

ORACLE™ 452 ORAL MASK PATIENT INSTRUCTIONS FOR USE

The Oracle™ Oral Mask is intended for multiple patient or single patient adult use by individuals who have been diagnosed by a physician as requiring CPAP or Bi-Level ventilator treatment. For optimal humidification it is recommended that you use the Oracle™ Oral Mask with the Fisher & Paykel Healthcare SleepStyle™ 600 Series CPAP system with ThermoSmart™ Technology.

FITTING YOUR MASK

Refer to the mask assembly diagram.

- 1) Attach Headgear by re-connecting one of the clips (I).
- 2) Pull the SnapFlap™ Cover (A) back to the retracted position.
- 3) Insert the Silicone Seal (B) into the mouth, one side at a time. It should sit in the gum region between the cheeks and the teeth. Move your lips around so they fit comfortably all the way over the Silicone Seal.
- 4) Return the SnapFlap™ Cover (A) back to its normal position, and adjust the mask tightness by rotating the Dial (C) as shown.
- 5) With Headgear (I) sitting loosely around base of neck, re-connect clip.
- 6) Adjust Headgear with Velcro™ tab (I1) to remove slack.
- 7) Use Nasal Plugs (H) for at least the first two weeks of use. Refer to Nasal Plug Instructions.
- 8) Connect to CPAP/Bi-Level machine set at prescribed pressure.

FITTING TIPS

- If the mask leaks around the teeth, tighten the SnapFlap™ Cover (A) by rotating the Dial (C).
- If problems persist, try using the large Silicone Seal, which is included in your Oracle™ Oral Mask box.
- 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.
- Do not overtighten Headgear.
- To release clip, simply pull on the Easy-Release Cord (I2).
- If discontinuing use of Headgear, simply remove by unhooking 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 ThermoSmart™ Technology at the following settings:

- Comfort Setting 3
- Climate Setting 3

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 for at least the first two weeks.

DRYNESS

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

- 1) Turn the comfort up one setting per night until a slight misting occurs in the Flexitube (D).
- 2) Alternatively if you find there is a high level of moisture build up in the tube, decrease the comfort by one setting at a time until only slight misting occurs in the Flexitube (D).
- 3) If you are still experiencing dryness, it could be due to a small air leak out of the nose. Nasal Plugs (H) will restrict this leak and help to retain some moisture in your mouth.

This should help you to achieve an optimum level of humidity and increase the comfort of your therapy.

If you are experiencing a dry mouth and not using the SleepStyle™ 600 Series CPAP system, try the following:

- 1) Increase the humidity on your machine.
- 2) If you still experience dryness, it could be due to a small air leak out of the nose. Nasal Plugs (H) will restrict this leak and help to retain some moisture in your mouth.

NASAL PLUGS

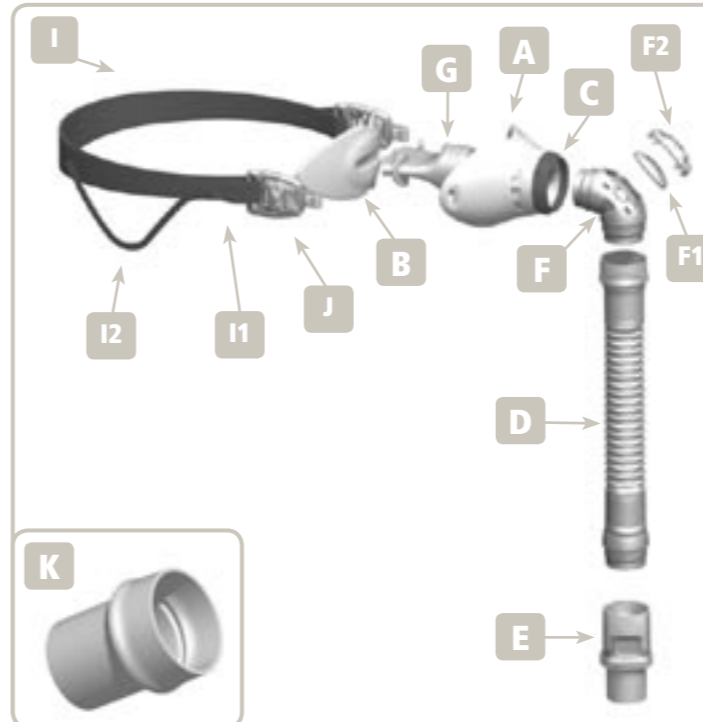
Nasal Plugs are used to aid in the training of natural mouth breathing. It is optional to discontinue use after the first two weeks. However, use Nasal Plugs if you experience any of the following:

- Oral dryness
- Nasal leak
- Poor sleep Quality

If discontinuing use of Nasal Plugs, replace the Non-rebreathing Valve (E) with the provided female swivel (K).

INSTRUCTIONS FOR USE

- 1) Your Nasal Plugs (H) come in three sizes, S / M / L.
- 2) Insert medium sized silicone Nasal Plugs into nose so that the base of the plugs are just inside the nostrils.
- 3) The plug should fit comfortably inside the nose and should seal off the flow of air. If not content, try the other sizes.
- 4) Use the Oracle™ Oral Mask as you normally would, with the Nasal Plugs inserted.



ASSEMBLING YOUR MASK

Your Oracle™ Oral Mask comes assembled and ready to use. However, when you need to clean your mask follow these instructions for reassembly.

- 1) Insert the flat end of the Centre Body (G) into the Silicone Seal (B). Ensure it is pulled up over all of the plastic lugs properly.
- 2) Orient SnapFlap™ Cover (A) into position shown. Rotate Dial (C) to screw onto Centre Body (G).
- 3) Connect Elbow (F) to the Centre Body (G) and the Flexitube (D) to the Elbow (F).
- 4) Connect the Non-Rebreathing Valve (E) to the Flexitube (D).

CLEANING YOUR MASK AT HOME

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

BEFORE FIRST USE:

- 1) Hand wash the Headgear in pure soap dissolved in lukewarm water. Do not soak for longer than 10 minutes, then rinse in fresh water and allow to air dry out of direct sunlight.

BEFORE EACH USE:

- 1) Inspect the mask for deterioration. Do not use if damaged.
- 2) Inspect the Non-Rebreathing Valve (E). Ensure the silicone flaps are present and undamaged.

AFTER EACH USE:

- 1) Disassemble the Silicone Seal (B) & SnapFlap™ Cover (A) from the Centre Body (G).
- 2) Wash all parts except the Headgear (I) and Diffuser (F1) in pure soap dissolved in lukewarm water. Do not soak for longer than 10 minutes, then rinse in fresh water and allow to air dry out of direct sunlight.
- 3) Alternatively, the Silicone Seal (B) may be soaked for 10 minutes in a clean solution of approximately 30 fl oz (1L) of water and 2 fl oz (50mL) of antiseptic mouthwash. Rinse in fresh water and allow to air dry out of direct sunlight.

NOTE: Do NOT immerse Elbow (F) unless Diffuser material (F1) has been removed.

The Diffuser (F1) should not be washed or rinsed. Simply replace it with a new diffuser if it becomes noisy or deteriorates. It should last two to three months. Small dots may appear on the Diffuser (F1) – these do not affect its performance. The Oracle™ Oral Mask may be used with, or without the Diffuser (F1) and Diffuser Cap (F2).

EVERY 7 DAYS:

- 1) Hand wash the Headgear in pure soap dissolved in lukewarm water. Do not soak for longer than 10 minutes, then rinse in fresh water and allow to air dry out of direct sunlight. It is not necessary to remove the Clip (H) from the headgear when washing.

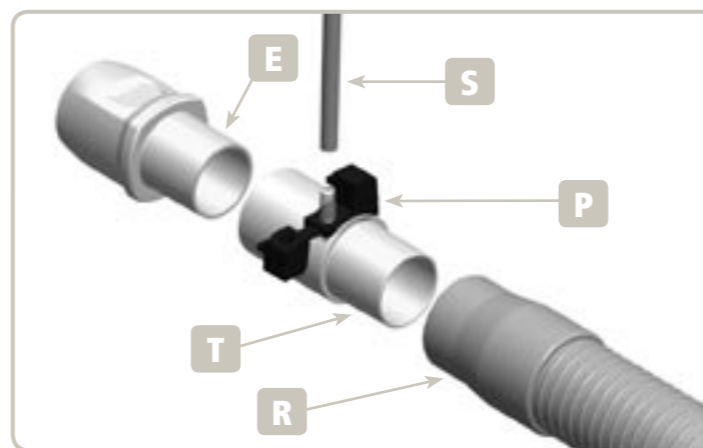
CAUTION:

- Do not soak the mask for longer than 10 minutes.
- Do not wash the mask in the dishwasher.
- Do not clean the mask with products containing alcohol, chlorine, antibacterial agents or bleach.
- Do not store the mask in direct sunlight.

The above actions may deteriorate or damage the mask and shorten its life. If your Oracle™ Oral Mask weakens or cracks, discontinue use immediately.

The Oracle™ Oral Mask and accessories are Latex free.

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OXYGEN/PRESSURE PORT CONNECTOR

If pressure readings and/or additional oxygen are required, an Oxygen/Pressure Port Connector is available. (Product 900HC452)

- 1) Connect the large end of the Connector (T) to the Non-Rebreathing Valve (E) and the small end of the connector to the main breathing tube (R).
- 2) Open the Port Cap(s) (P) and place the Pressure and/or Oxygen Tube (S) firmly over the Port(s).

The two Ports are identical; either Port may be used for oxygen or pressure measurement. Only remove the Port Cap from Ports that are being used.

- **Note:** At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection, and the leak rate.
- **Warning:** 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.

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.

- **Warning:** Do not smoke while using or in the vicinity of someone using oxygen with this mask.
- **Warning:** Do not use Polyvinyl Chloride (PVC) Pressure and/or Oxygen tubing. Use silicone tubing instead.

Explanation of Warning: Contact with PVC can cause premature cracking of ports.

TECHNICAL SPECIFICATIONS

EXHAUST FLOW INFORMATION

All masks for CPAP and Bi-Level have exhaust flow holes to expel the air that you exhale from the mask. The Oracle™ Oral Mask incorporates the unique Fisher & Paykel Healthcare Diffuser system that is designed to diffuse the air that is expelled from the mask. This noticeably reduces draft and noise.

The Diffuser does not significantly change the amount of air flowing from the mask, therefore the mask can be used with or without the Diffuser. It is important that these vents are not blocked by any object. This controlled leak ensures all exhaled CO₂ is expelled from the mask.

PRESSURE (cmH ₂ O)	3	5	7	9	11	13	15	17	19	21	23	25
Flow (l/min)	16	22	27	32	36	40	43	46	50	53	55	57

RESISTANCE TO FLOW

Pressure drop through mask @ 50 l/min 0.1 cmH₂O

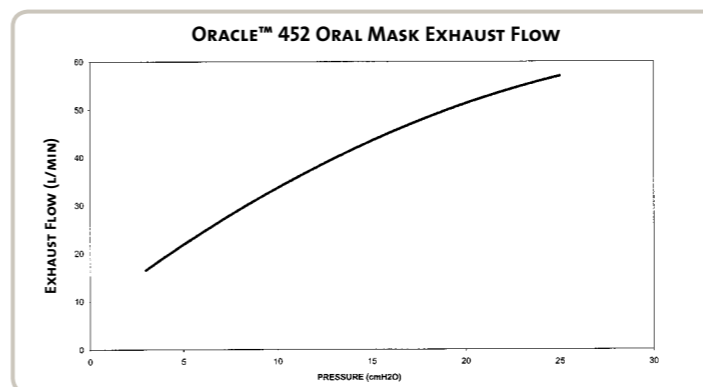
Pressure drop through mask @ 100 l/min 0.5 cmH₂O

MASK DEAD SPACE

16cc

OPERATING CONDITIONS

- Operating pressure range is 3-25 cm H₂O
- Operating temperature range is 40-120°F (5-50°C)
- Valve activation/deactivation pressure is 2 cm H₂O



MULTI-PATIENT CLEANING INSTRUCTIONS






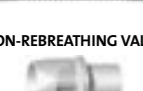


Your Oracle™ Oral Mask is provided patient ready. To re-use between patients please follow the guidelines below.




CLEANING/ DESOILING

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

FAILURE TO PROPERLY CLEAN THIS DEVICE MAY RESULT IN INADEQUATE DISINFECTION

HIGH LEVEL DISINFECTION PARAMETERS

 <p>SNAPFLAP™ COVER</p>	<p>THERMAL DISINFECTION</p> <p>Soak parts in hot water bath for 30 minutes at 70°C (158°F). or 10 minutes at 80°C (176°F)</p> <p>OR</p> <p>CIDEX® OPA</p> <p>Follow manufacturer instructions for high level disinfection. Immerse for 30 minutes at 20°C (68°F). Rinse thoroughly in potable water.</p> <p>OR</p> <p>SPOROX® II</p> <p>Follow manufacturer instructions for high level disinfection. Immerse for 30 minutes at 20°C (68°F). Rinse thoroughly in potable water.</p>
 <p>CENTRE BODY</p>	
 <p>SILICONE SEAL</p>	
 <p>ELBOW</p>	
 <p>DIFFUSER CAP</p>	
 <p>FLEXITUBE</p>	
 <p>NON-REBREATHING VALVE</p>	
 <p>FEMALE SWIVEL</p>	

 <p>HEADGEAR</p>	<p>Handwash the Headgear in pure soap dissolved in lukewarm water. Air dry out of direct sunlight.</p>
 <p>DIFFUSER</p>	<p>Replace with new part.</p>
 <p>NASAL PLUGS</p>	<p>Replace with new part.</p>

THE ORACLE™ ORAL MASK HAS BEEN VALIDATED TO WITHSTAND 20 CYCLES OF THE ABOVE PARAMETERS. DO NOT USE IF DAMAGED

Disclaimer: It is the user's responsibility to qualify any deviations from the recommended methods of reprocessing.

WARNINGS

- This CPAP 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 masks with connectors which have vents holes 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 attached mask 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 rebreathed. Rebreathing of exhaled air for longer than several minutes can in some circumstances lead to suffocations.

- At low CPAP pressures the flow through the exhalation port may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur.
- Do not use the mask without the Non-Rebreathing Valve in place while using nose plugs. This valve ensures CO₂ rebreathing is kept to a minimum in the event of power failure.
- Do not use the mask if vomiting, feeling nauseous or with an oral or throat infection.
- Discontinue using the mask if there is an allergic reaction, irritation, ulceration or inflammation due to any part of the mask. Consult your physician if this occurs.
- If re-using the Oracle™ Oral Mask between different patients, refer to the Multi Patient Cleaning Instructions for the Oracle™ Oral Mask.
- Replace the Non-Rebreathing Valve every 12 months.
- Use the Oracle™ Oral Mask only with the headgear provided.
- To avoid putting pressure on teeth, do not overtighten Headgear.
- Do not use if patient suffers from bruxism.
- 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.

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 device.
- If a 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.

CONTRAINDICATIONS

- This mask should also not be used by anyone incapable of removing the mask unaided, in the case of vomiting and aspiration, without continuous supervision.

**AUST PATENT NUMBERS:
746 574 / 765 265**

OTHER PATENTS PENDING

FOR ADDITIONAL INFORMATION CONTACT YOUR LOCAL HEALTHCARE PROVIDER

Oracle™ 452

ORAL MASK

INSTRUCTIONS FOR USE

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Fisher & Paykel
HEALTHCARE

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