<table>
<thead>
<tr>
<th>Pressure (cmH₂O)</th>
<th>3</th>
<th>5</th>
<th>7</th>
<th>9</th>
<th>11</th>
<th>13</th>
<th>15</th>
<th>17</th>
<th>19</th>
<th>21</th>
<th>23</th>
<th>25</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exhale Flow (l/min)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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</tr>
</tbody>
</table>

**Exhale Flow Information**

- Operating pressure range is 0-10 l/min
- Exhale Flow Information

**Technical Specifications**

- Room pressure range is 0-100 Torr
- Operating temperature range is 40-120°F (5-50°C)
- Valve activation/deactivation pressure is 2 cm H₂O

**Cleaning Your Mask At Home**

To ensure continuing safety and comfort for your Oracle™ Oral Mask:

- Wash the Headgear in warm soap-disolved lukewarm water. Do not soak for longer than 10 minutes. Rinse in fresh water and allow to air dry out of direct sunlight.

“Cleaning the Mask”

- Do not use any cleaner, detergent, or bleach.
- Do not soak the mask for longer than 10 minutes.
- Do not store the mask in direct sunlight.

**Oxygen/Pressure Port Connector**

- If oxygen is used with this CPAP/Bi-Level machine, the oxygen flow must be turned off when the CPAP/Bi-Level machine is not operating.
- Oxygen accumulated in the CPAP/Bi-Level machine enclosure will create a risk of fire.
- Do not use in the presence of an open flame or other oxygen source.

**Oxygen/Pulse Flow Connector**

If you are using the SleepStyle™ 600 Series CPAP system and experiencing a dry mouth, try the following:

- Increase the humidity on your machine.
- Use nasal plugs for at least the first two weeks.
- If you still experience dryness, it could be due to a small air leak out of the nose. Nasal Plugs will restrict this leak and help to retain some moisture in your mouth. (C)

**Oxygen Flow**

- The above actions may deteriorate or damage the mask and shorten its life.
- If your Oracle™ Oral Mask is not used for more than 10 minutes, rinse in fresh water and allow to air dry out of direct sunlight.
- If you are still experiencing dryness, it could be due to a small air leak out of the nose. Nasal Plugs will restrict this leak and help to retain some moisture in your mouth. (C)

**Nasal Plugs**

- Nasal Plugs are used to aid in the training of natural mouth breathing. It is optional to discontinue use after the first two weeks. However, use Nasal Plugs if you experience any of the following:
  - Oral dryness
  - Nasal leak
  - Poor sleep Quality
  - Nasal leak

**Instructions for Use**

1. Your Nasal Plugs (E) come in three sizes, 3/4/5/8. Insert medium sized nasal plugs into nostrils so that the base of the plugs are just inside the nostrils.
2. The plug should fit comfortably inside the nose and should seal off the flow of air (if not centered, try another size.
3. Use the Oracle™ Oral Mask as you normally would, with the Nasal Plugs inserted.

**Technical Specifications**

- Pressure drop through mask @ 50 l/min: 0.1 cmH₂O
- Resistance to Flow: 16 cc 32 cc 56 cc 90 cc 134 cc 178 cc 222 cc 266 cc 310 cc
- Operating Conditions:
  - Operating pressure range is 0-10 l/min
  - Operating temperature range is 40-120°F (5-50°C)
  - Valve activation/deactivation pressure is 2 cm H₂O

**Oracle™ 452 Oral Mask Exhaust Flow**

- Exhaust Flow (l/min):
  - 3
  - 5
  - 7
  - 9
  - 11
  - 13
  - 15
  - 17
  - 19
  - 21
  - 23
  - 25

**Exhaust Flow Information**

- Operating pressure range is 0-10 l/min
- Exhale Flow Information

**Oracle™ 452 Oral Mask Exhaust Flow**

- Exhaust Flow (l/min):
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  - 7
  - 9
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  - 15
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**Exhale Flow Information**

- Operating pressure range is 0-10 l/min
- Exhale Flow Information

**Oracle™ 452 Oral Mask Exhaust Flow**

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**Exhale Flow Information**

- Operating pressure range is 0-10 l/min
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**Oracle™ 452 Oral Mask Exhaust Flow**

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**Exhale Flow Information**

- Operating pressure range is 0-10 l/min
- Exhale Flow Information

**Oracle™ 452 Oral Mask Exhaust Flow**

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High Level Disinfection Parameters

Your Oracle™ Oral Mask is provided patient ready. To re-use between patients please follow the guidelines below.

CLEANING/DESOILING

Before cleaning, remove visible soil by disassembling and thoroughly cleaning the mask with a small brush under running potable tap water.

WARNINGs

- This CMB mask should be used only with CPAP/Bi-Level systems recommended by your physician or respiratory therapist. A mask should not be used unless the CPAP/Bi-Level system is turned on and operating properly. The vent slots associated with the mask should never be blocked.
- Explanation of Warning: CPAP/Bi-Level systems are intended to be used with special vents which lead to a constant flow of air or air out of the mask. When the CPAP/Bi-Level mask is turned on and functioning properly, air is exhaled through the mask exhalation port. However, when the CPAP/Bi-Level mask is not operating, enough air will not be provided through the mask, and re-breathing or rebreathing of exhaled air for longer than usual intervals can result in high levels of CO2.
- At low CPAP pressures the flow through the exhalation port may be inadequate to clear all exhaled gas from the tubing. Some re-breathing may occur.
- Do not use the mask without the non-rebreathing valve in place while using nose plugs.
- Do not use the mask if vomiting, feeling nauseous or with an oral or throat infection.

MESSDICATIONS

- Use of this device may cause tooth soreness, gingival soreness, and/or tooth movement (if symptoms occur a physician or dentist should be consulted before continuing use).
- If a patient has loose teeth or periodontal disease, a dentist should be consulted prior to use.
- The prescribing physician should consider the dental history and oral health status of the patient prior to prescribing the device.
- If a patient using this device develops these symptoms, a dentist should be consulted before continuing use.
- This valve ensures CO2 re-breathing is kept to a minimum in the event of power failure.
- Rebreathing of exhaled gas through the exhalation port. 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. Rebreathing of exhaled air for longer than usual intervals can result in high levels of CO2.
- To assist putting pressure on teeth, do not overtighten headgear.
- Do not use if patient suffers from bruxism.
- Use this device may cause tooth soreness, gingival soreness and/or tooth movement (if symptoms occur a physician or dentist should be consulted before continuing use).

CONTRAINDICATIONS

- This mask should not be used by anyone incapable of removing the mask unaided, in the case of vomiting and aspiration, without continuous supervision.
- The mask should not be used by anyone suffering from bruxism.
- Do not use if the patient has loose teeth or periodontal disease, a dentist should be consulted prior to use.
- If a patient using this device develops these symptoms, a dentist should be consulted before continuing use.

Cautions

- Use the mask for its intended use only as directed in this booklet.
- The prescribing physician should consider the dental history and oral health status of the patient prior to prescribing the mask.
- If a patient has loose teeth or periodontal disease, a dentist should be consulted prior to use.
- Use the Oracle™ Oral Mask only with the headgear provided.
- Do not use if the patient has loose teeth or periodontal disease, a dentist should be consulted before continuing use.

30 minutes at 20°C (68°F).
- Rinse thoroughly in potable water.
- Soak parts in hot water bath for 30 minutes at 70°C (158°F).
- Immerse for 10 minutes at 80°C (176°F).
- Follow manufacturer instructions for high level disinfection.
- Thermal Disinfection
- HANDHELD
- Handwash the Headgear in pure soap dissolved in lukewarm water. Air dry out of direct sunlight.
- HIGH LEVEL DISINFECTION PARAMETERS

- DISINFECT CAP
- FLEXITUBE
- NASAL PLUGS
- REPLACEMENT VOLUME VALVE
- SILICONE SEAL
- DIFFUSER CAP
- HEADGEAR
- DIFFUSER
- FEMALE SWIVEL
- CENTRE BODY
- SNAP/CAP® COVER