ACARE®

CPAP SILICONE NASAL MASK

Model: RAP-301 (Small)
RAP-302 (Medium)
RAP-303 (Large)

Expected Service Life: 3 years

Intended Use

The CPAP/VPAP Mask is intended to be used for patients greater than 30kg (66lbs) who have been prescribed CPAP or VPAP therapy and are under the specific direction of a physician. It is used in conjunction with continuous positive airway pressure (CPAP/VPAP) devices in home, hospital and Institutional environments.

⚠ Caution: US federal law restricts this device to sale by or on the order of a physician.

Features

* One piece molded silicone rubber; small, light and comfortable.
* Clear mask allows a good view of mouth and nasal area.
* Low dead space results in low CO_2 build up.
* Vent holes are included to reduce rebreathing.
* Dual 360 degree swivels at the mask attachment and at the standard 22mm tubing attachment point.
* Headgear with Velcro fasteners provide maximum versatility and movement.

Before Use

* Read and understand the instructions completely.
* Refer to manual for details on settings and operational information.
* Hand wash the mask according to the cleaning instructions.
* Wash your face and do not apply moisturizer/lotion to your face or hands prior to handling/wearing the mask.

⚠ Warnings

* The vent holes and exhalation port must be kept clear.
* Oxygen flow must be turned off when the CPAP machine is not in operation. Unused oxygen may accumulate within the CPAP machines enclosure and create a risk of fire.
* Must only be used by persons who have received adequate training and instruction from qualified medical personnel.
* The oxygen concentration may slightly fluctuate depending on the pressure settings, mask choosing, user breathing pattern, application and leak rate.
* Combination with other medical devices can alter the performance of the mask.
* Discontinue using the mask and contact your physician or a health care professional if chest discomfort, shortness of breath, stomach distention, belching, severe headache or any adverse reaction are experienced.

Contraindications

This mask may not be suitable for patients with the following conditions: impaired cardiac sphincter function, excessive reflux, impaired cough reflex and hiatal hernia.
It should not be used if the patient is unresponsive, obtunded, unable to remove the mask, or uncooperative.

Storage

* Temperature: -20°C ~ 60°C (-4°F ~ 140°F)
* Humidity: ≦ 95%, non-condensing
* Ensure the mask is clean and dry before storing.
* Avoid direct sunlight.

Disposal

* This mask does not contain any hazardous substances, please dispose it according to location legal rules.

Cleaning Instructions

Daily / After Use

* Detach headgear from mask.
* Hand wash gently with mild soap and warm water, rinse the mask and components thoroughly.
* Let mask and components air dry before reusing.

Weekly

* Hand wash the headgear with water and air dry before reusing.

⚠ Caution

The use of bleach, chlorine, alcohol or aromatic-based solutions may cause hardening of the materials of construction and reduce the life of the product.
The mask should be replaced in three years or when:
- The cushion is no longer clear and transparent after cleaning or excessive discoloration.
- There are cracks, tears or damages in any way.

⚠ Warnings

* This mask should only be used with CPAP systems recommended by your physician or respiratory therapist.
* Do not use this mask unless the CPAP or VPAP system is turned on and operating properly.
* Never block the mask's vent holes or exhalation port.

Note: CPAP systems are intended to be used with special masks with vent holes in either the connectors or the mask that allows continuous flow out of the mask. When the CPAP machine is turned on and functions properly, new air from the CPAP machine flushes the exhaled air out through the mask's exhalation port. However, when the CPAP 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 suffocation.

* If oxygen is used with the CPAP system, the oxygen flow must be turned off when the CPAP machine is not in operation.

Note: When the CPAP device is not in operation and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within the CPAP machines enclosure and create a risk of fire.
Note: At a fixed flow rate of supplemental oxygen, the inhaled oxygen concentration will vary depending on the pressure setting, patient pattern and leak rate.

* Do not smoke if oxygen is in use.
* Contact a health care professional if chest discomfort, shortness of breath, stomach distention, belching, or severe headache are experienced.
*Avoid eating or drinking three hours before using this mask to minimize the risk of vomiting during sleep.
* Do not use this mask if you are taking drugs that may cause vomiting.

⚠ Caution: At low CPAP pressures the flow though the exhalation port may be inadequate to clear all exhaled gas from the tubing and some rebreathing may occur.

* Must only be used by persons who have received adequate training and instruction from qualified medical personnel
* Combination with other medical devices can alter the performance of the mask, please consult with your physician or respiratory therapist.

Troubleshooting

Problem	Possible Cause	Solution
Mask is too noisy	Vent is blocked or partially blocked	Clean the vent by the description of cleaning instructions
	Incorrect assembly	Reassemble the mask according to the instructions.
Air Leaking	Mask is not positioned correctly	Gently pull your mask away. Reposition the mask according to the instructions.
	Mask is not tightened properly	Refit your mask according to the instructions.
	Mask is assembled incorrectly	Reassembled the mask according to the instructions.
	Wrong Connection	Check both ports of breathing tube. Reassemble both ports according to the instructions.
	Wrong Size	Ask your doctor for consultation.
	Cushion may be dirty	Clean the cushion by the description of cleaning instructions.

If headgear is included, follow assembling instruction below:

Place headgear with Velcro side down on a flat surface, detach 2 Velcro tapes on A1 & A2.

Identify headgear fastening positions on the mask.

Pull the upper headgear strap A1 through the slot B1 on the mask, making sure the Velcro faces outward.

Fasten the Velcro tape.

Pull the upper headgear strap A2 through the slot B2 on the mask, making sure the Velcro faces outward.

Fasten the Velcro tape.

Place the headgear over your head and adjust both upper headgear straps to a comfortable tension.

Hook the plastic buckle A3 onto B3 (or B5) on mask frame.

Hook the plastic buckle A4 onto B4 (or B6) on mask frame.

Adjust again both upper headgear straps A1 & A2 to a comfortable tension.

Adjust both lower headgear straps A3 & A4 to a comfortable tension.

Making sure the overhead strap is in proper position to avoid slipping down.

Specification

◆ Exhaust Flow Rate at Given Therapy Pressure

Pressure (cmH_2O)	Flow (L/mm)
3	15.30
10	29.00
20	45.10
30	55.90
40	62.80

◆ Therapy Pressure: 4 to 20 cmH_2O

◆ Dead Space Information:

Dead space is the empty mask volume to the end of the swivel.
Dead space differ due to cushion size.

Large size	70ml
Medium size	60ml
Small size	55ml

◆ Resistance to Flow (Pressure Drop)

At 50 L/min: 0.49 cmH_2O
At 100 L/min: 2.28 cmH_2O

◆ Sound Pressure Level:<30dB(A)
Sound Power: <38dB(A)

◆ Operating Conditions

Temperature: 5°C ~ 35°C (41°F ~ 95°F)
Humidity: 10% ~ 95%, non-condensing

◆ Storage Conditions

Temperature: -20°C ~ 60°C (40°F ~ 140°F)
Humidity: ≦95%, non-condensing

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