

CPAP/VPAP Nasal Mask and Accessories- CPAP NASAL MASK, Medium

REF 0806357

LOT

Date of Manufacture:

Use by:

Intended Use

This Mask is intended to be used under the specific direction of a physician. It is used in conjunction with Non Invasive Ventilators in home, hospital and Institutional environments.
*It is for single patient use

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 CO₂ build up.
- *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.

Cleaning instructions

- *Detach headgear from mask.
- *Handwash gently with mild soap and warm water, rinse the mask and components thoroughly.
- *Let mask and components air dry before reusing.
- *Replace mask if there are cracks, tears or excessive discoloration.

Disinfection and Sterilization for institutional environment and hospital

Refer to the *Disinfection & Sterilization Guide of CPAP and VPAP Mask*

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.

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.

Warnings

- *This mask should only be used with NIV systems recommended by your physician or respiratory therapist.
- *Do not use this mask unless the NIV system is turned on and operating properly.

Note: When ventilator 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 NIV system, the oxygen flow must be turned off when the ventilator is not in operation.

Note:When the ventilator is not in operation and the oxygen flow is left on, oxygen delivered into the ventilation tubing may accumulate within the ventilator 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.

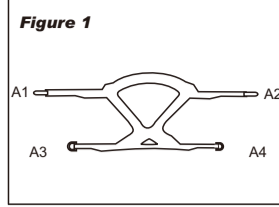
*Contact a health care professional if chest discomfort, shortness of breath, stomach distention, belching, or severe headache are experienced.

*Avoid eating or drinking three hours before using this mask to minimize the risk of vomiting during treatment.

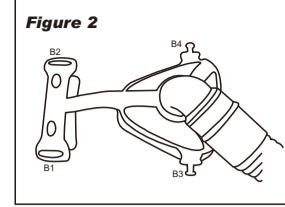
*Do not use this mask if you are taking drugs that may cause vomiting.

Caution: Must only be used by persons who have received adequate training and instruction from qualified medical personnel.

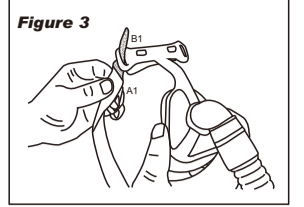
If headgear is included, follow assembling instruction below:



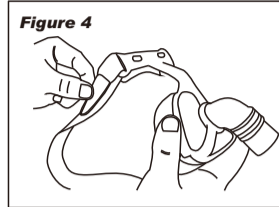
Place headgear with Velcro side down on a flat surface, detach 2 Velcro tapes on A1 & A2.



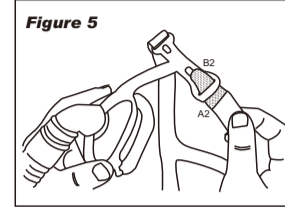
Identify headgear fastening positions on the mask.



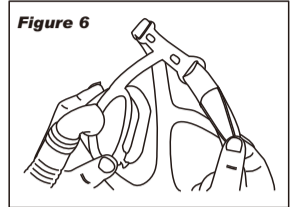
Pull the upper headgear strap A1 through the slot B1 on the mask, making sure the Velcro faces outward.



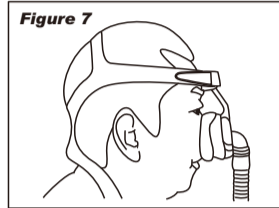
Fasten the Velcro tape.



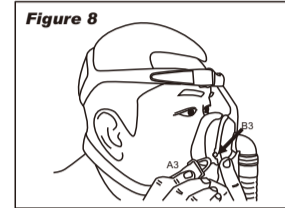
Pull the upper headgear strap A2 through the slot B2 on the mask, making sure the Velcro faces outward.



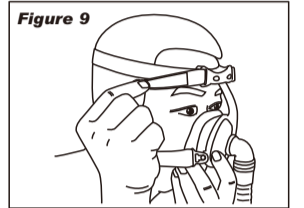
Fasten the Velcro tape.



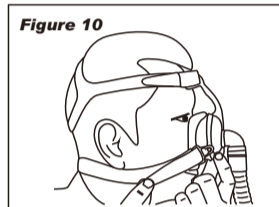
Place the headgear over your head and adjust both upper headgear straps to a comfortable tension.



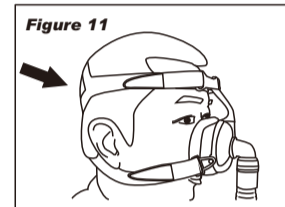
Hook the plastic buckle A3 onto B3 and A4 onto B4 on mask frame.



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.

*To remove the mask and headgear, simply unbuckle both buckles from the mask frame and pull the upper head strap away from the head.

*To reuse the mask and headgear, simply place upper headstrap over head and hook up to both buckles.

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Disinfection & Sterilization Guide of CPAP and VPAP Mask

This following disinfection and sterilization methods are intended for single patient use in hospital / institutional environment, and this guide is used for professional use only. These methods are the recommended procedures, and we advise that each healthcare facility consult its own procedures before carrying out the following instructions.

Disinfection and Sterilization Occasion:

- Whenever the mask is contaminated by secretions, vomit, or other foreign substances that is considered as hazard to patient.
- Judgment of respiratory therapist or doctor if the mask is for ICU patients.
- Every continuous 7 days of use of the same patient.

Procedure:

1. Disassemble the cushion out of the mask frame and remove headgear set.
2. Rinse all parts in clean water to remove residue.
3. Hands wash all parts of the mask thoroughly with neutral cleaning detergent about 5 minutes.
4. Rinse all parts in clean water to remove remaining detergent and let the parts air dry.
5. Disinfection/Sterilization:
 - Autoclaving not to exceed 121°C for 15 min (Not include headgear set)
 - Cidex 2% Glutaraldehyde disinfection for 20 min (Not include headgear set); Consult disinfectant supplier before first use. Rinse thoroughly with sterile water.
6. Dry them thoroughly. Inspect all components to confirm that they are clean and dry. If parts are worn or damaged, discard them.
7. Functional Check:
 - The re-assembled mask should be fully visual checked before use, and connected to the positive pressure ventilation machine.
 - Wear the mask on the patient's face with headgear and make sure the strength is enough.
 - Make sure the mask is adjusted to a comfortable position, and there is no obvious leakage from the touching surface of the cushion.
 - If the cushion still cannot seal well, please replace with one another.

Caution:

- The headgear is not suitable for this guide; it should be firmly washed, and not repacked with disinfected/autoclaved mask before next use.
- The dispose of mask should follow the local laws related to hospitals wastes in hospital / institutional environment.
- The main parts of CPAP/VPAP mask's maximum disinfection and sterilization cycles are recommended for 30 times. Washing with neutral detergent is recommended for 90 times. Do not remove the anti-asphyxia valve while disassembly the elbow connector.
- Disclaimer: it is the user's responsibility to qualify any deviations from the recommended method of reprocessing.
- Contact your distributor for additional information.

