

Ray Pediatric CPAP/VPAP Nasal Mask and Accessories

REF CM060-KITS Pediatric Nasal CPAP Mask Kit with Small and Medium Cushions
CM060-KITL Pediatric Nasal CPAP Mask Kit with Large and Extra Large Cushions

Intended Use

The CPAP/VPAP Mask is intended for use by patients 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 nasal area.
- Low dead space results in low CO₂ build up.
- Headgear with Velcro fasteners provide maximum versatility and movement.

Cleaning instructions

- 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.
- Replace mask if there are cracks, tears or excessive discoloration.

Disinfection and Sterilization for institutional environment and hospital

Refer to the *Ray Pediatric CPAP/VPAP Nasal Mask and Accessories Disinfection & Sterilization Guide* on next page.

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.

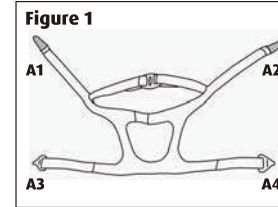
Contraindications

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.

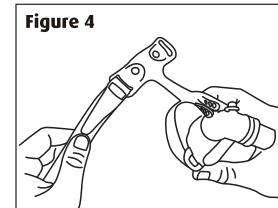
Warnings

- This mask should only be used with 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, not enough fresh air will 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 through 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.

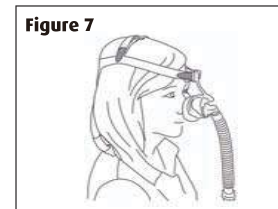
If headgear is included, follow assembly instructions below:



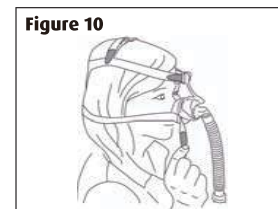
Place headgear with Velcro side down on a flat surface, detach 2 Velcro tapes on A1 & A2.



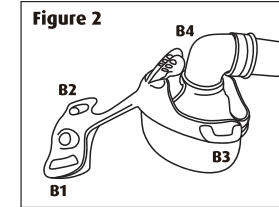
Fasten the Velcro tape.



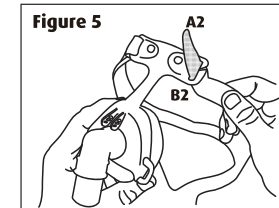
Place the headgear over head and adjust both upper headgear straps to a comfortable tension.



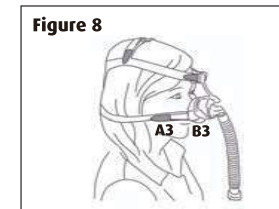
Adjust both lower headgear straps A3 & A4 to a comfortable tension.



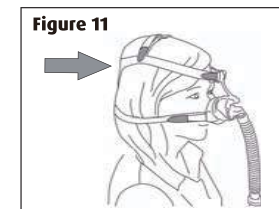
Identify headgear fastening positions on the mask.



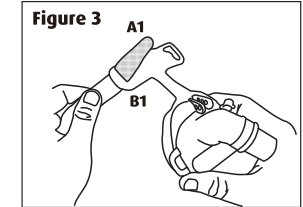
Pull the upper headgear strap A2 through the slot B2 on the mask, making sure the Velcro faces outward.



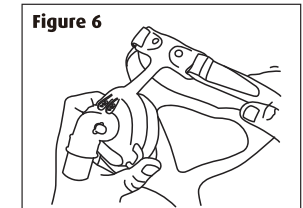
Hook the plastic buckle A3 onto B3 and adjust both upper headgear straps to a comfortable tension.



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



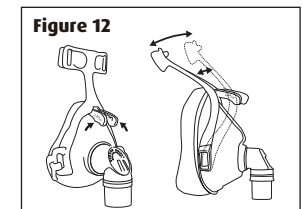
Pull the upper headgear strap A1 through the slot B1 on the mask, making sure the Velcro faces outward.



Fasten the Velcro tape.



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



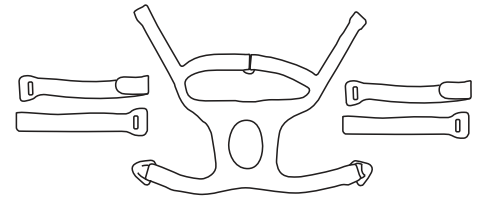
To further conform to the patient's face, adjust the Fin Tek levers by squeezing them together and swiveling back or forth. When the desired fit is reached, let go to lock in place.

- 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.

If a larger fit is needed, add the included extender straps. See instructions on next page.

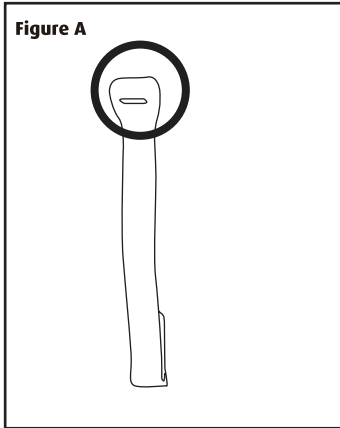
How to add Extender Straps

Each Sunset Ray Mask includes headgear, four extender straps, and mask.

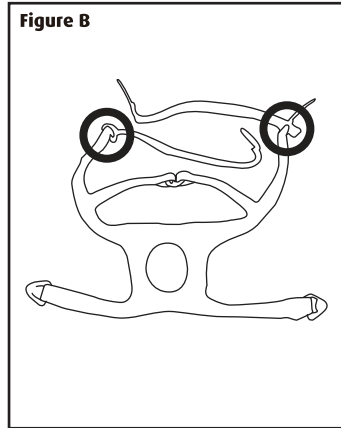


To Attach Extender Straps:

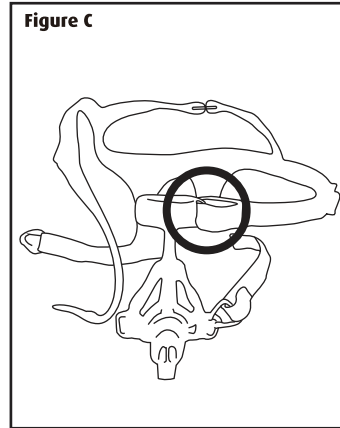
1. Remove extender straps from packaging.



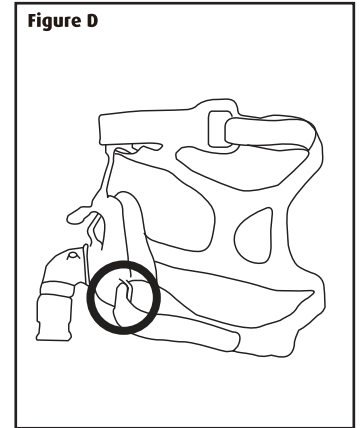
2. Locate the slits on the extender straps. (fig. A)



3. Thread the headgear strap through the slits. (fig. B)



4. Adjust as needed and secure the headgear. (fig. C & D)
5. Verify proper attachment before use.



Disinfection & Sterilization Guide

The following disinfection and sterilization methods are intended for hospital / institutional environments, and this guide is used for professional use only. These methods are the recommended procedures, and we advise that each healthcare facility consults 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 considered hazardous to patient.
- Upon judgment of respiratory therapist or doctor if the mask is for ICU patients.
- Every continuous 7 days of use with 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 should not exceed 121°C for 15 min (excluding headgear set)
 - Cidex 2% Glutaraldehyde disinfection for 20 min (excluding headgear set):
Consult disinfectant supplier before first use. Rinse thoroughly with sterile water.
6. Dry thoroughly. Inspect all components to confirm that they are clean and dry.
If parts are worn or damaged, discard them.
7. Functional Check:
 - The reassembled mask should be fully visually 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 should be firmly washed, and packed separately from disinfected/autoclaved mask before next use.
- If disposed, mask should follow the local laws related to hospital wastes in hospital / institutional environment.
- Disinfection and sterilization is recommended for a maximum of 30 cycles. Washing with neutral detergent is recommended for 90 cycles.
- Do not remove the anti-asphyxia valve while disassembling 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.